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

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

Date: May 7-8, 2019

Location: Department of Consumer Affairs – First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

Board Members Present:
Victor Law, Licensee Member, President
Gregory Lippe, Public Member, Vice President
Allen Schaad, Licensee Member, Treasurer
Lavanza Butler, Licensee Member
Ricardo Sanchez, Public Member
Maria Serpa, Licensee Member
Deborah Veale, Licensee Member
Stanley Weisser, Licensee Member – May 7 only
Albert Wong, Licensee Member
Valerie Muñoz, Public Member – May 7 only

Board Members Not Present:
Ryan Brooks, Public Member
Amjad Khan, Public Member
Shirley Kim, Public Member

Staff Present:
Anne Sodergren, Interim Executive Officer
Joshua Room, Senior Deputy Attorney General
Kelsey Pruden, DCA Staff Counsel
Laura Freedman, DCA Staff Counsel
Laura Hendricks, Staff Analyst

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

President Victor Law called the meeting to order at 12:35 p.m. Roll call was taken, and a quorum was established. Board members present: Victor Law, Gregory Lippe, Lavanza Butler, Allen Schaad, Ricardo Sanchez, Maria Serpa, Deborah Veale, Stanley Weisser, Valerie Muñoz, and Albert Wong.

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

Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

Pharmacist Steve Gray requested that board create a policy stating that the Enforcement Committee will meet annually in November or December before the new pharmacy laws take effect in January. The purpose of the meeting would be to educate the board and the licensees about the new laws and how they will be enforced.

Paige Talley stated that SB 2859 (safe storage containers) exempted owners of less than four pharmacies from displaying the safe storage containers. She asked if the exemption also applied to closed-door pharmacies. Additionally, Ms. Talley asked how a closed-door pharmacy would even display the containers since there are no front counters or patient reception areas at these types of pharmacies. The board asked the enforcement committee to place this item on a future agenda.

III. Approval of the January 30-31, 2019 Board Meeting Minutes

President Law noted that the following paragraph on page 6 of the January board meeting minutes needs to be corrected.

Mr. Schaad stated ~~that in response,~~ during the committee meeting Ms. Herold suggested enforcement discretion and SDAG Room supported the Executive Officer's option to not make enforcement of this law a priority for the first 6 months of 2019.

Motion: Approve the January, March and April 2019, meeting minutes with the changes noted to the January meeting minutes.

M/S: Weisser/Sanchez

Support: 9 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x
Law	x			

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

IV. Approval of the March 22, 2019 Board Meeting Minutes

See agenda item III.

V. Approval of the April 16, 2019 Board Meeting Minutes

See agenda item III.

VI. Recognition and Celebration of Pharmacists Licensed in California for 50 Years and Other Recognitions

The board recognized Gene Tsukamoto and Donna Ouchida for 50 years of service as California pharmacists.

The board recognized Stanley Weisser for his service on the board since 2007.

President Law thanked Mr. Weisser for his mentorship and spoke of Mr. Weisser's outstanding leadership strengths and his ability to get individuals with diverse opinions to work collaboratively.

Board member Veale thanked Mr. Weisser for his dedication to the board and to the consumers of California.

Mr. Weisser thanked the Governor's office for appointing him to the board and thanked board staff and legal counsel for their assistance during his tenure on the board.

VII. Board Officer Elections

President Law thanked the board for electing him as president of the board and stated that he would like the opportunity to continue in the position for another year. However, he stated that he also wanted Gregory Lippe to have the opportunity to serve as president for his last year on the board. President Law asked the board to consider allowing for a co-presidency.

Board member Albert Wong nominated Victor Law and Gregory Lippe as co-presidents of the board. DCA legal counsel Laura Freedman stated that the statute does not contemplate two presidents. She explained that the enforcement and decision-making powers are vested in a single human and having

two people in that position will create a conflict. Ms. Freedman also noted that having two presidents could also create problems with the Open Meetings Act.

Mr. Weisser recommended against having co-presidents. After further discussion the board decided against creating a co-presidency and held a vote which resulted in a tie as reflected below.

Motion: Nominate Victor Law for the position of president of the board.

M/S: Wong/Munoz

Motion: Nominate Greg Lippe for the position of president of the board.

M/S: Weisser/Veale

Board Member	Law for President	Lippe for President	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x
Law		x		
Lippe		x		
Muñoz	x			
Sanchez	x			
Schaad		x		
Serpa	x			
Veale		x		
Weisser		x		
Wong	x			

Following the tied vote, the board decided to flip a coin to determine who would hold the position of president.

Motion: Flip a coin to determine who will hold the position of president of the board.

M/S: Sanchez/ Muñoz

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x
Law	x			
Lippe	x			

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

At the request of the board DCA legal counsel conducted the coin toss which resulted in Victor Law being selected as the president of the board.

Motion: Nominate Gregory Lippe as Vice President of the board.

M/S: Weisser/Sanchez

Support: 10 Oppose: 0 Abstain: 0

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

Motion: Nominate Allen Schaad as Treasurer of the board.

M/S: Weisser/Sanchez

Support: 9 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x
Law	x			

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

VIII. Licensing Committee

Chairperson Veale provided the following summary of the committee's efforts at the April 3, 2019 meeting.

a. Presentation on Medication-Assisted Treatment and Discussion and Consideration of Proposal to Establish Authority for Pharmacist to Provide Non-Opioid Medication-Assisted Treatment

Chairperson Veale stated that there is a huge nationwide opioid crisis. One of the recommended solutions to address the crisis is to provide medication-assisted treatment (MAT) to help wean patients from opioids. There are three main medications used for this -- methadone, buprenorphine and naltrexone. Methadone and buprenorphine are controlled substances that require a DATA 2000 waiver to prescribe. Regrettably, pharmacists are currently not eligible to receive such a waiver. Rather, such waiver authority is currently limited to physicians, nurse practitioners, and physician assistants.

Chairperson Veale explained that naltrexone is a non-opioid medication that is also used in MAT. In Kentucky, pharmacists are allowed to provide naltrexone pursuant to a statewide protocol. Chairperson Veale also explained that the Kentucky protocol specifies the criteria and procedures for pharmacists to initiate the dispensing and administration of naltrexone for MAT to individuals as part of the patient's recovery.

Chairperson Veale reported that during the January 2019 Board Meeting, the board approved a policy statement that supports the role of pharmacists providing direct care to patients with opioid addiction and to assist medical providers in caring for such patients, thereby expanding access to treatment. As such the board's policy advocates for changes in the law that will permit pharmacists to provide MAT as part of a collaborative health care team.

Chairperson Veale reported that at the April 2019 committee meeting, the committee heard from two experts in the field, Talia Puzantian, PharmD, BCPP Associate Professor with Keck Graduate Institute School of Pharmacy and Health Sciences (KGI) and James J. Gasper, PharmD, BCPP Psychiatric and Substance Use Disorder Pharmacist with Pharmacy Benefits Division, California Department of Health Care Services (DCHCS).

Chairperson Veale stated that the committee asked Dr. Gasper and Dr. Puzantain to provide a condensed version of their presentation at today's board meeting.

Dr. Puzantian reported overdose deaths are now the leading cause of mortality for Americans under 50. There are millions of Americans in pain, misusing opioids, and dealing with opioid use disorder. The presenters provided background and relevant statistics on the three medications used in the treatment of opioid use disorder. Dr. Puzantian described a study in which the use of methadone and buprenorphine in MAT was shown to have a greater duration of time in treatment and approximately 50 percent reduction in mortality rate. The use of naltrexone was shown to have a much shorter duration in treatment and no reduction in mortality rate.

The presenters highlighted that one of the current gaps in treatment is a result of a lack of access to the medications as well as the stigma of opioid use disorder can be a barrier to treatment. It was emphasized that pharmacists have a responsibility to take a role in the treatment of opioid use disorder and are in a unique position to do so.

Dr. Puzantian described the use of naltrexone in MAT and provided the pros and cons of using this opioid antagonist. Unlike methadone and buprenorphine, naltrexone does not have regulatory restrictions on prescribing and can be prescribed by a licensed healthcare professional under a collaborative practice agreement (CPA). One issue with naltrexone is that a person cannot begin using naltrexone until they have been opioid free for 7-10 days. Due to this waiting period before starting naltrexone, solely utilizing naltrexone in MAT has shown to have a high relapse rate because patients are less likely to stay opioid free for those 7-10 days. Methadone and buprenorphine can be taken at the first sign of withdrawals within 1-2 days of last use of opioids thus resulting is more successful treatment.

Dr. Gasper described pharmacists' role in administration of methadone in licensed opioid treatment programs (OTP) including clinical management of methadone dosing and monitoring within scope of practice. Community pharmacies can become licensed as OTPs in collaboration with a community physician that is licensed as an OTP to enable pharmacists to become involved with the monitoring and the dosing of methadone and help fill the need for access to treatment. There are only two licensed pharmacies in California that have been licensed as OTPs.

Dr. Gasper described how DATA 2000 waivers for prescribers have expanded access to treatment outside of OTPs by enabling qualified practitioners to provide buprenorphine. The waiver is very underutilized as many professionals that have the authority to use the waiver are not either using their waiver or using the waiver far below its capacity. He further described pharmacists' role in community pharmacies and emphasized that pharmacists can make or break someone's MAT.

The board thanked Dr. Gasper and Dr. Puzantian for their presentation.
Chairperson Veale reported that the Licensing Committee discussed a draft statutory proposal to amend Business and Professions Code (BPC) section 4052 to allow pharmacist to provide non-opioid medication-assisted treatment pursuant to a state protocol in California.

Chairperson Veale explained that based on the information provided in the presentation, the committee voted to move forward with a three-pronged approach including (1) to recommend approving the proposed statutory language as written to amend BPC 4052 to add subdivision (a)(14) and move forward with developing a state protocol (similar to the Kentucky protocol) for

administering naltrexone that could be implemented immediately, (2) encourage pharmacies to become licensed as OTPs for methadone dosing, and (3) to direct the licensing committee to develop a sample CPA for pharmacists to provide MAT in collaboration with a practitioner that has obtained a DATA 2000 waiver. If approved by the board, the committee will continue to discuss this item and will bring forward their recommendations to the board once finalized.

Note: The proposed statutory language for BPC 4052(a)(14) and Kentucky's Opioid Use Disorder Naltrexone Therapy Protocol were provided in the board meeting materials.

Ms. Veale noted that there are a few items in the Kentucky protocol that the committee would not recommend including in the board's protocol, such as the requirement for a doctor to sign off on each training certificate.

Daniel Martinez stated that the California Pharmacist Association (CPhA) supports this committee recommendation and asked the board to consider adding pharmacists' reimbursement to the legislation. Ms. Veale stated that the board could ask the author if they would be willing to add this piece in the legislation; however, reimbursement is not under the board's jurisdiction.

A representative for the California Medical Association (CMA) stated that CMA has been heavily involved in MAT discussions to increase access to treatment. However, CMA is opposed to allowing pharmacists to provide MAT to high risk patients without the controls that were built into the board's naloxone protocol, such as training and reporting requirements. Chairperson Veale stated that the state protocol does require training and collaboration with physicians when a pharmacist is providing MAT to a patient.

The representative stated that CMA would be willing to further discuss pharmacist involvement with MAT. Mr. Weisser noted that the board has successfully worked with the Medical Board in the past and would continue to do so. He added that with the state of the opioid crisis it is critical to increase access to treatment and pharmacists are well positioned to assist in this area.

Should members agree with this new direction, the following language could serve as a motion.

Committee Recommendation (Motion): Approve the three pronged approach including: (1) to approval of the proposed statutory language as provided to amend BPC 4052 to add subdivision (a)(14) and move forward with developing a state protocol (similar to the Kentucky protocol) for administering naltrexone that could be implemented immediately, (2) encourage pharmacies to become licensed as OTPs for methadone dosing, and (3) to direct the licensing committee to develop a sample CPA for pharmacists to provide MAT in collaboration with a practitioner that has obtained a DATA 2000 waiver.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law	x			
Lippe	x			
Muñoz	x			
Sanchez				x
Schaad	x			
Serpa	x			
Veale	x			
Weisser	x			
Wong	x			

b. Discussion and Consideration of Pharmacy Law Related to Collaborative Practice Agreements

Chairperson Veale explained that there are several provisions of pharmacy law (summarized below) that establish authorities for pharmacists and advanced practice pharmacists to perform functions under a collaborative practice agreement.

- BPC 4052.1 in general provides the authority for a pharmacist to order and perform routine drug therapy-patient related patient assessment procedures, order drug therapy based on related lab results, administer drugs and biologics by injection, and initiate or adjust drug regimen pursuant to policies, procedures or protocols as specified in a licensed health care facility.
- BPC 4052.2 in general provides similar authorities for pharmacists included in the prior section but allows for the procedures to be performed in other health care settings including licensed clinics and other licensed facilities owned or operated by a health care service plan.
- BPC 4052.6 in general provides the authority for an advanced practice pharmacist to participate in and evaluate diseases and health conditions in collaboration with other health care providers.
- BPC 4052(a)(9), BPC 4052(a)(11) & BPC 4052(a)(12) provide general authorities for pharmacists, in any setting to participate in interdisciplinary review of patient progress, administer vaccinations, and order and interpret tests.

Chairperson Veale reported that the committee discussed that need to evaluate the current collaborative practice agreements to determine if pharmacy law has remained current with national trends and patient care needs.

Chairperson Veale explained that pharmacy law declares the practice of pharmacy as a profession to be a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes, and further provides that pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

Chairperson Veale reported that the committee reviewed the National Alliance of State Pharmacy Associations (NASPA) report: Pharmacist Collaborative Practice Agreements: Key Elements for

Legislative and Regulatory Authority. As part of its report, NASPA notes that state laws, if too restrictive, can impede innovative team-based care models.

Chairperson Veale stated that the committee considered the draft statutory language proposed to recognize the continued evolution of team-based care approaches. Under the proposal pharmacists would have the authority to initiate, adjust or discontinue drug therapy for a patient under the following conditions:

1. The pharmacist is performing the functions under a collaborative practice agreement with either a prescriber or medical group.
2. The pharmacist is aware of the underlying medical condition(s) for which the patient is being treated.

Chairperson Veale noted that the committee members discussed removing the phrase "whose diagnosis is known to the pharmacist" from the proposed language and discussed the term in the proposed language "a prescriber or medical group". She also stated that the committee agreed using a broader term instead of "prescriber or medical group" so as not to provide limitations in the future as well as not limit the authority of the CPA to the prescriber level.

Chairperson Veale reported that the committee voted to approve proposed language in BPC 4052 to add subdivision (a)(13) "Initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with a prescriber or medical group". The committee also decided to remove the following language from the proposal "whose diagnosis is known to the pharmacist".

Chairperson Veale explained that following the meeting counsel drafted language based on the committee's recommendation for the board's consideration.

Pharmacist Steve Gray spoke in support of the board's action.

The representative from CMA spoke in opposition to the board's proposal stating that it does not include enough oversite and will further fragment patient care. Board member Maria Serpa explained that if a pharmacist has any concerns about a patient or if any protocol is unclear he or she is required to call and consult with the doctor before any action can be taken.

The board asked that Ms. Sodergren speak with CMA to answer any questions they may have. Ms. Sodergren agreed to reach out to CMA; however, she noted that based on the comments made at the meeting it appears that CMA has a fundamental policy issue with the proposal.

Note: The draft language for BPC section 4052(a)(13), relevant law sections, and the National Alliance of State Pharmacy Associations (NASPA) report were provided in the board meeting materials.

Motion: Approve the proposed statutory language to amend BPC 4052 to add subdivision (a)(13) and to direct staff to secure an author to sponsor the statutory change.

M/S: Schaad/Weisser

Support: 9 Oppose: 0 Abstain: 0

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

c. Post Implementation Review of the Advanced Practice Pharmacist Licensing Program including Licensing Requirements and Functions Authorized

Chairperson Veale explained that pursuant to BPC 4052.6, a pharmacist recognized by the board as an Advanced Practice Pharmacist (APH) may do the following:

1) Perform patient assessments.
2) Order and interpret drug therapy-related tests.
3) Refer patients to other health care providers.
4) Participate in the evaluation and management of diseases and health conditions with other health care providers.
5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of BPC 4052.2.

Ms. Veale stated that as identified in BPC 4210 to qualify for an APH license, an individual must hold an active license to practice pharmacy and satisfy two of the following criteria under subdivision (a)(2):

- Earned certification in a relevant area of practice.
- Completion of a post graduate residency.
- Clinical experience for at least one year under a collaborative practice agreement or protocol.

Chairperson Veale reported that at the staff level, changes have been made to the application process to minimize deficiencies. For example, one of the most common deficiencies initially encountered was the required documentation to satisfy the qualifying criteria of experience under collaborative practice agreement or protocol. In response to this common deficiency, the board developed an affidavit that could be completed and signed by both the applicant and the supervising

practitioner, program director or health facility administrator to satisfy these required statements. The affidavit resolved the deficiencies pertaining to the specific language attesting under penalty of perjury. This change has reduced the deficiency rate but regrettably, some applicants continue to submit affidavits that lack the required signature from one of the required individuals listed in this section who must be either the supervising physician, program director, or health facility administrator. Chairperson Veale stated that board staff continues to amend the instructions for clarity when a trend in deficiencies is identified.

Chairperson Veale explained that another implementation challenge noted by board staff relates to applicants using a single pathway to licensure to fulfill two separate requirements. For example, this experience conflict or "double dipping" is encountered when an applicant wishes to apply the residency requirement to fulfill both that pathway as well as the certification pathway. In such cases the applicant must complete a second criterion which is typically the collaborative practice experience pathway. In this instance, the board allows applicants one year to satisfy one of the other criteria to complete their application, thus keeping the application in pending status. Chairperson Veale noted that as of March 2019, there were 57 applications pending in which an experience conflict was a deficiency with the application.

Further, Chairperson Veale reported that some individuals are completing a certification program that does not satisfy the requirements established in regulation, specifically some programs do not include a continuing education requirement. Regrettably, denial of the certification program results in the applicant having to qualify via another certification or another one of the qualifying criteria.

Chairperson Veale stated that on February 9, 2017, the board issued its first APH license. As of March 31, 2019, the board has issued a total of 515 APH licenses. The board currently has received 190 APH applications this fiscal year and has 179 pending applications.

Chairperson Veale reported that during the April 2019 committee meeting, Dr. Joe Guglielmo, Dean of the University of California San Francisco College of Pharmacy, shared with the members that he supports the committee in their efforts in reviewing the criteria of the APH license and the collaborative practice agreements.

Chairperson Veale also reported that the committee discussed the authority of an advance practice pharmacist as defined in BPC 4052.6 and possible ways to expand the authority beyond that of a licensed pharmacist as well as the proposed changes to the language.

Chairperson Veale stated that the committee discussed the licensing requirements under BPC 4210(a)(2) which requires a person to satisfy two of the three criteria to qualify for an APH license. The committee agreed based on public comment this section of the law needs to be revisited by the licensing committee to ensure that the requirements align with the scope of practice of an APH. Board member Allen Schaad noted that the requirements for APH licensure in Washington are considerably less restrictive.

Note: The proposed statutory language for BPC 4052.6(a)(5) as well as the relevant law sections were provided in the board meeting materials.

Committee Recommendation (Motion): Recommend the board consider directing the Licensing Committee to reassess the requirements in BPC 4210 to qualify for an APH license to bring in the scope of practice.

CPhA and Pharmacist Steve Gray spoke in support of the motion.

Support: 9 Oppose: 0 Abstain: 0

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

Chairperson Veale reported that following the meeting, based on the committee's recommendation counsel drafted language to amend BPC 4052.6(a)(5) for the board's consideration as follows.

> *Proposal to Amend Business and Professions Code section 4052.6 as follows:*
> *4052.6. Advanced Practice Pharmacist; Permitted Procedures*
> (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
> (1) Perform patient assessments.
> (2) Order and interpret drug therapy-related tests.
> (3) Refer patients to other health care providers.
> (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
> (5) Initiate, adjust, or discontinue drug therapy ~~in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.~~

The representative from CMA spoke in opposition to the proposed language. She stated that the language was included to ensure the proper coordination of care among providers and the removal could harm patients.
Pharmacist Steve Gray stated that the reference to paragraph 4 of subdivision (a) of Section 4052.2 was included to clarify that the pharmacist is not working independently from the doctor or diagnosing patients; instead, the patients are referred to the pharmacist by the doctor after diagnosis. Chairperson Veale noted that the protocol clearly outlines how the pharmacist is required to coordinate the care with the doctor.

Daniel Martinez representing CPhA spoke in support of the motion and stated that APHs have had extensive education and training which makes them well positioned to provide the additional level of care to patients.

Mark Johnston stated that there are ten states that successfully allow population based collaborative practice agreements with no doctor referral and encouraged the board to make similar allowances. He explained that the protocols are limited to minor ailments and conditions and some have restrictions regarding controlled substances.

Committee Recommendation (Motion): Amend BPC 4052.6(a)(5) as follows.

> *4052.6. Advanced Practice Pharmacist; Permitted Procedures*
> (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
> (1) Perform patient assessments.
> (2) Order and interpret drug therapy-related tests.
> (3) Refer patients to other health care providers.
> (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
> (5) Initiate, adjust, or discontinue drug therapy ~~in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.~~

Support: 9 Oppose: 0 Abstain: 0

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

d. Discussion and Consideration of the Current Provisions of Pharmacy Law Governing Board Licensed Facilities either Impacted by Declared Disasters or Otherwise Destroyed

Chairperson Veale stated that during the December 2018 committee meeting, members discussed the impact the recent declared state of emergency disasters have had on pharmacies licensed by the board. During the most recent declared emergency resulting from the Camp Fire,

five pharmacies were closed because the business either burned down or sustained significant fire damage and one wholesaler facility was destroyed. This resulted in facilities having to either secure a mobile pharmacy or relocate to another area to operate.

Chairperson Veale explained that currently, BPC 4062 only allows for a pharmacy or clinic to employ a mobile pharmacy in the impacted area. If the pharmacy or clinic relocates to another location in the impacted state of emergency area or surrounding area that is not a mobile pharmacy, this constitutes a license transfer pursuant to BPC 4201.

Chairperson Veale reported that during the April 2019 committee meeting, members heard from Pharmacist Lisa Hohenthaner, owner of two pharmacies impacted by the Camp Fire. Dr. Hohenthaner advised the committee that one of her pharmacies was completely destroyed, and second pharmacy was severely damaged. Dr. Hohenthaner described the challenges that resulted from the inability to transfer their pharmacy license to the new location and how it negatively impacted their ability to provide service to the residents of Paradise during this emergency.

Chairperson Veale stated that the committee discussed the barriers that Dr. Hohenthaner experienced as well as others who were impacted during this type of emergency and agreed that the law needs to be amended to allow for businesses that are impacted to quickly return to pharmacy practice and provide patient care during a declared emergency.

Daniel Martinez stated that CPhA supports the amendment of 4062 as proposed.

Committee Recommendation (Motion): Approve the proposed language as provided below; pursue an urgency clause; and direct staff to work with counsel to make the necessary changes in accordance with the policy discussed.

> *4062. Furnishing Dangerous Drugs during Emergency; Mobile Pharmacy*
>
> …
>
> (e) A pharmacy destroyed or damaged either as a result of a declared state, federal or local emergency, or otherwise destroyed by natural disaster may be relocated. Such a relocation shall not be considered transferred if no changes are made to the management and control, or ownership of the pharmacy. Notification of such relocation must be made to the board immediately upon identifying the new location.

M/S: Butler/Wong

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x

Board Member	Support	Oppose	Abstain	Not Present
Law	x			
Lippe	x			
Muñoz	x			
Sanchez				x
Schaad	x			
Serpa	x			
Veale	x			
Weisser	x			
Wong	x			

e. Discussion and Consideration of Proposed Language Establishing Parameters and Fees for Inspections of Sterile Compounding Pharmacies as a Result of Remodeling of the Facility

Chairperson Veale reported that during the December 2018 committee meeting, members discussed the requirements of inspecting a sterile compounding pharmacy at the time of issuance and renewal as well as the need to perform inspections of sterile compounding pharmacies due to a remodel of the pharmacy. The committee considered whether to assess a new inspection fee if the inspection occurs outside the parameters of the mandated renewal inspection.

Chairperson Veale explained that the board is mandated to ensure sterile compounding pharmacies are in compliance with pharmacy law. An inspection at the conclusion of a remodel is necessary to ensure that changes to the sterile compounding pharmacy as a result of a remodel do not pose a safety concern to consumers.

Chairperson Veale stated that currently, the board does not have the authority to require notification of, nor assess a fee for, an inspection as a result of a remodel. Currently when the board is notified of a remodel, the board makes every effort to conduct the inspection as part of the mandated renewal inspection. However, if the remodel concludes outside of the typical time frame for renewal inspection the board currently absorbs the cost, which impacts the board's budget. Chairperson Veale noted that the board must immediately respond to perform such remodel inspections because a delay could impact patient care.

Chairperson Veale stated that remodels vary in scope ranging from simple projects to full remodels or expansions. There are several reasons that a remodel may trigger an inspection such as: unforeseen damage (e.g., flood, fire); planned upgrades (e.g., replacement of a PEC, addition of a PEC, repairing walls, floors, ceilings); and expansion of a facility.

Chairperson Veale reported that the committee also discussed establishing the following parameters to determine if the remodel of the sterile compounding pharmacy requires an inspection and to assess if an inspection fee is required.

1. Require a remodel notification application prior to the conclusion of a remodel to collect the anticipated completion date and identify what is impacted by the remodel for the board to determine if an inspection is required.

2. Require the board to notify the sterile compounding pharmacy if the remodel impacts patient care in a manner that will result in an inspection of the pharmacy.
3. Assess an inspection fee if the remodel concludes more than 90 days prior to the expiration date of the license.
4. If the remodel concludes within the 90 days prior to the expiration date of the license, then the inspection would also serve as the renewal inspection.

Chairperson Veale stated that, as part of the proposed revisions to USP 797, the standards provide that recertification of a classified area must occur if there are changes to the area such as redesign, construction, or replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality. She explained that the committee determined that alignment with such requirements appears appropriate.

Chairperson Veale reported that the committee discussed the board's mandate to inspect the facility to ensure compliance after the conclusion of a remodel as well as addressed the concerns received by public comment regarding charging a fee for the inspection outside of the renewal period. After receiving additional public comment, the committee proposed moving forward with accepting the proposed language as written, which includes charging a fee if the facility is unable to coordinate the completion of the construction within the renewal inspection. Chairperson Veale stated that the committee also agreed that nonresident sterile compounding facilities will need to continue to pay for the cost of the travel for board inspectors to conduct the inspection.

Note: The proposed language to amend BPC 4400 and to add BPC 4127.5 was provided in the meeting materials.

Daniel Martinez representing CPhA asked the board to consider a fee exemption for facilities that cannot coordinate the completion of the construction with the renewal inspection due to unforeseen circumstances (i.e. natural disasters, fire, flooding, etc.). Ms. Sodergren asked if CPhA is seeking an exemption for only pharmacies located in California or for all pharmacies, including those in other states. Mr. Martinez stated that they are only seeking an exemption for California pharmacies.

Committee Recommendation (Motion): Approve the proposed language in BPC 4400 to assess a remodel inspection fee for in-state sterile compounding pharmacies and to assess the remodel inspection fee and travel costs for out-of-state sterile compounding pharmacies.

M/S: Schaad/Wong

Support: 7 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x
Law	x			
Lippe	x			

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

Note: Valerie Muñoz and Stanley Weisser left the meeting prior to the vote.

Pharmacist Steve Gray sought clarification on when an inspection is required. Chairperson Veale explained that the language states that an inspection is required for any remodel that results in ISO5 recertification. He also asked if the application must be received by the board 30 days in advance of the remodel or 30 days after the remodel begins. It was clarified that it must be submitted 30 days after the remodel begins.

Committee Recommendation (Motion): Approve the language as proposed and seek legislation to add BPC 4127.5.

M/S: Schaad/Butler

Support: 7 Oppose: 0 Abstain: 0

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

f. Licensing Statistics

Chairperson Veale briefly reviewed the licensing statistics as provided in the board meeting materials. There were no comments from the board or from the public.

g. Future Committee Meeting Dates

Chairperson Veale reported that the next committee meetings will be held on June 26 and October 2, 2019.

The board recessed for a break at 3:50 p.m. and resumed at 4:10 p.m.

IX. Enforcement Committee

Chairperson Schaad provided the following summary of the committee's efforts at the March 14, 2019 meeting.

a. Discussion and Consideration of Ethics Course Provisions in California Code of Regulations, Title 16, Section 1773.5

Chairperson Schaad stated that provided in the chair report are the requirements for the board's ethics program as established in California Code of Regulations Section 1773.5. He noted that the board currently uses this program as a disciplinary term in certain administrative cases as well as in certain citations as an order of abatement.

Chairperson Schaad reported that during the committee meeting members received a presentation from a representative of the Institute of Medical Quality (IMQ) regarding the content and objectives of IMQ's course. The course includes a full two-day program followed by a 6-month progress report and 12-month final report. Chairperson Schaad stated that the committee was advised that IMQ uses pre-test and post-tests and costs $1995. Following completion of the course participants are provided a satisfaction survey.

Chairperson Schaad reported that the committee heard public comments in support of the ethics program. Further, it was suggested that the course would be beneficial for pharmacy students.

Chairperson Schaad stated that the Enforcement Committee requested that moving forward a report of satisfaction surveys be provided to the board on an annual basis.

Note: Additional information was provided in the meeting materials, including a copy of the presentation provided by IMQ.

There were no comments from the board or from the public.

b. Discussion and Consideration of Senate Bill 1442 (Weiner, Chapter 569, Statutes of 2018) Relating to Community Pharmacy Staffing

Chairperson Schaad reported that the committee discussed Senate Bill 1442 which prohibits a community pharmacy from requiring a pharmacist to work alone unless specified conditions are met. The committee reviewed DEA requirements related to required background checks for employees. Chairperson Schaad noted that pharmacies need to be mindful of these federal requirements when implementing the bill's provisions.

Chairperson Schaad stated that Senator Stone addressed the committee and requested that

inspectors conduct after-hour visits to observe activities that happen in pharmacies. Senator Stone also requested that staff ensure that the measure is appropriately implemented throughout the state. Chairperson Schaad reported that as part the discussion with Senator Stone, President Law suggested that Senator Stone consider amending the law to clarify that pharmacist technicians are required to provide assistance under the conditions of the measure.

Chairperson Schaad reported that the committee also received public comment that some retail staff sent to assist the pharmacist under the provision of SB 1442 lack the training, knowledge and pharmacy skills necessary to provide assistance to pharmacist.

Chairperson Schaad noted that the committee did not take action on this item.

Board member Butler stated that when she speaks with pharmacists they are not getting the help that SB 1442 intends. She added that many pharmacists are afraid to ask for help for fear of retaliation from their employer.

Pharmacist Steve Gray asked how the Enforcement Committee expects the requirements to enforced. Chairperson Schaad stated that the committee agreed that it needs to be enforced but did not have a recommendation on how to enforce it.

A pharmacist from San Diego stated that the bill was written to address the lack of staffing in pharmacies. However, the new law is not being enforced and as a result there has been no change. He added that non-pharmacy managers are inaccurately interpreting the law to get around compliance.

Board member Wong asked why a pharmacy owner might not want to hire additional help. The pharmacist explained that many of the pharmacies are owned and managed by non-pharmacists who are only looking at the bottom line, not patient care.

A Rite Aid pharmacist stated that they have seen no improvements since the implementation of the law and it is negatively impacting patient care. Another Rite Aid pharmacist explained that as a relief pharmacist she has not seen any changes in staffing as the result of this law. She provided personal examples of how the lack of staffing negatively impacted both her safety and her patients' safety.

A representative from the National Association of Chain Retailers stated that they thought this legislation was intended to provide relief for short periods of time such as for lunch breaks. She added that it is the understanding of NACDS that when no help is needed in the pharmacy the employee can return back to his or her normal duties.

c. Summary of a Presentation on the Board's Routine Pharmacy Inspections

Chairperson Schaad reported that the committee received a presentation from Board Inspector Steven Kyle on the inspection process. Following the presentation, the committee was advised that board staff intends to record a future presentation similar to the one provided to the committee which will be made available on the board's website.
Note: A copy of the presentation was included in the meeting materials.

There were no comments from the board or from the public.

d. Update on and Discussion of Board's Citation and Fine Program

Chairperson Schaad explained that goal 2.10 of the board's strategic plan calls for evaluation of the Board's citation and fine program. During the meeting, the committee focused its review on two areas specific to this strategic goal - - post evaluation of the Order of Abatement provisions since the board's May 2018 meeting and review of the policy considerations and guidance staff has been provided by both the president and vice president as it relates to completed citations issued with a fine of $2,000 or greater.

Chairperson Schaad reported that during the meeting the committee reviewed data that demonstrates that orders of abatement are used with a far greater frequency than in previous years which is consistent with direction board members provided to staff. Whereas in 2016/17 about 1% of citations were issued with an abatement order, this year about 20% contain such an order. Chairperson Schaad stated that during the meeting, committee members noted that the number of abatements accepted is relatively low and were advised that individuals typically are provided with a period of time to comply with the order. He noted that the committee will be provided another follow up report to evaluate the compliance rate.

Chairperson Schaad stated that the committee also reviewed the following suggestions the president and vice president have been providing to staff regarding citations. He noted that as each investigation is unique, each case must be individually reviewed to determine the appropriate outcome.

1. Consider the ability of the respondent to pay and recognize that fines assessed may be more difficult for some respondents to pay.
2. Consider referral to the Attorney General's (AG) Office if respondent has been the subject of more than two substantiated investigations.
3. Consider referral to the Pharmacists Recovery Program as well as the AG's office if a respondent refuses to submit to a BAC screen as part of a DUI related incident.
4. Consider referral to the AG's Office in lieu of a citation if the respondent has previous incidents including multiple violations.
5. Consider whether the status of an employee, e.g., floater pharmacist, is a matter of aggravation or mitigation, for example in the cases of a drug loss.
6. Consider the impact to a patient when investigations involve compounding violations.
7. Consider the license history including changes in responsible personnel, e.g. pharmacist-in-charge positions.
8. For medication error cases, consider the type of drug involved and the potential or real harm caused by the error.
9. Consider if patient consultation would have stopped the error from occurring if the prescription was a first-time fill, change in directions, etc.
10. Consider assessing a single fine when multiple violations are related to a single issue, e.g., a medication error.

11. For cases involving failure to report an event to the board, e.g., change of PIC, consider the duration of time.

President Law noted that the number and dollar amount of the citation and fines have gone down over the last year as a result of the board's directive to educate licensees instead of issuing a citation when appropriate.

There were no comments from the public.

e. Discussion and Consideration of Efforts to Reduce Investigation Times and Case Resolutions

Chairperson Schaad stated that goal 2.1 of the board's strategic plan seeks to implement processes to shorten the cycle times for investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.

Chairperson Schaad reported that for several meetings the committee has been discussing investigation closure times and receiving updates on current data. He noted that included in the meeting materials are statistics on pending investigation cases as well as case closure data.

Chairperson Schaad stated that a review of the statistics reflects improvement in overall investigation time for cases that are closed. He noted that the committee will continue to monitor investigation times and provide updates to the full board.

There were no comments from the board or from the public.

f. Discussion on Attorney General's Annual Report on Accusations Prosecuted for Department of Consumer Affairs Client Agencies

Chairperson Schaad reported that goal 2.5 of the board's strategic plan is to evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.

As required by law, the Office of the Attorney General is required to publish data annually on certain disciplinary matters. Chairperson Schaad reported that during the committee meeting SDAG Room provided additional information. SDAG Room noted that board matters may not move as quickly as some other programs within the DCA because of the case complexity and the number of respondents in each case.

Chairperson Schaad stated that the committee did not take action on this item. There were no comments from the board or from the public.

Note: Additional information and relevant portion of the AG's report were included in the meeting materials.

g. Discussion and Consideration of AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction

Chairperson Schaad reported that the committee previously discussed this measure which places restrictions on the acts and convictions the board can consider when making a decision on an application. During the meeting the committee discussed the following two aspects of this measure.

1. Based on the previous request to staff, statutory changes that if enacted could restore some the board's licensing decision authority for specific types of underlying conduct.
2. Review of proposed regulations that are required to be promulgated as part of the requirements established in AB 2138.

Chairperson Schaad explained that during the discussion of item 1, the committee reviewed language that would provide statutory changes to allow the following:

- Consideration of convictions of felony financial crimes.
- Acts that would be grounds for denial of a federal registration to distribute controlled substances.
- Acts that involve fraud in violation of state or federal law related to health care. An example would be Medi-Cal Fraud.
- Convictions related to identify theft.
- Convictions related to the sale of counterfeit products.

Chairperson Schaad reported that after discussion the committee agreed with the proposed statutory change and recommend the board seek an author to make the statutory amendments, including language specific to criminal history.

There were no comments from the board or from the public.

Committee Recommendation (Motion): Recommend the board seek an author to make the statutory amendments, as included in Attachment 6 of the meeting materials, and including language specific to criminal history.

Support: 7 Oppose: 0 Abstain: 0

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

Chairperson Schaad explained that the board is also required to promulgate regulations. In general terms, the board is required to develop criteria to determine whether a crime is substantially related to the duties of the license being sought and rehabilitation criteria. He added that during the meeting, the committee considered regulatory proposals offered by counsel.

Note: Attachment 6 of the board meeting materials included the draft regulation language as provided to the committee.

Committee Recommendation (Motion): Approve the proposed amendments to Title 16 CCR Section 1770, Substantial Relationship Criteria and Section 1769 Criteria for Rehabilitation as included in Attachment 6 of the board meeting materials.

Support: 7 Oppose: 0 Abstain: 0

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

Legal Counsel Laura Freedman recommended making a motion to initiate the formal rulemaking process.

Motion: Initiate the formal 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: Lippe/Law

Support: 7 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim				x

Board Member	Support	Oppose	Abstain	Not Present
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

h. Summary of a Presentation and Discussion on Disciplinary Guidelines

Chairperson Schaad reported that during the meeting the committee heard a brief overview of the board's Disciplinary Guidelines. The guidelines are used by the board and others in reaching decisions in administrative matters. The guidelines detail the factors to be considered in determining penalties as well as the mitigating factors. Further, the guidelines provide categories of violations and recommended penalties. The guidelines provide model language and terms and conditions of probation.

Chairperson Schaad stated that the committee will complete a further review of the guidelines at the next few committee meetings to determine what, if any, changes should be recommended to the full board for consideration. He noted that the committee did not take action on this item but will keep the board apprised of our efforts as we continue our review of the guidelines.

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

i. Summary of a Presentation by the California Pharmacists Association on Proposal to Modify the Board's Current Enforcement Process

Chairperson Schaad stated that during the meeting the committee received a presentation from Danny Martinez and Veronica Bandy, on behalf of CPhA. The presentation focused on the establishment of a Pharmacy Advisory Committee to review investigations prior to initiation of the formal disciplinary process. Mr. Martinez indicated that the board should permit licensees to go before a consortium of their practicing peers in order to help the board prioritize issues.

Chairperson Schaad reported that the committee expressed concerns not only with the construct of the proposed membership of the advisory committee but also the inherent conflict between the board's mandate of protection of consumers and a having a panel of only pharmacists reviewing cases.

Chairperson Schaad reported that counsel highlighted several legal objections include putting members of the board in greater jeopardy for anti-trust violations. Specifically, the committee was reminded about issues of anti-trust and possibilities of treading too close to the line of having licensees exclusively policing other licensees under the North Carolina Dental Board case.

Chairperson Schaad stated that the committee also considered alternative models that were provided during public comment. Ultimately, the committee did not take action on the item except to direct board staff to develop alternative solutions to be presented to the board for consideration.

Note: A copy of the presentation made by CPhA as well as a summary of the committee's discussion was included in the meeting materials.

Daniel Martinez thanked the board for its continued interest in this subject and stated that CPhA looks forward to working with the board further.

j. Review of Final Report Submitted by University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)

Chairperson Schaad stated that attachment 10 of the meeting materials includes the updated study information from UCSD. As indicated in the materials, the study will end in June 2019 and the board should expect to receive a final report in the Fall 2019. Chairperson Schaad reported that during the study period 1,496 new prescriptions have been delivered via the ADDS and 1,650 refill prescriptions. He noted that there have been no complaints filed regarding use of the device.

There were no comments from the board or from the public.

k. Discussion and Consideration of Proposed Changes to Self-Assessment Forms Incorporated by Reference in Title 16, California Code of Regulations, Sections 1715 and 1784

Chairperson Schaad reported that the committee reviewed the proposed changes to self-assessment forms incorporated by reference in CCR Section 1715 and CCR Section 1784. He explained that the self-assessment forms are a compilation of relevant laws that are intended to allow for the entity to self-evaluate compliance with various provisions of law.

Chairperson Schaad explained that because the various forms are incorporated by reference in the respective regulation sections, a regulation change is necessary whenever the forms require update. The prior version of the self-assessment forms is currently undergoing promulgation.

Chairperson Schaad stated that the committee reviewed the draft assessments and are recommending their approval.

Committee Recommendation (Motion): Approve the self-assessment forms as provided in the board meeting materials.

Support: 7 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

Ms. Sodergren stated that while the rulemaking process is occurring the proposed forms will be posted online so licensees can use them if they would like.

l. Discussion and Consideration of Title 16, California Code of Regulations, Section 1715.6 Related to the Reporting of Drug Losses

Chairperson Schaad reported that as part of the board's discussion on the development of its inventory reconciliation requirements, the board's requirement to report drug losses was mentioned. He also explained that an owner is required to report any loss of a controlled substance, including the amount and strength. This report must be made to the board within 30 days.

Chairperson Schaad stated that previous committee discussions noted the difference between our law and DEA reporting requirements.

Chairperson Schaad noted that included in the chair report is data for both loss reports for several fiscal years and the first six months of FY 2018/19. He added that the committee did not take action on this item but requested that staff survey other states to determine their drug loss reporting requirements as well as research the types of drugs included in 1 to 100 dosage units threshold noted within the data.

There were no comments from the board.

m. Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask An Inspector Program

Chairperson Schaad reported that the Communication and Public Education Committee is evaluating the board's Ask An Inspector Program. One of the outcomes of the work of that committee was directing staff to develop FAQs based on questions received. He explained that during the January Board Meeting, it was suggested that the draft FAQs be vetted through the Enforcement Committee.

Chairperson Schaad explained that the committee deferred discussion on this item but will review the draft FAQs during its next meeting.
There were no comments from the board or from the public.

n. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Schaad noted that the enforcement statistics for the first three quarters of the fiscal year were provided in the board meeting materials. He explained that as indicated the board has received 2,229 complaints and closed 2,160 investigations. In addition the board has issued 879 citations and referred 193 investigations to the AG's Office, secured 8 immediate protection orders and issued 3 cease and desist orders.

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

o. Future Committee Meeting Dates

Chairperson Schaad announced that the next committee meeting would be held on July 2.

X. Compounding Committee

Chairperson Serpa reported that the Compounding Committee met on February 20, March 13 and April 16, 2019. The focus of these first meetings has been the education of committee members on the proposed revisions to the compounding chapters. She added that as part of each committee meeting, all present were advised of the USP process for updating chapters within the USP as well as the proposed revisions timeline.

a. Summary of a Presentation on the Current Proposed Revisions to USP General Chapter 795, Regarding Pharmaceutical Compounding – Nonsterile Preparations

Chairperson Serpa reported that on February 20, 2019, the committee convened its first meeting, focusing on education on the proposed revisions to USP General Chapter 795, Regarding Pharmaceutical Compounding – Nonsterile Preparations. The committee was provided with a general timeline for the development of the proposed chapter revisions, including a public comment period that ran from March 30, 2018 through July 31, 2018. She noted that USP's intended publication date for the revised chapter is June 1, 2019, with an intended official date of December 1, 2019.

Chairperson Schaad stated that the committee was presented with a summary of the minimum standards for each section within the chapter relating to nonsterile preparations including:

- Introduction and Scope
- Personnel Qualifications – Training, Evaluation, and Requalification
- Personal Hygiene and Garbing
- Buildings and Facilities
- Cleaning and Sanitizing
- Equipment and Components
- SOPs and Master Formulation and Compounding Records
- Release Testing
- Labeling
- Establishing Beyond-Use Dates
- Quality Assurance and Quality Control
- Compounded Nonsterile Preparation Handling, Packaging, Storage, and Transport

- Complaint Handling and Adverse Event Reporting
- Documentation

Chairperson Serpa stated that a copy of the approved minutes from this meeting were included in the board meeting materials.

b. Summary of a Presentation on the Current Proposed Chapter Revisions to Pharmaceutical Compounding – Sterile Preparations, Chapter 797

Chairperson Serpa reported that on March 13, 2019, the committee convened its second meeting, focusing on education on the proposed revisions to USP General Chapter 797, Regarding Pharmaceutical Compounding – Sterile Preparations (CSPs). The committee was provided with a general timeline for the development of the current proposed chapter revisions, including a public comment period that ran from July 27, 2018 through November 30, 2018. USP's intended publication date for the revised chapter is June 1, 2019, with an intended official date of December 1, 2019.

Chairperson Serpa stated that the committee was presented with a summary of the minimum standards to be followed within each section within the chapter relating to sterile preparations including:

- Introduction and Scope
- Personnel Qualifications – Training, Evaluation, and Requalification
- Personal Hygiene and Garbing
- Facilities and Engineering Controls
- Microbial Air and Surface Monitoring
- Cleaning and Disinfecting Compounding Areas
- Equipment, Supplies, and Components
- Sterilization and Depyrogenation
- SOPs and Master Formulation and Compounding Records
- Release Testing
- Labeling
- Establishing Beyond-Use Dates
- Use of Conventionally Manufactured Products
- Use of CSPs as Components
- Quality Assurance and Quality Control
- CSPs Storage, Handling, Packaging, Shipping, and Transport
- Documentation
- Compounding Allergenic Extracts

Chairperson Serpa noted that a copy of the approved minutes from this meeting was included in the board meeting materials.

c. Summary of a Presentation on the Proposed USP Chapter 800 – Hazardous Drugs – Handling in Healthcare Settings

Chairperson Serpa stated that on April 16, 2019, the committee convened another meeting, focusing on education on the USP General Chapter 800, Hazardous Drugs (HDs) – Handling in Healthcare Settings. The committee was provided with a general timeline for this chapter, including its original publication date of February 2016 and its intended official date of December 1, 2019.

Chairperson Serpa reported that the committee was advised that Chapter 800 covers all aspect of the handling of HDs in healthcare settings, including the compounding of such preparations. The committee was provided with an overview of the development of the National Institute for Occupational Safety and Health (NIOSH) and its relevance to the chapter. Chairperson Serpa also reported that the committee was advised that the goal of the USP standard is to increase awareness, product uniform guidance to reduce the risk of managing HDs, and help reduce the risk posed to patient and healthcare workers.

Chairperson Serpa explained that the committee was presented with a summary of the minimum standards to be followed within each section of the chapter relating to HDs including:

- Introduction and Scope
- List of Hazardous Drugs
- Types of Exposure
- Responsibilities of Personnel Handling Hazardous Drugs
- Facilities and Engineering Controls
- Environmental Quality and Control
- Personal Protective Equipment
- Hazard Communication Program
- Personnel Training
- Receiving
- Labeling, Packaging, Transport, and Disposal
- Dispensing Final Dosage Forms
- Compounding
- Administering
- Deactivation, Decontaminating, Cleaning, and Disinfecting
- Spill Control
- Documentation and Standard Operating Procedures
- Medical Surveillance

Chairperson Serpa noted that a copy of the draft minutes from this meeting was included in the board meeting materials.

d. Future Committee Meeting Dates

Chairperson Serpa announced the following committee dates.

- June 4, 2019
- July 11, 2019

- August 29, 2019
- September 24, 2019
- October 16, 2019

Chairperson Serpa asked if the PowerPoint presentations could be provided on the board's website so that licensees can reference them. Chairperson Serpa noted that a disclaimer could be included stating that the presentations are only *summaries* of the law. Ms. Sodergren stated that the presentations can be provided online if board staff is able to convert the presentations into an ADA compliant format.

The board recessed for the day at 5:20 p.m.

Wednesday, May 8, 2019

President Law called the meeting to order at 9:10 a.m. Roll call was taken, and a quorum was established. Board members present: Victor Law, Gregory Lippe, Lavanza Butler, Allen Schaad, Ricardo Sanchez, Albert Wong and Deborah Veale.

XII. Closed Session Matters

Pursuant to government code section 11126(c)(1), the board convened in closed session at 9:12 a.m. to consider the preparation, approval, grading or administration of one or more licensing examination(s).

President Law returned the meeting to open session at 9:50 a.m.

XI. Organizational Development Committee

a. Budget Update/Report

Fiscal Year 2017/2018

President Law reported that the Chief of Fiscal Operations for DCA recently released a memo regarding the FI$CAL system and the delay in the final 2017/18 budget information. As indicated in the memo, due to challenges in the reconciliation and closing of fiscal year 2017/18 the year-end statistics will not be available until after June 30, 2019.

Note: The board meeting materials contain a copy of the memo.

Fiscal Year 2018/2019

President Law stated that on June 28, 2018, the Governor signed the budget for FY 2018/19. The new budget year began July 1, 2018. The board's spending authorization for the year is $26,007,000, which is an 11.3% increase from the prior year.

President Law explained that as previously noted there continues to be a delay in receiving budget information due to the problems with the FI$CAL accounting system. He noted that based on the preliminary reporting the board believes it has received approximately $19,638,700 in revenue and expended $13,831,705 through February 2019.

b. Board Member Attendance Information

President Law stated that a summary of the board member attendance was provided in the board meeting materials. There were no comments from the board or from the public.

c. Discussion and Consideration of Consolidation of Committee Meetings and Board Meetings

President Law stated that the Organization Development Committee is requesting the board's consideration of a proposal to streamline committee and board meetings. Specifically, the committee requests members consideration of modifying the meeting structure.

President Law explained that the proposal would include that annual basis each committee would meet independent of a board meeting to establish the policy goals for the committee for the upcoming year. The policy goals should directly link to the board's strategic plan and could coincide with the management of the plan. Following the annual meeting, committee members would be advised of updates on progress of the policy goals through committee meetings that coincide with the full board meeting. He explained that this will allow committees to provide additional guidance to staff and address any unexpected issues. President Law stated that staff notes that there are some committee where this revised model may provide a challenge, e.g. the Compounding Committee where the amount of work and limited period of time to complete the work creates challenges.

President Law explained that the full board would continue to meet quarterly; however, the first day of meeting would transition to committee meeting updates, with the second day focusing on consideration of issues for the full board.

President Law noted that a similar process is currently in use for the Legislation and Regulation Committee, which typically meets the morning of the first day of the board meeting, preceding the start of the full board meeting. This process allows for public comment during the committee meeting that is summarized for members the following day during the committee chair's report to the full board.

President Law stated that such an approach would reduce some of the challenges members face with balancing board work with other priorities. Further, it would streamline the development of meeting materials.

The board heard comment from the public in support of the proposal. However, pharmacist Steve Gray expressed concern that the new schedule would prohibit public comments and in-depth discussion.

After hearing public comment, the board decided to try the new schedule and reassess its effectiveness later in the year after trying the schedule a few times.

d. Discussion and Consideration of designating all or portions of the decision, *In the matter of the Citation Against: ESI Mail Pharmacy, Inc. dba Express Scripts, Case No. CI 2009 44657; OAH Case*

***No. 2011060384 as* Precedential pursuant to Government Code section 11425.60**

Note: A memo from DCA counsel Kelsey Pruden providing more detail on the matter as well as a copy of the decision was provided in the board meeting materials.

President Law reported that as indicated in the memo, the board issued a citation to ESI Mail Pharmacy Services, Inc., (ESI) for violations of California pharmacy law. He noted that ESI is licensed with the board as a nonresident pharmacy.

President Law explained that on appeal of the citation, ESI argued that the board lacked the jurisdiction to cite for a violation of California law. Rather ESI asserted that the board could only cite for violations of the resident state's law. President Law reported that the board was successful on the appeal.

President Law noted that staff recommends the board's action to adopt as a precedential decision the ESI Mail Pharmacy Services matter as outlines in the memo from Kelsey Pruden.

There were no comments from the board or from the public.

Motion: Adopt as precedential the below portions of the decision.

PORTIONS OF THE DECISION TO BE DESIGNATED AS PRECEDENTIAL

1. Factual Finding: 8 (*"Issue Number One (Regulatory Authority) and Ruling"*); and
2. Legal Conclusion: The first sentence of Legal Conclusion 8.

M/S: Sanchez/Lippe

Support: 7 Oppose: 0 Abstain: 0

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

e. Update on Implementation of the Acceptance of Credit Cards for Renewal Payments

President Law reported that on December 17, 2018, the board implemented the online credit card renewal payment process for pharmacy technicians. Between December 17, 2018 and March 31, 2019, the board received 2,218 pharmacy technician renewal payments through the credit card process.

President Law stated that on February 27, 2019, the board implemented the online credit card renewal payment process for pharmacists (including advanced practice pharmacists). Between February 27 and March 31, 2019, the board received 193 pharmacist renewal payments through the credit card process.

President Law noted that this process will be implemented for designated representatives in May 2019.

f. Discussion of Assembly Bill 434 Related to Accessibility Standards

President Law explained that Assembly Bill 434 states that before July 1, 2019, and biennially thereafter, the director of each state agency is required to post on the home page of their website a signed certification that the agency's website is in compliance with specified accessibility standards.

President Law stated that the department's Office of Information Services has developed standards that each board and bureau must meet to ensure that all DCA websites are ADA compliant on July 1, 2019.

President Law reported that meeting compliance guidelines is proving challenging is some areas and has resulted in delays in posting materials. In addition, current elements of the webpage will need to be eliminated. For example, the board's webpage currently uses a Google translate function. Regrettably this functionality will no longer be supported in a manner that is consistent with ADA guidelines. Further, the board's calendar of events will need to be removed as well. President L aw stated that staff is exploring different options to reestablish some of the capabilities.

Ms. Sodergren thanked that board and the public for their patience during this transition time and stated that board staff is striving to maintain as much of the current functionality and posting and will keep the board apprised.

g. Sunset Report Update

President Law explained that about every four years the board undergoes the Sunset Review Process. As a precursor to the process, the board is typically asked to prepare a report. He noted that although the board has not received its formal notice requesting preparation of the report, staff believes it will be forthcoming. It is anticipated that the report will be due the end of the year.

President Law stated that the preparation of the report takes several months and is an opportunity to provide information for the legislative oversight committees to learn about the board's achievements related to its mission.

President Law reported that currently board staff is preparing various datasets that it believes will be required as part of the reporting elements of the report. The data will also provide some of the context from which the board can highlights its achievement.

President Law stated that as the board prepares to undergo the process the board's strategic committees may wish to consider possible issues to highlight during the sunset process. Further, the board may wish to designate one or two board members that can provide guidance to staff on elements of the report.

President Law explained that once completed, the report will be provided to all board members for review and approval, which is expected late in 2019.

The board determined that it would be most effective for board staff to work directly with President Law and Vice President Lippe on the development of the report.

h. Personnel Update

President Law reported that the board currently has 11 vacant positions detailed below.

- Executive Officer
- Three inspector positions
- Two Licensing positions
- Four Enforcement positions
- One Administrative position

Ms. Sodergren noted that staff is actively recruiting to fill the vacant positions.

i. Update on the Relocation of Board Office

The relocation of the board's office is still underway and board staff was just advised that the move will occur on June 28.

Ms. Sodergren noted that board staff is working on a communication plan to advise stakeholders of the move and is working with the Department of General Services to ensure that there is no stoppage in work.

j. Update on the Controlled Substance Utilization Review and Evaluation System (CURES)

President Law reported that tables outlining the CURES data released from the Department of Justice for January through March 2019, including registration numbers, usage data and prescription volume information were provided in the board meeting materials. He noted that over 9,690,000 controlled substances prescriptions were reported to CURES in the first three months of 2019.

There were no comments from the board or from the public.

k. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)

President Law reported that the examination scores for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and North American Pharmacist Licensure Examination (NAPLEX) are released twice a year, generally in spring and fall. He noted that the CPJE and NAPLEX statistics for the period of October 2018 to March 2019 were provided in the board meeting materials. President Law explained that typically, candidates that have taken the examination during this period are retaking the CPJE or graduated later in a calendar year.

President Law reported that the Semi-Annual CPJE statistical report for October 2018 through March 2019 reflects that the overall pass rate for the CPJE is 48.9 percent. The pass rate for graduates from the California schools of pharmacy was 54.5 percent. The overall pass rate for the NAPLEX was 91.4 percent.

President Law stated that the pass rates for the CPJE are slightly lower when compared to the same period last year when the passing rate was 51.8 percent.

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

l. Discussion and Consideration of a Staff Request to Award Continuing Education to Pharmacists Who Complete the Job Analysis Questionnaire

President Law explained that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). The Competency Committee, in concert with the board's contracted psychometric firm, has initiated development of job analysis questionnaire used to complete the occupational analysis with the board's contracted psychometric firm. (The job analysis questionnaire consists of duties a licensed pharmacist is authorized to perform in California.) President Law noted that board staff anticipates releasing this questionnaire to pharmacists in the next few months.

President Law explained that as part of the process participants will assess the importance of each duty as well as the frequency the duty is performed. The information obtained will serve as the basis for developing a new content outline from which future iterations of the CPJE will be based upon.

President Law stated that pharmacists who complete the job analysis questionnaire have historically been awarded three hours of CE credit through an action of the board. President Law stated that staff requests that the board again approve this award to acknowledge both the importance of the questionnaire as well as the time commitment necessary to complete the questionnaire.

There were no comments from the board or from the public.

Motion: Approve three hours of CE credit to pharmacists who complete the job analysis questionnaire.

M/S: Lippe/Veale

Support: 7 Oppose: 0 Abstain: 0

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

XIII. Communication and Public Education Committee

Chairperson Sanchez provided the following summary of the committee's efforts at the May 7, 2019 meeting.

a. Discussion and Consideration of Policy on Subscriber Alerts

Chairperson Sanchez explained that the board uses listservs to send information specifically for facilities, pharmacists, intern pharmacists, pharmacy technicians and designated representatives via subscriber alerts. The facilities listserv is also used for alerts about board meetings, new laws and regulations, The Script, and other general topics.

Chairperson Sanchez reported that some facilities feel they receive too many subscriber alerts. Meanwhile, individual licensees do not receive alerts sent to facilities. He added that the board does not have listservs to send alerts to non-licensee audiences – including consumers, news media, and other interested groups.

Chairperson Sanchez stated that other DCA boards and bureaus use a variety of listservs to target alerts to the public as well as licensees.

Chairperson Sanchez explained that during the committee meeting staff suggested creating new listservs to reach non-licensee groups. Staff also suggested creating listservs for specific types of messages such board announcements, new laws, etc.

Chairperson Sanchez reported that the committee directed staff to report back with a plan including possible new listservs. The committee also directed staff to consider whether the board should set policy on how subscriber alerts are targeted or give staff discretion to make those decisions.

b. Staff Update on the "Ask an Inspector" Program

Chairperson Sanchez reported that at the January 8 committee meeting, members directed staff to report back on the possibly expanding the "Ask an Inspector" program hours.

Chairperson Sanchez explained that at the committee meeting staff reported that inspectors are now assigned to "Ask an Inspector" duty Monday through Thursday from 9 a.m. to 1 p.m. This change took effect April 1. Previously, duty inspectors were assigned to answer phone calls from 8 a.m. to 4:30 p.m. on Tuesdays and Fridays.

Chairperson Sanchez also reported that staff has drafted FAQs about controlled substances, the most common type of "Ask an Inspector" question. The FAQs are undergoing legal review and are expected to be presented at the Enforcement Committee meeting on July 2.

Chairperson Sanchez noted that the committee asked staff to report back on whether the number of "Ask an Inspector" calls has changed since the expanded hours began.

President Law and board member Butler stated that pharmacists find the program to be very helpful and expanding the hours will make it easier for them to speak with the inspector.

c. Discussion and Consideration of Educational Materials for Consumers and Licensees during Declared Disasters

Chairperson Sanchez reported that at the January 8 committee meeting, members discussed ways to provide better information to pharmacy patients before and during declared disasters. The committee directed staff to report back with recommendations to improve communications with licensees and the public during disasters. He added that at the January board meeting, the board asked staff to explore awarding CE credit to pharmacists who volunteer services during disasters.

Chairperson Sanchez stated that at the committee meeting staff reported that the board has established a social media account on Twitter, which is widely used to provide information to the public during disasters. Staff also is drafting a consumer tip sheet on how to prepare for a disaster.

Chairperson Sanchez explained that no other states offer CE to pharmacists who volunteer during disasters. However, Florida, Virginia, Michigan, and West Virginia do offer CE credit or other incentives for pharmacists who volunteer in indigent or medically underserved communities.

Chairperson Sanchez reported that the committee recommended advising consumers to review their disaster preparation kits once a year to ensure supplies are up to date. The committee also suggested creating information sheets for licensees on what to do during a disaster and directed staff to report back on the possibility of providing disaster CE training for pharmacists.

There were no comments from the board or from the public.

d. Update on Communication and Public Education Activities by Board Staff

Chairperson Sanchez provided a summary of the board's communication and public education activities as provided below.

1. The Script
   Staff reported the current issue of the newsletter was published in March. Work is underway on the next issue, which is expected to be published in the summer.

2. Projects

   - Pharmacy inspections
     Staff is creating an information brochure describing what happens during a pharmacy inspection and how licensees can contact the board afterward with feedback. The committee suggested creating a separate brochure for compounding inspections. Staff also is creating a video on how to prepare for inspections that will be posted on the board's website.

   - Billboards
     Outfront Media is working to finalize locations and install five billboards being donated to the board to raise awareness of prescription drug abuse in two weeks. Staff will follow up with Outfront on the final installation date and billboard locations.

   - CE webinars
     Staff has created a free CE webinar on ethics that is now posted on the board's website. Pharmacists can view the webinar to comply with the requirement to complete at least two hours of CE in law and ethics courses created by the board.

3. News Media
   Chairperson Sanchez noted that the board meeting materials contains a list of recent media inquiries received by the board's public information officer.

4. Public Outreach
   Staff provided training at CE events hosted by the board on February 23 in Clovis and April 6 in La Jolla. Additional public outreach activities are listed in the board meeting materials.

e. Review and Discussion of News or Journal Articles

Chairperson Sanchez stated that a list of news articles on pharmacy related issues were provided in the board meeting materials.

There were no comments from the board or from the public.

f. Future Meeting Dates

Chairperson Sanchez explained that the committee agreed to reschedule its next meeting from June

25 to July 24 to coincide with the board meeting. He added that the last committee meeting of 2019 is scheduled for October 9.

The board recessed for a break at 10:50 and resumed at 11:05

XIV. Petition from United Food & Commercial Workers Union (UFCW) for Rulemaking to Implement Business and Professions Code Section 4113.5 (SB 1442, Weiner) Regarding Pharmacist Assistance

Department of Consumer Affairs legal counsel Laura Freedman explained that the board received a petition from UFCW which recommended that the board adopt regulations to further clarify the requirements created by SB 1442. She stated that the board could choose to formally accept or reject the recommendation presented by UFCW in the petition. Ms. Freedman also explained that the board could send the matter to a committee for further review and discussion.

Ms. Freedman reported that as part of the formal petition process the Office of Administrative Law requires that the board publish a notice explaining the action taken by the board regarding the petition. She explained that typically the board must publish the response in 30 days; however, due to the timing of the submission of the petition, a notice of delay was provided informing UFCW that the petition would be discussed at the May 2019 board meeting.

Ms. Freedman again stated that at this meeting the board must consider the language provided in the UFCW petition and decide what action is appropriate.

Note: The entire petition packet was provided in the board meeting materials.

President Law asked what the process would be if the board chooses to adopt the regulation language presented by UFCW. Ms. Freedman explained that it would go through the entire rulemaking process, including the DCA review process. Ms. Freedman noted that if the board decides to pursue rulemaking, staff will need also time to work on the initial statement of reasons. President Law noted that it could potentially take two years to complete the rulemaking process. Ms. Freedman agreed.

Ms. Freedman stated that the board could decide it would be helpful from an enforcement perspective to define the phrase “make available” and to further clarify what type of documentation should be required for policies and procedures in each pharmacy. Ms. Sodergren also stated that while the board is pursuing the rulemaking process, the Deputy Attorney General can use the board’s policy discussion as a guide when making enforcement decisions.

Ms. Sodergren explained that the board must decide if a regulation is necessary and, if so, the board must then decide if it wants to adopt the language as provided by UFCW or draft its own.

Board member Greg Lippe stated that due to the confusion created by the requirements in SB 1442, regulations should be adopted to provide clarity. Ms. Freedman explained that if the board does not want to adopt the proposed language from UFCW, then the board could direct a committee to further develop the language and present it to the board at its next meeting. President Law and Mr. Lippe asked that DCA counsel assist the committee with drafting the language.

The board heard testimony from numerous pharmacists who stated that in their experience the requirements in SB 1442 are not being enforced. They explained that leaving pharmacists alone in a pharmacy poses a threat to both pharmacists and the public.

Ed Howard, counsel for UFCW, spoke in support of sending the language to a committee for further review and modification; however, he asked that the board first approve the petition and use the language provided by UFCW as the starting point for the committee's discussion.

Jennifer Snyder, representing the National Association of Chain Drug Stores and the California Retailer's Association, stated that as the new law recently became effective the board should allow time for large organizations to implement the new requirements. She stated that both associations would be opposed to adopting regulations.

Following the discussion and testimony, the board decided not to grant the petition and instead refer the matter to the Legislation and Regulation Committee to further review and draft language for the board to review and approve at a future meeting.

Motion: Take other action on the Petition as allowed in statute and refer the development of regulation language to the Legislation and Regulation Committee.

M/S: Lippe/Sanchez

Support: 6 Oppose: 0 Abstain: 1

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

XV. Legislation and Regulation Committee

Chairperson Lippe provided the following summary of the committee's efforts at its May 7, 2019 meeting. He explained that his report would focus on items that the committee took action on during its meeting. Chairperson Lippe noted that additional information on all agenda items can be found in the board meeting materials.

a. Discussion and Consideration of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations

1. AB 387 (Gabriel) Physician and Surgeons: Prescriptions

Chairperson Lippe explained that as amended April 22, 2019, AB 387 would require a prescriber to include on the prescription the purpose for the dung unless the patient opts out. Further it would require the board to reassess its patient-centered labeling regulations and provide guidance on the way a pharmacist should include this information.

Status: Assembly Appropriations Suspense File

Chairperson Lippe reported that the committee received public comment both in support and in opposition to the measure. As part of the public comments the committee was provided with historical perspective on the issue including the results of surveys conducted that indicated patients' desire to have this information included on prescription. Further, it was noted that such information provides necessary information to care givers and can ensure more meaningful patient consultation.

Chairperson Lippe stated that the committee discussed the logistics of a patient opting out and was advised that at the time the prescription is written, the prescriber has an obligation to advise patients of their ability to opt out.

Chairperson Lippe noted that comments in opposition indicated concerns with off label use of medication.

President Law asked if the Medical Board has a position on this bill. Ms. Sodergren stated that the Medical Board as not yet established a position.

Committee Recommendation (Motion): Establish a Support position.

Support: 7 Oppose: 0 Abstain: 0

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

Board Member	Support	Oppose	Abstain	Not Present
Wong	x			

Committee Recommendation (Motion): Refer to the Communication and Public Education Committee, development of education materials for consumers and licensees about the current requirements of the law and the value of including the purpose of the medication on a prescription and prescription label.

Support: 7 Oppose: 0 Abstain: 0

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

2. AB 528 (Low) Controlled Substances: CURES Database

Chairperson Lippe explained that as introduced February 13, 2019, this measure would require reporting to CURES within one business day. As indicated in the analysis, the board voted to sponsor a similar provision.

Status: Senate Desk

Chairperson Lippe reported that as part of the meeting the committee was advised that CPhA and CSHP will be offering amendments to allow for the cancellation of a script through the CURES system. In addition, the organizations are requesting that the author of the measure remove the urgency clause.

Daniel Martinez confirmed that CPhA and CSHP will be offering amendments. Ms. Sodergren noted that the board typically only takes a position on the language that is in print; however, if needed the chair of the committee can take an interim position on a bill to be ratified by the board at its next meeting.

Steve Gray representing CSHP asked the board to consider removing the urgency clause to allow for implementation time.

The board discussed how the urgency clause could potentially cause problems with implementation and considered if the board should take a support if amended position to remove the clause.

Motion: Establish a Support if Amended position to remove the urgency provision contained in the measure.

M/S: Lippe/Butler

Support: 7 Oppose: 0 Abstain: 0

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

3. <u>AB 544 (Brough) Professions and Vocations: Inactive License Fees and Accrued and Unpaid Renewal Fees</u>

Chairperson Lippe explained that as amended March 21, 2019, the measure would establish a lower fee for renewing a license on an inactive status and prevent the board from assessing accrued and unpaid renewal fees

Chairperson Lippe stated that staff projects this measure will reduce the board's annual revenue by somewhere between $200,000 and $280,000.

Status: Assembly Appropriations Committee suspense file

Chairperson Lippe reported that as part of our discussion the committee contemplated why someone would elect to put their license on an inactive status if they were still obligated to pay the full renewal fee. Public comment noted that in some circumstances individuals may not want to work as a pharmacist but want to retain their ability to return to the practice in the future without being required to retake the pharmacist examinations. The committee also highlighted the negative impact this measure would have to the board's fund and was reminded that a license can be disciplined even when on an inactive status.

There were no comments from the board or from the public.

Committee Recommendation (Motion): Establish an Oppose position

Support: 7 Oppose: 0 Abstain: 0

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

4. AB 613 (Low) Professions and Vocations: Regulatory Fees

Chairperson Lippe explained that as introduced February 14, 2019, this measure would provide that DCA programs could increase any fee authorized in an amount not to exceed the consumer price index for the preceding four years. Under the conditions the board would provide the calculations to the director for approval.

Chairperson Lippe stated that staff notes that this measure would provide the board greater flexibility to increase fees consistent with the consumer price index and would streamline the process.

Status: Ordered to the Senate

Chairperson Lippe reported that the committee discussed the benefit of the streamlined process being sought in this measure and was advised that the board will retain the option to pursue fee increases as it is doing so now.

There were no comments from the board or from the public.

Committee Recommendation (Motion): Establish a Support position.

Support: 7 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x

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

5. AB 1076 (Ting) Criminal Records: Automatic Relief

Chairperson Lippe explained that as amended March 27, 2019, the measure would require the DOJ to review summary criminal history information and identify individuals who are eligible for automatic relief by having their arrest and criminal records withheld from disclosure. He added that it would also require the DOJ to provide automatic relief to eligible persons.

Chairperson Lippe stated that staff suggests an Oppose Unless Amended position to allow the DOJ to release background information on those individuals seeking licensure if prior conduct is proven.

Status: Assembly Appropriations Committee Suspense File

Committee Recommendation (Motion): Oppose Unless Amended position to allow the DOJ to release background information on those individuals seeking licensure if prior conduct is proven.

Support: 7 Oppose: 0 Abstain: 0

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

Board Member	Support	Oppose	Abstain	Not Present
Wong	x			

6. AB 1131 (Gloria) Medi-Cal: Comprehensive Medication Management

Chairperson Lippe reported that as amended April 11, 2019, this measure would establish comprehensive medication management (CCM) are covered by Medi-Cal and would require CCM services to include a care plan that would encompass identified medication therapy problems. The measure would establish the minimum criteria to receive CCM services and would require the Department of Health Care Services to establish reimbursement rates for pharmacists providing such services.

Chairperson Lippe explained that in the analysis of this measure staff noted that the board routinely receives public comment indicating that the lack of reimbursement for services sometimes becomes a barrier to access. Further noted is that this measure is consistent with the board's vision, "Health Californians through quality pharmacist care."

Chairperson Lippe stated that the committee was advised that AB 1131 is cosponsored by CPhA and CSHP.

Status: Referred to Assembly Appropriations Committee

Daniel Martinez and Steve Gray asked the board to support AB 1131.

Committee Recommendation: Establish a Support position.

Support: 7 Oppose: 0 Abstain: 0

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

7. AB 1545 (Obernolte) Civil Penalty Reduction Policy

Chairperson Lippe reported that as amended April 8, 2019, this measure would require state

agencies to assist small business with complying with all statutes and regulations administered by the state agency and in any enforcement action taken by the state agency. Further, state agencies would be required to establish a policy that provides for the reduction of civil penalties for violations for small businesses.

Chairperson Lippe explained that as the analysis highlights, the board currently provides the ask.inspector program that provides licensees with an opportunity to seek guidance from an inspector. Further, the board's newsletter and self-assessment process provide other educational resources for all licensees.

Ms. Sodergren explained that the measure would require the board to assist people with enforcement matters; however, because the board is the investigator that would create an inherent conflict.

There were no comments from the public.

Status: Assembly Appropriations Committee hearing scheduled for May 8, 2019.

Committee Recommendation (Motion): Establish an Oppose Unless Amended position to address the conflicts this measure creates with the APA.

Support: 7 Oppose: 0 Abstain: 0

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

8. SB 159 (Wiener) HIV Preexposure and Postexposure Prophylaxis

Chairperson Lippe explained that as amended April 30, 2019, this measure would authorize a pharmacist to furnish preexposure and postexposure prophylaxis under specified conditions. The most recent amendments would prohibit a health plan or pharmacy benefits manager from prohibiting a pharmacy from dispensing these medications.

Chairperson Lippe noted that this measure expands access points for these medications.

Status: Senate Appropriations Committee Hearing scheduled for May 13, 2019

Chairperson Lippe stated that this measure seems consistent with previous policy measures the board has such supported, such as those included in Senate Bill 493 from several years ago.

Chairperson Lippe reported that the committee heard from CPhA who is cosponsoring this measure. They noted that high success rate of the medications and that the proposal requires pharmacists to follow the CDC guidelines. Also in support of the measures is the United Nurses Association of California.

The committee was advised that CSHP has an oppose unless amended position. They are seeking amendments to broaden who the board can consult on its implementation efforts.

The United Nurses Association of California and CPhA spoke in support of the measure.

Committee Recommendation (Motion): Establish a Support position.

Support: 7 Oppose: 0 Abstain: 0

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

9. SB 425 (Hill) Health Care Practitioners: Licensee's File: Probationary Physician's and Surgeon's Certificate: Unprofessional Conduct

Chairperson Lippe explained that as recently amended on April 30, 2019, this measure would require any health facility or clinic to report to the relevant state agency, any allegation of sexual abuse or sexual misconduct made against a healing arts licensee within 15 days of receiving the allegation. Further this would establish significant civil fines for failure to make such a report.

Status: Senate Appropriations Committee hearing scheduled for May 13, 2019.

Chairperson Lippe reported that during the committee meeting members expressed concern that

the bill does not clarify when such allegations must be reported. The committee requested clarification from DCA legal counsel on the issue of a reporting an allegation and what standard would be used.

Ms. Freedman explained that section two of the measure would add a new section into the general business and professions code. She read the following excerpt from the bill.

A health facility or clinic, the administrator or chief executive officer of a health care service plan, or other entity that makes any arrangement under which a healing arts licensee is allowed to practice in or provide care for patients shall file a report of any allegation of sexual abuse or sexual misconduct made against a healing arts licensee to the agency within 15 days of receiving the allegation of sexual abuse or sexual misconduct.

Ms. Freedman stated that a willful failure to file a report is punishable by a fine of up to $100,000. She explained that an unintentional failure to report can be punishable by a fine of up to $50,000. Ms. Freedman provided further clarify by reading the following excerpt.

The amount of the fine imposed, not exceeding fifty thousand dollars ($50,000) per violation, shall be proportional to the severity of the failure to report and shall differ based upon written findings, including whether the failure to file caused harm to a patient or created a risk to patient safety; whether any person who is designated or otherwise required by law to file the report required under this section exercised due diligence despite the failure to file or whether the person knew or should have known that a report required under this section would not be filed; and whether there has been a prior failure to file a report required under this section. The amount of line 40 the fine imposed may also differ based on whether a health care facility or clinic is a small or rural hospital as defined in Section 124840 of the Health and Safety Code.

Pharmacist Steve Gray expressed concern that the measure does not clarify if the allegation must be related to the professional duties of the licensee. Ms. Sodergren asked if CSHP is seeking clarification on this point. Pharmacist Grey stated that CSHP was not.

Ms. Sodergren explained that the board currently acts on cases regarding unprofessional conduct and the unprofessional conduct does not have to occur while the licensee is practicing in a pharmacy. Ms. Freedman added that as the scope of practice for pharmacists expands the potential for harmful interactions with patients will increase.

Board member Serpa stated that the committee discussed concern that the term “credible allegation” is not clearly defined.

The board decided not to take a position on the measure.

10. SB 601 (Morrell) State Agencies: Licenses: Fee Waiver

Chairperson Lippe reported that as amended March 28, 2019, this measure would authorize a

state agency to reduce or waive any required fee if a person or business demonstrates to the agency that the individual or business has been displaced or affected by a declared federal emergency or proclaimed state emergency.

Status: Senate Appropriations Committee hearing scheduled for May 13, 2019.

Chairperson Lippe explained that the committee noted that the policy of the measure seems consistent with the policy direction of the board related to declared emergency provisions, including a proposal we will be considering by the Licensing Committee, which was subsequently approved yesterday by the board.

Committee Recommendation (Motion): Establish a Support position.

Support: 8 Oppose: 0 Abstain: 0

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

11. SB 617 (Glazer) Pharmacy Technicians: Supervision

Chairperson Lippe explained that as amended April 25, 2019, this measure would allow an employer and a labor union representing pharmacists and/or pharmacy technicians to enter into a collective bargaining unit that provides for a ratio of up to three pharmacy technicians to one pharmacist under specified conditions. Further, it would provide that the employer must apply to the board for approval to use the ratio.

Status: Senate Appropriations Committee hearing scheduled for May 13, 2019.

Chairperson Lippe reported that the committee received significant public comment on this measure both in support or and in opposition to the measure. Those in support of the measure discussed the benefits to patient care by freeing up the pharmacist to provide more clinical and patient care services. Those in support included UFCW who is a sponsor of the measure as well as SEIU and CVS. As part of the discussion with UFCW, it was clarified that the board would have the ultimate authority to ensure the public is protected.

Chairperson Lippe stated that the committee was also advised about ratio requirements in other states.

Chairperson Lippe stated that the committee was advised that Albertsons/Safeway has a support if amended position. They are seeking to remove the board approval requirement established in the proposed legislation.

Chairperson Lippe reported that CPhA expressed concerns with the bill and indicated they believe education and training requirements for technicians need to be addressed first.

Chairperson Lippe also reported that the United Nurses Association of California spoke in opposition indicating three concerns with the measure.

1. Increasing the workload of pharmacist through supervisory duties
2. The collective bargaining process where pharmacist engagement is not required
3. Ambiguity in the bill related to the board's role.

Chairperson Lippe stated that during the committee meeting member Butler spoke in support of the measure and indicated that the proposal is consistent with the feedback she receives from pharmacists asking for additional pharmacy technician assistance.

Chairperson Lippe reported that member Serpa expressed some concern that the provisions did not apply to all practice settings thus creating inconsistent standards.

Chairperson Lippe stated that ultimately the committee did not make a recommendation on the bill but noted that clarification should be sought on some components of the measure including if, as written, the board would have the authority to make a determination on approval and if a pharmacist retains the ability to refuse to supervise a second pharmacy technician as is the case under current law.

Kelsey Pruden stated that based on her research and analysis the pharmacist would not be able to refuse supervision of a second pharmacy technician if the board approves the ratio.

The board heard testimony from two pharmacists who asked the board to support the measure as it will free up pharmacists to provide better patient care.

Board member Veale asked if the pharmacy and the labor union must agree on the ratio before it can be approved by the board. She noted that this would create different ratios depending on what agreements the labor union can reach with different pharmacies. Ms. Pruden confirmed.

Michelle Reevis stated that the California Pharmacists Association opposes the legislation. She explained that CPhA believes education and training requirements for technicians need to be addressed before ratios can be changed. Ms. Veale noted that the Licensing Committee has looked extensively at the education and training requirements for technicians.

A representative from the United Nurses Association of California spoke in opposition of the measure and stated that instead of increasing the ratio pharmacies should be hiring additional pharmacists.

A representative from Rite Aid stated that despite being the only fully unionized pharmacy chain, Rite Aid is opposed to the measure. He explained that Rite Aid believes that the ratio should be based on patient care issues not bargaining agreements.

A representative from Walgreens stated that while they support the general principle of considering ratio changes, they believe that the ratio should be based on patient care issues not bargaining agreements.

A representative from the United Food and Commercial Workers stated that UFCW represents both pharmacy technicians and pharmacists and they believe that using the bargaining unit process will protect both parties. He added that patient will be protected by the fact that the board must approve the ratio changes.

A representative from Ellison Wilson Advocacy stated that the bill is ambiguous and asked the board to oppose the measure.

Board member Wong expressed concern that patients may be harmed because the pharmacist will have to check the work of three technicians. Ms. Veale noted that as the scope of practice increases for pharmacists they will need help to handle non-clinical tasks.

Ms. Butler stated that when she speaks with pharmacists they always say that they need more help and they were supportive of the bill.

Mark Johnston, Senior Director with CVS Health stated that limiting ratios require pharmacists to engage in non-judgmental tasks, as opposed to providing direct patient care at a time when California faces a provider shortage. Pharmacists spend an average of 44% of their workday performing pharmacy technician level tasks. Mr. Johnston stated that CVS Health believes this this bill is long overdue and asked the board to support the measure.

Pharmacist Steve Gray stated the board should consider what the approval process would involve and what authority the board is provided.

Chairperson Lippe asked if the board has any discretion to approval or deny the increased ratio when they are reviewing applications. Ms. Pruden stated that as written, if the application meets the criteria listed in the bill the board would not have the discretion to deny the application.

Chairperson Lippe motioned to send the item back to the Legislation and Regulation Committee for further discussion and consideration. Ms. Veale expressed concern with further delaying the discussion. The representative from UFCW (sponsor of the legislation) stated that if the bill is agendized for a future committee meeting they will be sure to have experts to attend that can answer the board's questions.

Motion: Direct the Legislation and Regulation Committee to discuss SB 617 at its next committee meeting.

M/S: Lippe/Sanchez

Support: 7 Oppose: 1 Abstain: 0

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

b. Discussion and Consideration of Board Approved Regulations Undergoing Public Comment Period

Chairperson Lippe explained that the board currently has three regulations undergoing public comment. He provided a brief summary of each proposal as provided below. Chairperson Lippe also noted that during the meeting held May 7, the committee did not discuss any of the regulations in detail.

1. Proposed Regulations to Add Title 16 CCR Section 1793.9 Related to Remote Dispensing Technicians

Summary of Regulation: This proposal establishes regulatory requirements for pharmacy technicians working in a remote dispensing site pharmacy. As indicated under the legislation portion of the report, there is legislation pending (AB 690, Aguiar-Curry) to establish these requirements in statute.

Status: 45-Day Comment Period began: April 12, 2019 (Closes May 28, 2019).

There were no comments from the board or from the public.

2. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Summary of Regulation: This proposal amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

Status: 45-Day Comment Period began: April 26, 2019 (Closes June 10, 2019).

There were no comments from the board or from the public.

3. Proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board's Fee Schedule

Summary of Regulation: This proposal updates the board's fee schedule by increasing the board's fees to address the structural imbalance within the board's budget.

Status: 45-Day Comment Period began: April 26, 2019 (Closes June 10, 2019).

There were no comments from the board or from the public.

The board recessed for a break at 1:00 p.m. and resumed at 1:36 p.m.

XVI. Executive Officer Recruitment – Update on Recruitment Efforts

President Law reported that at its March 2019 meeting the board interviewed four candidates for the position of Executive Officer. He stated that during closed session the board selected a candidate and submitted a letter to the department asking for their approval of the candidate. President Law explained that until the department approves the board's request the matter will remain confidential.

XVII. Update from the Department of Consumer Affairs

Deputy Director for Board and Bureau Services Chris Castrillo provided the board with a brief update as follows.

- Dean Grafilo has accepted a new position with another agency. The executive office staff will strive to continue to provide excellent customer service. Chris Schultz will fill the position until a new director is appointed.
- The executive officer salary study has been completed and is under final review. In the next two weeks a conference call will be scheduled to review the results with board presidents and executive officers.
- The Substance Abuse Coordination Committee will be conducting a survey of stakeholders to determine what areas of the Uniform Standards should be reviewed at future meetings.
  - Ms. Sodergren asked when the newly updated Uniform Standard #4 will be published. She was advised that the updated standards have been provided to executive officers and will be published online shortly.
- The Technology Advisory Committee held their first meeting in March with the goal of improving the technology used by boards and bureaus.
- The DCA Open Data Portal is now live and can be used to provide statistical data to the public as well as board members. https://www.dca.ca.gov/data/index.shtml

President Law asked why there are so many problems and delays with the new Fi$CAL accounting system. Mr. Castrillo stated that unfortunately the problem with the Fi$CAL system is statewide. He added that the DCA budget office is working overtime to provide the boards with as much budget

information as possible until the problems with Fi$CAL can be resolved. Ms. Sodergren thanked the DCA budget office for their work and assistance during the difficult transition.

President Law stated that the board has had numerous discussion regarding the hiring of its own legal counsel and asked what the board should do to continue the process now that there is no DCA director. Mr. Castrillo recommended scheduling a meeting with Chris Schultz and the Deputy Director of Legal Affairs to resume the discussions.

XVIII. Closed Session Matters

The board recessed to closed session at 1:49 p.m.

The board returned to open session at 2:15 p.m. and President Law adjourned the meeting at 2:16 p.m.