California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Governor Edmund G. Brown Jr.

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

Date:	October 23-24, 2018
Location:	Radisson Hotel - Fresno Conference Room 1055 Van Ness Ave. Fresno, CA 92732
Board Members Present:	Victor Law, Licensee Member, President Gregory Lippe, Public Member, Vice President Allen Schaad, Licensee Member, Treasurer Ricardo Sanchez, Public Member Albert Wong, Licensee Member Deborah Veale, Licensee Member Maria Serpa, Licensee Member Ryan Brooks, Public Member Valerie Munoz, Public Member – October 24 only Lavanza Butler, Public Member Shirley Kim, Public Member
Board Members Not Present:	Amjad Khan, Public Member Stanley Weisser, Licensee Member
Staff Present:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Staff Counsel Charlissa Strong, Senior Staff Manager Kelsey Pruden, DCA Staff Counsel Joshua Room, Supervising Deputy Attorney General

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

President Law called the meeting to order at 12:03 a.m.

Board members present: Victor Law, Gregory Lippe, Ricardo Sanchez, Albert Wong, Allen Schaad, Maria Serpa, Shirley Kim, Lavanza Butler, Deborah Veale, and Ryan Brooks.

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

Former board member, Raffi Simonian asked the board to reconsider extending the construction waivers for sterile compounding facilities.

Steve Gray asked the board to discuss implementation of newly enacted legislation at each committee meeting.

Former board member, Holly Strom stated that furnishing naloxone is too time consuming for pharmacists. She asked that the board discuss simplifying the requirements.

Daniel Martinez asked that the Enforcement Committee discuss board member involvement in the enforcement process (including the possibility of pre-hearing meetings) at their next meeting.

III. Approval of the July 24-25, 2018 Board Meeting Minutes

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

Motion: Approve the July board meeting minutes.

M/S: Lippe/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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

IV. Approval of the September 7, 2018 Board Meeting Minutes

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

Motion: Approve the July board meeting minutes.

M/S: Lippe/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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

V. Approval of the September 26, 2018 Board Meeting Minutes

Board member Maria Serpa stated that the name of a pharmacist who provided public comment needs to be corrected to Candice Fong. She also asked that the following sentence be modified.

> "Board member ~~and compounding pharmacist~~ Maria Serpa recommended simplifying the language by removing the upper temperature limit from 1751.4 as room temperature is defined in another section of the regulation."

The board agreed with board member Serpa's corrections.

Motion: Approve the September 26 board meeting minutes with the corrections indicated by the board.

M/S: Veale/Sanchez

Support: 5 Oppose: 0 Abstain: 4

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			

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

The board recognized Stan Goldenberg and Erin Wirtz for 50 years of service as pharmacists.

VII. Recognition of the Retiring Executive Officer

Former board presidents recognized executive officer Virginia Herold for her years of service and dedication to the board and consumers. The board also presented Ms. Herold with a plaque to thank her for her service.

VIII. Discussion and Consideration of the Board's Strategic Plan, Including Committee Recommendations for Changes to Committee Goals

President Law reported that during its October 26-27, 2016 meeting, the board approved its current strategic plan. Historically the board has conducted an annual review of its plan. He explained that the strategic plan is intended to be living document and needs to be updated to reflect changes in board priorities that may result from changes in the marketplace, legislation, etc.

President Law stated that in preparation for this annual review, each of the committees reviewed the strategic goal areas for their committee and determined if additional goals should be incorporated into the plan.

President Law asked that each committee chair review their current strategic goals and the status of each goal. He also asked that the chairs provide any recommended changes to their committee goals. Below is a summary of each committee's strategic goals.

Licensing Committee

1.1 Research and identify issues that result from unlicensed vendors in the marketplace to proactively maintain patient safety and health.
Status: The Executive Officer serves on the NABP's. PHARMACY task force and provides updates on the national efforts to address unlicensed internet pharmacy sales.

1.2 Implement online application, license renewal, and fee payment for applicants and licensees to improve licensing conveniences.
Status: The board is currently working with the department to secure the ability to accept credit card payments for renewal payments. Further, the board is in the initial stages of Business Modernization, the process used to evaluate legacy computer systems.

1.3 Complete a comprehensive review of at least five licensure categories and update requirements to ensure relevancy and keep licensing requirements current with professional practices.
Status:

- Post implementation review of the Advanced Practice Pharmacist is underway.
- Occupation Analysis is underway for both of the currently recognized pharmacy technician certification examinations and regulation changes are pending to update the training requirements.

- Review of hospital pharmacy practice was evaluated, and legislative changes secured to establish satellite compounding pharmacies. The board has started to receive hospital satellite compounding applications for licensure.

1.4 Explore, and possibly implement, opportunities to use contracted organizations to administer the board's California Practice Standards and Jurisprudence Examination to increase access to the examination.
Status: No action has been taken on this goal.

1.5 Improve the application process for new licensees, including providing informational resources directed toward applicants to offer more guidance about the application process.
Status: Applications are in various stages of being streamlined and standardized.

1.6 Establish requirements to form a licensing process for alternate work sites and vendors in the pharmacy marketplace to advance patient safety and health.
Status: Statutory changes to allow for the use of ADDS is awaiting signature by the Governor.

1.7 Identify opportunities to expand electronic interfaces with licensees to allow for online application and renewal.
Status: The board is currently working with the department on Business Modernization.

Licensing Committee Recommendations for Additional Goals:

- Proposed new 1.8: Implement new licensing programs
- Proposed new 1.9: Perform annual benchmarking with national practice standards

Pharmacist Steve Gray recommended amending 1.9 to add a review regarding the scope of practice. The board agreed with his recommendation.

Motion: Approve the Licensing Committee strategic goals with the addition of an annual review of scope of practice to goal 1.9.

M/S: Veale/ Butler

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x

Board Member	Support	Oppose	Abstain	Not Present
Wong	x			

Enforcement Committee

2.1 Implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.
Status: As part of its meetings, the enforcement committee is receiving information on investigations and efforts currently underway to reduce such times.

2.2 Strengthen patient consultation outcomes for Californians and increase medication safety.
Status: The board is seeking to strengthen patient consultation requirements for mail order pharmacies. In addition, the board has received general information about board investigations involving patient consultation violations and efforts taken by district attorneys reaching settlements to gain better compliance.

2.3 Collect data and report to board members about enforcement trends that are presented at case closure so the board can better educate licensees about board priorities.
Status: Multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information online, the board's newsletter includes summaries of the violations leading to disciplinary action.

2.4 Evaluate industry technology trends to develop future regulatory infrastructures that promote patient safety.
Status: The board convened a technology summit on the use of automated drug delivery systems (ADDS) and evaluated the findings of a pilot project to expanding the use of ADDS. The board is currently sponsoring legislation to establish a regulatory framework for ADDS, as well as expand the conditions when such a device can be used.

2.5 Evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.
Status: A presentation on the disciplinary process as well as performance statistics was provided by the Office of the Attorney General.

2.6 Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery.
Status: No work has been done on this strategic goal.

2.7 Investigate options on the interoperability with a National Prescription Drug Monitoring Program.
Status: The board secured legislation to ensure the CURES system's interoperability with other PDMPs.

Enforcement Committee Recommendations for Additional Goals:

- Proposed new 2.8: Develop a process to submit complaints about Inspectors Anonymously and Report Back to the Board.
- Proposed new 2.9: Assess the collateral consequences of post discipline and research options.

- Proposed new 2.10: Evaluation of the board's Citation and Fine program.
- Proposed new 2.11: Review the role and responsibility of the PIC.

Daniel Martinez representing CPhA asked the board to amend strategic goal 2.9 to create a "pre-discipline" review process. DCA counsel Laura Freedman recommended making this a separate goal since it will require a statutory change.

A representative from Albertsons commented that they have seen an improvement in enforcement timeframes and look forward to working with the board on ways to continue to improve them.

After discussion the board decided not to amend the goals and noted that Mr. Martinez's request would be discussed by the Enforcement Committee at a future meeting.

Motion: Approve the Enforcement Committee strategic goals.

M/S: Schaad/Wong

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

Legislation and Regulation Committee

3.1 Educate the board on national pharmacy initiatives impacting consumers and the future of pharmacy (e.g., pharmacists, pharmacy, technicians, distributors, etc.) to strategize the board's efforts in alignment with where the profession is going to be in 2020.
Status: The board's Executive Officer provides updates to the board about discussions occurring at the national level.

3.2 Support legislative and regulation proposals from board approval to enactment to effectuate the goals of the board.
Status: Last fiscal year, 5 regulations took effect. Further, at the end of this legislative year, 1 board-sponsored measure will be signed by the governor. An additional 5 measures were signed where the board was the originator of the measure.

3.3 Advocate for or against legislation that impacts the board's mandate for consumer protection.
Status: During the legislative year, the board established support positions on 10 measures and oppose positions on 3 measures.

3.4 Establish a systemized, ongoing review process for board regulations to improve and maintain clear and relevant regulations.
Status: Board staff and counsel are working to improve the quality of regulation packages including ensuring regulation language is clear, consistent, and necessary.

Legislation and Regulation Committee Recommendations for Additional Goals:
Keep current goals and continue to monitor progress.

Motion: Approve the Legislation and Regulation Committee strategic goals.

M/S: Lippe/Butler

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

Communication and Public Education

4.1 Develop and implement a communication plan for licensees and consumers to improve communication and keep these stakeholders better informed.
Status: The committee approved a communication plan at its September 2016 meeting in accordance with the board's Strategic Plan goal to "[educate] consumers, licensees and stakeholders about the practice and regulation of the profession."

4.2 Identify and use additional resources for public and licensee outreach services to implement the communication plan.
Status: The board reinstated the Ask an Inspector program for licensees. The board also sponsors CE training events throughout the state and has created webinars for law and ethics CE and naloxone training. In addition, staff is proposing the use of social media to expand communications with the general public.

4.3 Establish a process to collect e-mail addresses and mobile numbers for text messaging to all licensees for better ability to improve communication.
Status: The board has expanded its email notification program. In addition to facilities and pharmacists, the board now also requires pharmacy technicians, intern pharmacists, and designated representatives to register email addresses to receive official notifications.

4.4 Provide implementation guidance on newly enacted changes to Pharmacy Law by publishing summaries and explaining implementation tactics.
Status: The board is providing extensive guidance on the inventory reconciliation regulation through FAQs, newsletter articles, and live CE training forums. The board also has published on its website FAQs about compounding, drug take-back programs, and SB 493.

4.5 Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings.
Status: Board inspectors are working to meet this goal by adjusting schedules and workloads to increase the frequency of routine inspections.

4.6 Communicate the availability of new or specified pharmacy services and locations so that the public is aware of pharmacies that can meet their needs.
Status: The board has developed an online search tool to help consumers find local pharmacies that offer drug take-back services.

4.7 Revise consumer-facing materials (e.g., posters, point-to-your-language notices, television messages) to achieve better consumer understanding of their rights and optimal use of medications.
Status: The board has updated its "Counterfeit Prescription Drugs" brochure, which warns consumers about the dangers of buying drugs online.

4.8 Promote board initiatives to improve patient knowledge, medication adherence, and medication safety.
Status: The board is planning a campaign about prescription drug abuse with a public service message on five billboards donated by Outfront Media. The Board also has sponsored periodic CE training forums on prescription drug abuse throughout the state.

Communication and Public Education Recommendations:
Keep current goals and continue to monitor progress. Annual reports will be provided updating members on the "Ask an Inspector" program and the post inspection surveys conducted.

Motion: Approve the Communication and Public Education Committee strategic goals.

M/S: Sanchez/Lippe

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

Organizational Development Committee

5.1 Conduct a full annual review of the board's strategic plan to monitor progress.
Status: The annual review of the board's strategic plan will occur during the October 23-24, 2018 Board Meeting.

5.2 Provide leadership training opportunities to managers to expand skills and improve performance.
Status: All management staff completed True Colors and training on the Unruh Civil Rights Act. In addition, individual members of the management team completed the following trainings:

- Leadership Fundamentals
- Leader as Communicator
- Creating Effective Teams
- Regulations Process: Putting the Pieces Together
- Performance Management
- Labor Relations for Managers and Supervisors
- Strategic Management
- Hiring and Onboarding New Employees
- Investigative Subpoena Preparation and Delegation
- Safety, Wellness and Accommodation
- Effective Business Writing
- CSHP and Touro University Sterile Compounding Refresher Course

5.3 Expand annual individual development plans for staff to promote growth and development.
Status: 33 Individual Development Plans were provided to inspector staff and 15 office staff. (Note: Because of changes to union contracts, annual individual development plans are no longer required. Rather, staff must elect to participate in the process.)

5.4 Collaborate with the Department of Consumer Affairs (DCA) to explore the feasibility of procuring electronic management tools to increase efficiencies and reduce reliance on paper.
Status: The board has completed the preliminary stages of Business Modernization which

will replace legacy systems, as well as include workflow design improvements and scanning management.

5.5 Maintain procedure manuals to capture institution knowledge and enable consistent operations.
Status:
- The inspector training manual is currently under revision.
- Standardized training plans were developed and are used to onboard new staff.

5.6 Establish customer service metrics to track board efforts to meet customer expectations.
Status: Forty-eight post inspection surveys were conducted by Supervising Inspectors.

5.7 Evaluate options for improvement of licensing renewal processes to allow for online renewal.
Status: Board staff in collaboration with the DCA is looking for a vendor to facilitate credit card renewal payments via an online portal.

5.8 In collaboration with the Executive Officer, ensure appropriate resources for board issues related to staff activities and development.
Status: Field staff completed the CSHP and Touro University Sterile Compounding Refresher course.

Organizational Development Committee Recommendations:
Keep current goals and continue to monitor progress.

Motion: Approve the Organizational Development Committee strategic goals.

M/S: Law/Lippe

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

The board recessed for a break at 1:30 p.m. and resumed at 1:39 p.m.

IX. Discussion and Consideration of Proposal to Modify Pharmacy Compounding Regulations (Title

16, California Code of Regulations, Sections 1735.1, 1735.2, 1735.6, 1751.1, & 1751.4), Including Review of Public Comments

President Law reported that at the July 2017 Board Meeting, the board approved proposed text to amend Sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4 of Title 16 CCR, related to Compounded Drug Preparations. This proposal formally amends the board's regulations regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations. He added that this regulation allows for the use of a double filtration system and further aligns the board's regulations with The United States Pharmacopeia - National Formulary (USP), which is the professional industry standards used across the nation.

President Law explained that USP contains standards developed by a committee of experts that, among other things, help ensure the quality of compounded medications. USP's General Chapters for compounding establish procedures, methods, and practices that are utilized by practitioners to help ensure the quality of compounded preparations. The General Chapters for compounding include Chapter 795 (Pharmaceutical Compounding – Nonsterile Compounding), Chapter 797 (Pharmaceutical Compounding – Sterile Preparations) and Chapter 800 (Hazardous Drugs – Handling in Healthcare Settings). President Law also explained that the U.S. Federal Food, Drug, and Cosmetics Act designates the USP as the official compendium for drugs marketed in the United States. All drug products within the U.S. market must conform to the standards in USP to avoid possible charges of adulteration and misbranding.

President Law stated that as required by the Administrative Procedure Act, board staff released the proposed text for the 45-day comment period on August 3, 2018, which ended on September 17, 2018. At the September 26, 2018 Board Meeting, the board approved a modified text to address concerns expressed by stakeholders and initiated a 15-day comment period. He noted that the 15-day comment period began on September 26, 2018 and ended on October 11, 2018.

President Law indicated that the comments received during the 15-day comment period are included as an attachment. He added that board staff prepared recommendations in response to the comments were also included in the meeting materials.

Tim Lopez from Community Medical Centers asked that board reconsider removing the temperature range in 1751.4(k). He explained that including a temperature range will provide clarity to the regulated public. He also explained that staff working in the compounding room may need the temperature lower or higher based on their individual body chemistry. Mr. Lopez stated that having a range allows the employer to modify the temperature of the compounding room based on their employee's needs.

Ms. Sodergren explained that the board discussed the temperature range in great detail at previous meetings. She stated that the use of the term "typically" is consistent with the language and temperature recommendations within USP 797. Ms. Sodergren added that it is critical that the comfort of the individual compounding be ensured to avoid possible contamination and ensure patient safety. Perspiration contains bacteria which can ultimately compromise the sterility of the environment and of the compounded drug preparations. As individuals may perspire at higher temperatures, the use of the term "typically" will give the employer flexibility to modify the temperature as needed to ensure the safety of the medication.

Board member Maria Serpa stated that the board wants to ensure that the regulations align with USP 797 standards in order to avoid conflicts between the two.

Mr. Lopez expressed concern that without a temperature range, the board inspectors may interpret the term "typically" differently and possibly will penalize the employer if the temperature is too high. The board's legal counsel Laura Freedman responded that the board's inspectors will be looking to see if staff is comfortable in the compounding room (i.e. not sweating) and that the medication is being prepared and stored at a safe temperature. Board member Veale added that the Enforcement Committee is focusing on training the inspector staff to ensure that their interpretation and application of pharmacy law is consistent and follows the policy set by the board.

Ms. Sodergren stated that as part of the rulemaking process, the board reviews comments and responds to each one. She explained that when the board responds to a comment, they are creating policy, which is memorialized in both the meeting minutes and the rulemaking file.

Robert Stein from KGI School of Pharmacy stated that the USP storage standards for controlled room temperature is 68 degrees.

Pharmacists Steve Gray stated that employee comfort is essential for maintaining proper sterile compounding procedures.

A representative from DynaLabs read the section of USP 797 relating to the temperature of the sterile compounding room.

Following the discussion, the board decided not to modify the language in response to the public comments.

Motion: Adopt the regulation language as noticed on September 26, 2018, and delegate to the Executive Officer the authority to make technical or non-substantive changes as may be required by a Control agency to complete the rulemaking file.

M/S: Lippe/Veale

Support: 10 Oppose: 0 Abstain: 0

X. Enforcement and Compounding Committee Related Items

Chairperson Schaad provided a summary of the committee's efforts at the September 14, 2018 meeting as follows.

a. Summary of Presentation on the Board's Enforcement Program

Chairperson Schaad reported that Anne Sodergren provided an overview of the board's enforcement program (a copy of the presentation was provided in the meeting materials).

Chairperson Schaad stated that during the meeting, Ms. Sodergren informed the committee that board staff are collecting information specific to drug loss reports and whether law enforcement agencies are notified by the pharmacy. Once that data set is obtained, the board can review the data and determine whether it is normal practice to notify law enforcement at

the time they determine employee pilferage. Additionally, Script articles could be published to recommend law enforcement notification.

Chairperson Schaad noted that during the committee meeting, clarification was sought on what information is reported to the National Practitioner Data Bank (NPDB) and when is it reported. Board staff advised the committee that disciplinary information is required to be reported to NPDB by Federal Law. Subsequently, once there is a change in the status of a license, for example once a licensee has completed probation, a follow-up report is submitted to NPDB to inform them of the completed probation.

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

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

b. Summary of Presentation on Enforcement Trends

Chairperson Schaad reported that at the committee meeting, Virginia Herold presented information on compounding enforcement trends and Anne Sodergren presented information on drug loss enforcement trends.

Chairperson Schaad explained that as part of the committee's discussion on drug losses, it was suggested that pharmacies may want to consider transitioning to a more real-time inventory for controlled drugs to reduce the stock on hand. Such a change could reduce the number of robberies and night break-ins.

Chairperson Schaad noted that as the Inventory Reconciliation regulations take effect, it is expected that losses due to employee pilferage will also be reduced as identification of the losses should happen more quickly.

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

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

c. Summary of Presentation and Discussion on Efforts to Reduce Investigation Times and Case Resolutions

Chairperson Schaad explained that at the June 7, 2018 Enforcement Committee Meeting, the committee discussed average time frames for case investigations. One of the committee's strategic goals is to implement processes to shorten cycle time from initial investigation to case resolution.

Chairperson Schaad reported that Chiefs of Enforcement, Julia Ansel and Tom Lenox, provided a presentation of the board's current pending investigations, including the average days by the identified benchmarks as of August 1, 2018.

Chairperson Schaad stated that DCA's target for intake, which is defined as the number of days from receipt of the complaint to the date the complaint is either closed or assigned to an investigator, is 20 days. The Board of Pharmacy's average intake time, for FY 2017-18 was 27 days. For the month of July 2018, the intake time had improved to 19 days.

Chairperson Schaad reported that DCA's target for case investigations, not transmitted to the Office of the Attorney General, is 210 days, which includes both intake and investigation. The Board of Pharmacy's average days for cases under investigation in the field during FY 2017-18 was 235 days. For the month of July 2018, investigation time had improved to 165 days.

Pending Field Investigations as of 8/1/2018			
Pending Case Status	**# of Cases**	**Avg. Days at this Status**	**Avg. Case Age**
Team Review for Assignment	76	19	27
Under Investigation	1070	165	209
Report Review	220	42	261
2nd Level Report Review	127	26	339
Closure Times	268	48	387

Chairperson Schaad stated that public comment at the committee meeting included a recommendation that the board establish a sub-committee whose responsibility would be to evaluate each case, before referral to the Office of the Attorney General. It was suggested that such a committee could include a peer review by an independent expert and provide board member input during the AG referral consideration process.

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

Board member Deborah Veale asked if the improved timeframes were sustainable. Ms. Herold responded that board staff is working hard on reducing processing times, and they are focusing on reducing case closure time.

There were no comments from the public.

d. Summary of Discussion of the Board's Citation and Fine Program

Chairperson Schaad explained that the committee asked staff to provide information regarding board-issued citations and fines. Board Chiefs of Enforcement Julia Ansel and Tom Lenox provided information on the board's citation and fine program.

Chairperson Schaad reported that during the committee meeting, members of the public requested clarification on what constitutes unlicensed practice and who determines the amount of citations and fines within the board. Ms. Herold provided examples of unlicensed practice and emphasized that in regard to unlicensed activity, the primary goal is to obtain compliance; the board has the ability to issue cease and desist orders when unlicensed activities do not stop. It was also clarified that the Chiefs of Enforcements review and approve citations and fines issued as a result of inspections and field investigations.

Chairperson Schaad stated that the committee did not take action on this item, but the committee will continue to discuss the topic at its meetings.

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

e. Summary of Discussion of Convening Administrative Case Hearings Before Board Members

Chairperson Schaad stated that during the June 2018 committee meeting, board members were informed that pharmacy boards in other states have opted for administrative case hearings to be heard with board members.

Chairperson Schaad explained that although the law allows for two different adjudication processes, the board's administrative case hearings are currently only heard before an Administrative Law Judge (ALJ). Alternatively, at the discretion of the agency, GC section 11517 also allows that an administrative case hearing may be heard by the agency itself with an ALJ presiding over the proceeding. He noted that this is similar to the method used by the board to consider petitions for modification to penalties.

Chairperson Schaad reported that the committee took into consideration that in FY 17-18, 42 proposed decisions were received from ALJs. That equated to 62 days of hearings. Although the majority of cases heard before an ALJ are one day, as case complexity increases so do the number of hearing days, which are typically consecutive days.

Chairperson Schaad stated that no action was taken regarding disciplinary case adjudication but noted that this topic would be discussed further at future committee meetings.

f. Summary of Presentation on the Board's Inventory Reconciliation Process and Review of Frequently Asked Questions

Chairperson Schaad explained that on April 1, 2018, a new board regulation took effect – California Code of Regulations, Title 16, section 1715.65. The board believes this regulation will aid pharmacies and clinics in preventing losses of controlled drugs and identifying losses early.

Chairperson Schaad reported that since the adoption of the regulation, the Executive Officer and board inspectors have received numerous questions from licensees regarding the new reconciliation regulation. In response, the board has focused on education to promote an understanding of the regulation. Chairperson Schaad also reported that during this transition, inspectors will focus on the pharmacy's or clinic's good faith efforts to comply with the regulation.

Chairperson Schaad stated that during the committee meeting, board supervising inspector Michael Ignacio and Chief of Enforcement, Tom Lenox, provided general information on the board's inventory reconciliation process and frequently asked questions.

Chairperson Schaad explained that these FAQs were developed by board staff and DCA counsel. The first FAQs are available on the board's website and were published in the July 2018 edition of The Script. A second FAQs are being developed and include items identified during interactions between inspectors and licensees, typically as part of the inspection process.

Chairperson Schaad reported that a presentation on the reconciliation regulation has also been incorporated into the board's quarterly Pharmacist Drug Abuse and Diversion Training Program. It was presented to over 200 pharmacists at the July 28, 2018 event.

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

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

g. Discussion and Consideration of Remodel Inspections of Sterile Compounding Pharmacies and Possible Authority to Assess a Fee for Such Inspections

Chairperson Schaad explained that a sterile compounding license shall not be issued or renewed until the location has been inspected by the board and found in compliance. A fee is assessed for the issuance or renewal of a sterile compounding license.

Chairperson Schaad stated that under current law, the board does not charge a fee for an inspection resulting from the remodel of a sterile compounding pharmacy. Since the beginning of fiscal year 2015/16, the board has conducted approximately 60 sterile compounding remodel inspections. Inspections are conducted by the board after a facility has completed the remodel of their location. There is no requirement in the law for the board to conduct remodel inspections, but it is a safety issue that must nevertheless be done. Chairperson Schaad noted that board staff believes that not conducting these remodel inspections could pose a patient safety risk. Remodel inspections are triggered by unforeseen damage, planned upgrades, or expansion of a facility. The scope of a remodel ranges from simple projects to a full remodel or an expansion. All sterile compounding inspections have the same requirements, to ensure full compliance with regulations adopted by the board.

Chairperson Schaad reported that when notified of a pending remodel to a sterile compounding facility, the board attempts to conduct an inspection within six to eight weeks from the date of notification. Most remodel inspection requests are planned projects that the facility is aware of months in advance. He added that travel costs and inspector time for remodel inspections are currently being absorbed by the board.

Chairperson Schaad stated that public discussion included whether sterile compounding facilities should be required to pay fees for inspecting the remodeled areas or if such a fee could be covered by other fees (e.g., renewal and application fees) necessary to maintain regulatory compliance. Further, it was questioned if inspection fees would discourage licensees from improving their facilities.

Chairperson Schaad reported that after further discussion, it was recommended that this issue should be discussed and considered by the Licensing Committee.

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

h. Update on 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 at the July 2017 Board Meeting, the board heard and discussed the results of the UCSD experimental study involving the use of ADDS technology to dispense new and refill medications to outpatients in an area nonadjacent to a pharmacy counter. This study involves a waiver of California Code of Regulations Title 16, section 1713,

in that it allows first-time fills to be dispensed via an ADDS machine, and the ADDS is not adjacent to a pharmacy counter but is installed in a hospital location.

Chairperson Schaad reported that during the July Board Meeting, the board heard the final report of this study and supported a request from UCSD to extend the study for one year to provide additional data.

Chairperson Schaad explained that ultimately the board voted to both expand and extend the study. During that meeting the board also directed UCSD to provide study updates to the Enforcement Committee every six months.

Chairperson Schaad reported that during the committee meeting, Ms. Herold reminded the members that the board had requested a data comparison of people who received truly new prescriptions versus those who were getting refills. Due to the reported difficulty in collecting this data, Ms. Herold asked the committee if they still wanted UCSD researchers to continue this collection of data. Chairperson Schaad stated that the committee opted to discontinue collection of this data category.

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

Committee Recommendation (Motion): Direct UCSD to discontinue the collection of truly new prescription data.

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

i. Summary of Discussion of Federal and State Law Regarding Cannabidiol

Chairperson Schaad stated that Supervising Deputy Attorney General (SDAG) Joshua Room authored an opinion on the legal status of products containing cannabidiol (CBD), in light of the FDA approval of Epidiolex and AB 710 (Wood), which was enacted in mid-2018.

Note: the opinion by Supervising Deputy Attorney Joshua Room was provided in the board meeting materials.

Chairperson Schaad reported that during the committee meeting, SDAG Room clarified that the opinion regards *only* the prescribing of products containing CBD, not the selling of products. He informed the committee that current Federal and State law has not changed in status, for the purpose of prescribing or dispensing. In addition, the Federal Drug Enforcement Agency (DEA) has taken no action to reschedule CBD and there is no indication on their agency website they will.

Chairperson Schaad reported that during the committee meeting, SDAG Room was asked what a pharmacist should do if he/she has knowledge that a patient is currently taking a product containing CBD, which may have negative interactions with medication being dispensed. SDAG Room responded that a pharmacist is still responsible for consulting with the patient and informing the patient of the possible impact of the CBD product on their dispensed medication.

Chairperson Schaad noted that during the public discussion at the committee meeting the board discussed, in part, included whether the board should partner with other agencies to discourage the sale of CBD products in non-pharmacy settings and advocate to reschedule CBD.

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

SDAG Room reported that since writing the original opinion that was provided in the board meeting materials, the DEA has taken action to reschedule Epidiolex and other similar medications. SDAG Room stated that in light of the action by the DEA, he has written an updated opinion which has been sent out via the board's subscriber alert email.

Note: the updated opinion has been provided immediately following these minutes.

The board thanked SDAG Room for reviewing the laws and writing the opinions.

President Law asked if the updated opinion addresses CBD products that contain less than one percent THC. Mr. Room confirmed that the opinion provides the following information.

> "…FDA-approved drugs containing CBD derived from cannabis and no more than 0.1 percent residual tetrahydrocannabinols (THC) have been moved to federal Schedule V. So far, this is a category that only includes Epidiolex. No other CBD products or products that contain CBD have been approved by the FDA as yet."

President Law asked if a pharmacy could carry CBD products other than Epidiolex if they contain no more than one percent THC. SDAG Room stated that the only approved product is currently Epidiolex. He explained that all other CBD products are still Schedule I and a pharmacy that sells these products risks enforcement action by the DEA.

The board heard public comment from pharmacist Raffi Simonian who supported the potential health benefits of CBD. Mr. Simonian asked if a board inspector found CBD products in a pharmacy, if they would take enforcement action. SDAG Room stated that this would be a policy decision for the board, and they could choose to make a statement saying this is not an

enforcement priority.

A pharmacist spoke in support of removing CBD products from Schedule I. They noted that CBD that is derived from industrial hemp contains minimal amounts of THC. SDAG Room stated that the CA Bureau of Cannabis Control has determined that CBD oil must be derived from the cannabis plant and products that are derived from industrial hemp are not subject to sale.

A representative from Ananda Professional, a company that sells products containing hemp-flower extract, stated that section 7606 of the 2014 Farm Bill provides specific exemptions for state departments of agriculture to license farmers to grow hemp and extract *all* parts of the plant. He explained that the flower part of the plant is where CBD is contained. The Ananda Professional representative added that in 2016, the federal government defunded the DEA from enforcing federal prosecution for compliant hemp products. The board asked if any of their products were sold in California pharmacies. The representative stated that there are very few pharmacies in California that sell their products, and that the majority of their business is on the east coast. The board asked SDAG Room to further research the laws regarding hemp derived products and provide an updated opinion.

Sonja Logman from the Business and Consumer Housing Agency recommended that SDAG Room work with the legal staff CA Bureau of Cannabis Control when drafting his opinion. SDAG Room noted that their legal counsel had provided input on both of his opinions.

Mr. Simonian stated that there has been success in helping people get off of opioids by using CBD products. He added that while it is a challenging situation with the conflicts in state and federal law, the board should continue to monitor action taken by the federal government and possibly advocate for changing the federal schedule.

A representative from DynaLabs reported that they receive requests to test CBD products for potency and there are several other labs in California that also conduct testing.

j. Board's Enforcement Statistics

Chairperson Schaad reported that during the June 2018 committee meeting, members directed board staff to include the following data elements into the Enforcement Statistics: Proof of Abatements Requested, Average Investigation Times, Cease & Desist Orders, and Unlicensed Activity.

Chairperson Schaad noted that the statistics describing the enforcement activities of the board were provided in the meeting materials. During the first quarter of the fiscal year, the board has initiated 773 investigations, closed 772, and had 1,889 pending.

Chairperson Schaad stated that the board denied 9 applications, issued 79 letters of admonishment, issued 425 citations/citations and fines, and referred 67 investigations to the Office of the Attorney General.

Chairperson Schaad also noted that the board was granted restrictions on two licenses pursuant to Penal Code section 23.

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

k. Summary of Discussion on Bifurcation of the Enforcement and Compounding Committees

Chairperson Schaad stated that during the May 2018 Board Meeting, members voted to pursue a statutory proposal to incorporate USP compounding chapters into the board's requirements for compounding drug preparations. As part of its discussion, the board noted that two of the compounding chapters, <795> and <797>, are in the revision process by USP and USP <800> has been finalized, but is not yet in effect.

Chairperson Schaad explained that subsequent to that meeting, in recognition of the large impending policy work that will be required, President Law bifurcated that Enforcement and Compounding Committee into two committees. Provided below is the membership for the respective committees.

Enforcement Committee
Allen Schaad, Chair
Albert Wong, Vice-Chair
Victor Law
Greg Lippe
Ricardo Sanchez
Stan Weisser

Compounding Committee
Stan Weisser, Chair
Allen Schaad, Vice-Chair
Shirley Kim
Victor Law
Maria Serpa

Chairperson Schaad reported that it is anticipated that the Compounding Committee will begin its work in early 2019.

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

l. Future Committee Meeting Dates

Chairperson Schaad provided the following future committee meeting dates.

- December 13, 2018
- March 14, 2019
- July 2, 2019
- September 25, 2019

The board recessed for a break at 2:50 p.m. and resumed at 3:09 p.m.

Note: Board member Shirley Kim left the meeting at 3:00 p.m.

XI. Discussion and Consideration of Employment of Legal Counsel

President Law explained that Senate Bill 574 (Chapter 429, Statutes of 2017) amended Business and Professions Code Section 4008 to establish the board's authority to hire its own legal counsel. Subsequent to enactment, as part of the January 2018 Board Meeting, the board directed staff to begin the recruitment process to hire its own legal counsel per the provision in SB 547. Consistent with the board's directive, staff submitted the recruitment package to the department.

President Law reported that since that time, board executive staff have met with the department to discuss the recruitment. President Law and Vice President Lippe met with DCA Director Grafilo; Ryan Marcroft, Deputy Director, Legal Affairs Division; and Grace Arupo Rodriguez, Assistant Deputy Director, Legal Affairs Division. As part of this meeting, board leadership was advised that the current administration does not support a decentralized legal counsel model. President Law stated that in lieu of the board hiring counsel that would report directly to the board's executive office, DCA is offering a compromise proposal. Under the DCA's proposal, the department would establish a limited term attorney position and would enter into an MOU with the board to fund the position. DCA would complete the recruitment for the position but would allow a member of board staff to participate in the recruitment process. The attorney would be an employee of the department and would report to the Legal Affairs Office for supervision. The attorney would be dedicated exclusively to board work and would be available to work at the board's office part-time.

President Law stated that board leadership is comfortable with the DCA proposal and is presenting this alternative to the full board for its consideration. Should the board agree to accept the DCA proposal, recruitment could be expedited.

Board member Ryan Brooks asked who would have the authority to discipline or fire the attorney. President Law stated that the department would have hiring and firing authority. Mr. Brooks expressed concern with giving the department this authority.

President Law stated that he asked the department to reach out to board members Brooks, Weisser, and Serpa to discuss their concerns with the proposal. He also stated that after speaking with the department, Mr. Weisser (who was not in attendance) was in support of the proposal. Mr. Brooks confirmed that the department had called him, but he still has concerns with the proposal.

Board member Serpa noted that at the last board meeting, the board had requested that the department come before the entire board to discuss the issue. She expressed concern that the department contacted board members outside of a public meeting to discuss the proposal. She stated that the board should not have to conduct a two-year trial period when the board has the legal authority to hire its own counsel.

Mr. Brooks stated that even if the board agreed to the proposal, there is no guarantee that the next administration would uphold the agreement. He added that the department could also choose to reassign the attorney if they were short-staffed in other areas.

Board member Lippe noted that the new administration could choose to fire the board's attorney. Mr. Brooks responded that statute provides the board with the authority to hire and fire its own attorney - only if the board agrees to the proposal could the department fire the

attorney.

The board asked how long it would take to hire an attorney. Joshua Room noted that the state hiring process usually takes at least 90 days. He also stated that it would be unlikely that a current department attorney would want to move into a two-year limited term position.

Board member Lavanza Butler asked if the board would still have two part-time attorneys in addition to the full-time attorney. President Law confirmed that the board would still keep its two part-time attorneys.

Ms. Serpa stated that at the last meeting, the board members had asked that the department attend the next meeting to answer questions from the board. She asked why the board's request had been ignored. President Law explained that instead of coming to the meeting, the department called the members who had expressed concern about the proposal.

Ms. Veale recommended that the board again request that the department attend the January Board Meeting to provide information on their proposal in a public meeting. The board agreed with this recommendation.

Motion: Table the discussion and request that the department attend the January Board Meeting to provide information on the proposal and answer board member questions in a public meeting.

M/S: Veale/Butler

Support: 7 Oppose: 2 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			

The board recessed for a break at 2:50 p.m. and resumed at 3:09 p.m.

XII. Licensing Committee

Chairperson Deborah Veale provided a report of the committee's efforts at the September 26, 2018 meeting.

a. Presentation by the California Department of Corrections to Provide an Overview of the Correctional Clinic Model as a Result of AB 1812

Chairperson Veale explained that pursuant to enactment of Assembly Bill 1812 (Statutes of 2018), the California Department of Corrections (CDCR) redefined its drug storage and delivery within correctional facilities. As the provisions of the measure became effective July 1, 2018, board staff is working on implementation.

Chairperson Veale reported that at the committee meeting, CDCR's representatives Linda MacLachlan, Statewide Pharmacy Services Manager and Gregory B. Doe, PharmD, Chief of Pharmacy Services presented changes to the CDCR model, as well as an overview of the benefits of such changes. The changes impact state correctional institutions only and include authority for the board to issue clinic licenses to areas within the CDCR correctional institutions to store drugs in various locations providing for secure storage and accountability of medications. Further changes allow for the use of automated drug delivery systems. She added that this new model will improve continuity of care for inmates and reduce the amount of medication waste.

Chairperson Veale stated that according to the presenters, it is anticipated that each correctional institution will have several licensed clinics in areas where inmates will receive their medication from nurses at a "pill line", as well as other areas within the prison where medical care is received, such as dental clinics, and treatment and triage areas.

Chairperson Veale reported that the presentation included various challenges experienced by CDCR within the current system as the medication is packaged as patient specific in a "pill pack or punch card" and the amount of medication waste that occurs as a result of the current system. Representatives also noted that one of the most common medication challenges occurs when an inmate is transported to another correctional institution and the difficulties of ensuring the inmate has his or her medication at the time of arrival at the new prison. Chairperson Veale explained that under the current system, medication may not always be available, which can result in delays in therapy.

Chairperson Veale explained that this new model allows for the inmate to receive his or her medication at a licensed clinic within the CDCR institutions as medication is stocked as nonpatient specific, which allows the nurses to administer the medication to the inmate from a common stock of medications. She noted that the representatives also provided information about the electronic system for maintaining medical records in a statewide healthcare system which allows for immediate access to medical records and improved ability to receive the required medication.

Chairperson Veale noted that CDCR is anticipating applying for 20 clinic licenses at each of their state correctional institutions, as well as installing 450-700 automated drug delivery systems statewide. CDCR presented their roll out plan which included submission of correctional clinic applications for the first prison in August of 2018. It is anticipated that full implementation will be achieved by 2020.

Chairperson Veale stated that as part of the committee discussion, it was clarified that board staff will be implementing this new licensing program with existing resources.

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

b. Presentation by California Department of Health Care Services on the Los Angeles Moratorium relating to New Medi-Cal Numbers

Chairperson Veale reported that during the committee meeting, members heard a presentation on the current Moratorium in Los Angeles that relates to issuing new Medi-Cal numbers to licensed facilities from representatives of the DHCS. As part of the presentation, it was noted that the pharmacy moratorium was implemented in June 2002 to safeguard public funds and maintain the fiscal integrity of the Medi-Cal program. The DHCS re-evaluates the moratorium every 180 days to assess its effectiveness and necessity pursuant to their statute. As part of the presentation, it was noted that changes to the moratorium are based upon data and recommendations from the Audits and Investigations Unit within DHCS.

Chairperson Veale explained that in September 2016, based on their ongoing re-evaluation of the moratorium, the moratorium was changed to no longer exempt pharmacist owned pharmacies. In May 2018, the moratorium was revised again to allow for specific exemptions and is set to expire on October 28, 2018. The exemptions include:

1. The enrollment of chain pharmacy providers (20 or more service locations).
2. An application based on the purchase or a change of control interest of an existing Medi-Cal provider pharmacy in Los Angeles County, whether It constitutes a change of ownership or not. This exception is only available when the applicant has assumed or retained all debts, obligations, and liabilities to which the existing provider was subject prior to the transfer or sale and the Department confirms that an access to care issue exists.
3. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.55, Requirements for Continued Enrollment.
4. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.30(a), by an existing Medi-Cal enrolled pharmacy provider for the sole reason of changing its location, provided that its previous business address was located in Los Angeles County.
5. Applicants that are the exclusive persons or entities in the United States to provide a specific product or service that is a Medi-Cal covered benefit.
6. The enrollment of a county, state, or federally owned and operated pharmacy.
7. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.30(b)(6) with no change in the person(s) previously identified in the last complete application package that was approved for enrollment as having a control or ownership interest in the provider totaling five percent or greater.
8. Applicants who will be enrolled solely for reimbursement of Medicare cost sharing amounts.
9. Applications submitted by a provider to operate at the same business location as a Federally Qualified Health Clinic (FQHC). The pharmacy, in whole or in part, must be owned and operated by the same entity that owns the FQHC.
10. Applications submitted by an Academic Specialty Pharmacy. For purposes of this Moratorium, an Academic Specialty Pharmacy is defined as a specialty pharmacy that is owned or operated by a higher education institution that is currently a Medi-Cal pharmacy provider.

Chairperson Veale also reported that the presentation included an overview of instances when a new Medi-Cal provider application is required including:

1. New enrollment
2. Continued enrollment
3. New, additional or change in location
4. Change of ownership
5. 50% plus assets are sold or transferred
6. Issuance of a new TIN issued by IRS
7. New license number issued by the Board of Pharmacy
8. Change in 50% or more in the ownership or controlling interest.

Chairperson Veale stated that as part of the committee's discussion, members expressed concern about the change of exemption status for independent pharmacy owners.

Chairperson Veale reported that in response to committee questions regarding exemption requests, members were advised that DHCS independently reviews each request to determine if there are other pharmacies in existence in the area that offer the same services or if the pharmacy applying for an exemption is a specialized pharmacy. The exemptions are evaluated to ensure patient care is provided in all areas within Los Angeles county. If the explanation provided by the pharmacy is reasonable and the pharmacy meets the criteria, then the exemption is typically approved. During the review process, the pharmacy can continue to bill using their current Medi-Cal number until such request is denied or a new Medi-Cal number is issued.

President Law asked why DHCS removed the exemption for independent pharmacy owners. Chairperson Veale stated that the committee was concerned about this as well. She stated that the representatives from DHCS explained to the committee that the exemption was removed because their data shows that more fraud is committed by independent pharmacies than chain pharmacies.

Daniel Martinez representing CPhA stated that a study had been conducted that showed that the moratorium is causing drug prices in certain areas to increase. The board asked Mr. Martinez to provide a copy of the study to board staff to determine if it should be agendized for discussion at a future committee meeting.

c. Discussion to Amend Section 1732.5(b) of Title 16, California Code of Regulations, to Require a Pharmacist to Pass the Continuing Education Course Relating to Pharmacy Law

Chairperson Veale reported that as of August 1, 2018, the Board's one-hour webinar was available on the Board's website for pharmacist to earn continuing education (CE) credit as a result of CCR 1732.5, which states that at least two of the 30 CE hours required for a pharmacist license renewal be completed by participating in a Board-certified CE course in Law and Ethics. As of September 12, 2018, 1,542 pharmacists have completed this online webinar.

Chairperson Veale explained that while reviewing completion data gathered from this course, staff has found that some individuals have completed the training in less than 10 minutes and in many instances, the individuals are not answering the questions correctly. It appears that

some individuals are fast-forwarding through the course and may be missing out on the content. Approximately 14 percent of the individuals that completed the webinar scored less than 80 percent on the quiz questions. She noted that the board's current regulation only requires pharmacists to complete the course but does not require pharmacists to pass the course.

Chairperson Veale stated that during the committee meeting, members discussed whether it may be appropriate for the committee to consider if, as currently written, the regulation is meeting its intended goal or if further refinement to the language is necessary. The committee members expressed concern that the online webinar does not have restrictions in place to prevent a licensee from completing the webinar in what appears to be 10 minutes in some instances.

Chairperson Veale reported that the committee directed staff to work with counsel to develop suggested language for the board's consideration to address the inadequacies that currently exist regarding the amount of time it takes to complete the online webinar.

Chairperson Veale explained that subsequent to the committee meeting, staff learned that this issue could be corrected through the use of technology. Specifically, the board could purchase software that will prevent an individual from progressing in a webinar until the correct answer is given. As such, staff is requesting as part of its discussion, the board consider this approach as an alternative to its original recommendation to amend the regulation language.

The board agreed that it would be more efficient to fix the problem by purchasing the appropriate software and working with the department to implement safeguards to prevent someone from completing the course if they do not answer the questions correctly.

There were no comments from the public.

MOTION: Direct staff to work with DCA's SOLID Training Group and Office of Information Services to incorporate changes within the online webinar to prevent a person from completing the webinar if the licensee answers questions specific to the content of the webinar incorrectly.

M/S: Veale/Butler

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			
Munoz				x
Sanchez	x			

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

d. Discussion of Continuing Education Requirements for an Advanced Practice Pharmacist that Includes the Option for an Inactive Status of an Advanced Practice Pharmacist License

Chairperson Veale explained that as of December 13, 2016, the board began accepting applications for advanced practice pharmacists and shortly thereafter in 2017 began issuing advanced practice pharmacist licenses to those that met the licensure requirements.

Chairperson Veale also explained that an advanced practice pharmacist is required to complete an additional 10 hours of continuing education each renewal cycle, in addition to the 30 hours required for their pharmacist license renewal.

Chairperson Veale reported that during the April 2018 Committee meeting and the May 2018 Board Meeting, members discussed the current continuing education requirements for pharmacists and advanced practice pharmacists' renewal requirements. As part of the discussion, it was noted that while the board has the authority to issue an inactive pharmacist license under specified conditions, the board does not have similar authority for an advanced practice pharmacist license renewal.

Chairperson Veale explained that at the conclusion of the board's discussion, staff was asked to further review the continuing education requirements and bring recommendations to the Licensing Committee to create renewal requirements for an advanced practice pharmacist that mirror the requirements for pharmacists.

Chairperson Veale reported that during the committee meeting, members discussed the following concerns identified below that are not included in the renewal requirements for advanced practice pharmacists.

1. Pharmacists are exempt from earning CE hours during their first renewal cycle. A similar provision does not exist for advanced practice pharmacists. Staff noted that the advanced practice pharmacist expiration date is issued coterminous with their primary pharmacist license and as such, the licensee may not receive the full two years during the first renewal cycle.
2. The board has the authority to issue an inactive a pharmacist license to an individual that has not satisfied the CE requirements. Staff noted that this ability applies when either the pharmacist fails to provide satisfactory proof as part of a renewal or in response to an audit. A similar provision does not exist of advanced practice pharmacists.
3. Provisions exist to establish the process to reactivate a pharmacist license, however there is no similar process to reactivate an advanced practice pharmacist license.
4. Pharmacists are required to retain their CE certificates for four years, but there is no similar requirement for advanced practice pharmacists.

The board agreed the renewal requirements for advanced practice pharmacists should mirror

the renewal requirements for pharmacists.

There were no comments from the public.

Committee Recommendation (Motion): Direct staff to in concert with counsel, develop language for the board's consideration to align the advanced practice pharmacist renewal requirements with the renewal requirements for the pharmacists.

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

Note: Board member Shirley Kim returned to the meeting at 4:20 p.m.

The board discussed the possibility of making a statutory change rather than a regulatory change. Ms. Sodergren confirmed that this could be accomplished via a statutory change and asked the board if they would like staff to find an author.

e. Discussion of Amending Business and Professions Code Section 4400, subdivisions (n) and (o), to Regarding the Fees for a Duplicate License or for Updating Licensing Record Information

Chairperson Veale explained that BPC section 4400(n) establishes the fee for the board to reissue a license certificate at the request of the licensee when a license has been lost or destroyed or due to a name change. The current fee to reissue a license is $45.

Chairperson Veale stated that BPC section 4400(o) establishes the fee for the board to reissue a license when there has been any change to the license information. The current fee to reissue for such a change is $100.

Chairperson Veale also noted that BPC section 4101 establishes requirements for notification of changes in a pharmacist-in-charge or designated representative-in-charge and that CCR Section 1709 establishes the reporting requirement for an entity to notify the board of specified changes including changes in owners, officers, and pharmacist-in-charge.

Chairperson Veale reported that the committee considered a proposal from staff that would amend BPC 4400 to provide clarity and transparency regarding the fees collected and the purpose for which the fee is collected. Under the current construct with BPC 4400(o), all reported changes are processed and either approved or denied under the board's authority. In all such instances, when such a change is approved, the entity receives a new license.

Chairperson Veale stated that the committee noted the confusion with the current statutory language and considered questions from the public about events that would trigger a new printed license to be issued.

Board staff noted that given the number of questions during the committee meeting regarding the reporting requirements, staff will develop an FAQ to include in a future issue of *The Script.*

The board agreed that the current language was confusing and needed to be changed to provide clarity.

Committee Recommendation (Motion): Direct staff to work with legal counsel to develop language for the board's consideration (provided below) to update the law to provide more clarity on the fee to update the license record and the reissuance of the printed license certificate.

Proposal to Amend Section 4400 subdivisions (n) and (o) of the Business and Professions Code as follows:

4400. Fees
The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is fixed by the board according to the following schedule:
…..
(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).
(o) The fee for processing of an application to change information on a premises license record ~~reissuance of any license, or renewal thereof, that must be reissued because of a change in the information,~~ shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

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			
Munoz				x
Sanchez	x			
Schaad	x			

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

f. Discussion of Amending Business and Professions Code Section 4115.5, Regarding Pharmacy Technician Trainee Externship Hour Requirements

Chairperson Veale explained that BPC section 4115.5 establishes the provisions that allows an individual to work as a pharmacy technician trainee if specified conditions are met. Under the conditions of this section, a pharmacy technician trainee is limited in the number of hours of experience that can be earned. Such limitations include a maximum of 120 hours of experience in a work site, as well as a total maximum of 320 hours.

Chairperson Veale stated that BPC section 4202 establishes the general requirements for licensure as a pharmacy technician. Further, (a)(2) of this section provides as one of the pathways to licensure, completion of a course of training specified by the board.

Chairperson Veale also explained that CCR section 1793.6(a) expands upon such training courses and designates a pharmacy technician training program accredited by the American Society of Health Systems Pharmacies (ASHP) as one such training course approved by the board.

Chairperson Veale reported that ASHP accredited pharmacy technician training programs require a total of 130 pharmacy technician trainee hours at each location, which exceeds the 120 hours limit established in BPC 4115.5. This is results in a conflict for the ASHP accredited pharmacy technician training programs to comply with Pharmacy Law as well meet the accreditation standards with ASHP. Further, the current limitation on the maximum number of hours a pharmacy technician trainee can gain, 320 hours, prevents an individual from meeting the elements for advanced level training under ASHP guidelines. Advanced level training must include at least 340 hours experiential hours.

Chairperson Veale reported that during the committee meeting, members discussed the conflict in the number of trainee hours allowed currently in BPC section 4115.5 and the conflict it creates for individuals seeking licensure as a pharmacy technician through completion of an ASHP pharmacy technician training.

Committee Recommendation (Motion): Direct staff to work with counsel to develop language (below) for the board's consideration to modify section 4115.5(c)(1) to amend the language to read no less than 120 and no more than 140 hours as well as to amend 4115.5(c)(2) to increase 320 hours to 340 hours and remove the last sentence in this subdivision.

Proposal to Amend Section 4115.5 subdivision (c)(2) of the Business and Professions Code as follows:

4115.5. Pharmacy Technician Trainee; Placement; Supervision; Requirements

(a) Notwithstanding any other provision of law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.
(b)(1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.
(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.
(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.
(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.
(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.
(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no ~~more~~ less than 120 and no more than 140 hours.
(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to ~~320~~ 340 hours. ~~No more than 120 130 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy~~
(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.
(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her trainee status.

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			

Board Member	Support	Oppose	Abstain	Not Present
Veale	x			
Weisser				x
Wong	x			

g. Discussion of Establishing Authority to Allow for an Advanced Practice Pharmacist to Provide Medically Assisted Treatment

Chairperson Veale stated that in the midst of a huge nationwide opioid crisis, one of the recommended solutions to address the crisis is to provide medication assisted treatment to help wean patients from opioids. There are three main medications used for this treatment: methadone, buprenorphine, and naltrexone.

Chairperson Veale explained that pharmacists are medication specialists who are skilled in the assessment and management of substance related disorders such as opioid addiction. Today pharmacists have six to eight years of collegiate education with focused experience in performing medication management. Increasingly this also includes additional residency experience. Under California law, for a number of years and in conjunction with collaborative practice agreements with prescribers, pharmacists have the ability to:

1. Design treatment plans
2. Initiate medications
3. Monitor patient progress
4. Order and review necessary laboratory tests
5. Coordinate care with other medical providers.
6. Serve as expert consultants to support prescribers in making medication decisions for patients with opioid addiction and co-occurring conditions

Chairperson Veale stated that this skill set serves a dual purpose of positioning pharmacists so they may provide direct care to patients with opioid addiction and assist other medical providers in caring for this population, thereby expanding access to treatment. Additionally, in California pharmacists with appropriate education and experience may secure an additional pharmacist license, that of Advanced Practice Pharmacist, which authorizes collaborative practice with primary care providers.

Chairperson Veale explained that although pharmacists in many states can prescribe controlled substances under collaborative drug therapy management agreements, they are not eligible to obtain a federal DATA 2000 waiver to prescribe buprenorphine for opioid addiction. Under federal regulations only physicians, nurse practitioners, and physician assistants can obtain this authority. Having this authority would allow them to fully exercise their pharmaceutical expertise in this area and expand the pool of providers for medication assisted treatment.

Chairperson Veale reported that during the meeting, the committee spoke in support of adding pharmacists to the group of health care providers who can perform collaborative therapy using buprenorphine.

Chairperson Veale stated that during the committee meeting, board staff explained that the committee could develop a policy statement outlining the committee's support of allowing

pharmacists to prescribe buprenorphine for opioid addiction. Staff also noted that the committee could also direct staff to work to change the federal law to allow pharmacists to obtain a DATA 2000 waiver.

Chairperson Veale reported that members of the public spoke in support of adding pharmacists to the group of health care providers who can perform collaborative therapy using buprenorphine. It was also recommended that when drafting the policy statement, the committee focus on seeking approval for pharmacist to provide MAT rather than listing specific medications that a pharmacist can provide. This approach would ensure that if new medications become available to use for MAT a pharmacist could provide them.

Chairperson Veale reported that the committee directed staff to work on development of a draft policy statement supporting the role of pharmacists in providing MAT services. Further, the committee requested staff to develop options for advocating changes in federal law to allow such services to occur. She noted that both items will be brought to the committee at its next meeting.

h. Licensing Statistics

Chairperson Veale briefly reviewed the licensing statistics for July 1-September 30, 2018, as provided below.

As of September 30, 2018, the board has received 5,664 initial applications, including:

- 1,400 intern pharmacists.
- 550 pharmacist exam applications.
- 57 advanced practice pharmacists.
- 1,439 pharmacy technicians.
- 1 outsourcing facility.
- 1 nonresident outsourcing facilities.

As of September 30, 2018, the board has issued 3,557 licenses, renewed 16,580 licenses and has 140,558 active licenses, including:

- 7,104 intern pharmacists.
- 46,741 pharmacists.
- 389 advanced practice pharmacists.
- 71,316 pharmacy technicians.
- 6,476 pharmacies.
- 468 hospitals and exempt hospitals.
- 21 nonresident outsourcing facilities.
- 2 outsourcing facilities

i. Future Committee Meeting Dates

Chairperson Veale reported the following 2018 and 2019 Licensing Committee dates:

- December 19, 2018
- April 3, 2019

- June 26, 2019
- October 2, 2019

XIV. Communication and Public Education Committee

a. Discussion of a Proposal by the Chapman University School of Pharmacy Group to Require a Warning Label on Prescription Containers for Chemotherapy Medications

Chairperson Sanchez reported that at the March 2017 committee meeting, students and faculty from Chapman University School of Pharmacy presented their research about proper handling and disposal of oral chemotherapy medications. The group proposed requiring a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs.

Chairperson Sanchez stated that the group returned at the September 2017 committee meeting and presented early findings of a survey of health care professionals on the use and handling of oral chemotherapy drugs. The group also said it was a preparing a similar survey for patients.

Chairperson Sanchez reported that at the Oct. 11 committee meeting, Chapman faculty and students presented additional survey findings.

Chairperson Sanchez explained that the students surveyed 24 pharmacists and 12 patients about their knowledge, awareness, and practices in handling and disposing of oral chemotherapy drugs. In summary, the findings indicated an important need for more education in these areas for pharmacists and patients.

Chairperson Sanchez stated that the committee members expressed concern about the lack of public awareness and education revealed by the surveys. The committee suggested larger surveys with more respondents are needed to better understand the scope of the problem and possible solutions.

Chairperson Sanchez explained that the students were urged to focus on increasing awareness and education about safe handling and drug disposal – rather than seeking a mandated requirement for adding a hazard symbol on prescription labels. Committee members also suggested advocates work with pharmacies that are willing to voluntarily add the hazard symbol to prescription labels.

Chairperson Sanchez reported that the committee also directed staff to develop a possible policy statement by the board about proper handling and disposal of oral chemotherapy drugs. Staff will draft proposed language and return to the committee for review.

b. Update on the Proposal for a Public Service Billboard Message and Related Communications Materials on Prescription Drug Abuse

Chairperson Sanchez explained that Outfront Media is donating five billboards to the Board of Pharmacy for a public service message about prescription drug abuse. The committee approved a design created by board staff and chose “Use, Don’t Abuse” as the message theme.

Chairperson Sanchez reported that at the Oct. 11 committee meeting, staff reported that a no-cost contract for five billboards has been sent to Outfront Media for approval and signature. As of Oct. 11, the board was waiting for Outfront to respond.

Chairperson Sanchez stated that the committee directed staff to ask Outfront how long it would take to get the billboards printed and where they will be erected. Committee members said staff should use data on drug abuse to identify locations where the signs would be most effective.

The board thanked Ryan Brooks for donating the billboards and his work in getting the project completed.

c. Discussion of Educational Materials Regarding Drug Take-Back Collection Receptacles and Providing Public Access to Such Information

Chairperson Sanchez reported that in June 2017, the board adopted regulations for pharmacies and clinics to establish prescription drug take-back services. In July 2017, the board directed staff to develop consumer information on accessing drug take-back programs.

Chairperson Sanchez stated that at the February 2018 board meeting, staff demonstrated an online search tool being developed to help consumers find locations for collection receptacles by city, ZIP code, or pharmacy name.

Chairperson Sanchez explained that at the Oct. 11 committee meeting, staff gave a brief demonstration of the completed online search tool on the board's website. A total of 233 receptacle locations were registered with the board as of Sept. 25, 2018.

Chairperson Sanchez noted that the new search tool includes only take-back locations that are registered with the board; it is not a comprehensive list of all take-back locations in California. Staff noted that the board's website includes links to search tools for take-back locations operated by DEA, Don't Rush to Flush, and the California Department of Public Health.

Staff also reported the Department of Public Health has received $3 million to fund grants to pharmacies for drug take-back services. The first grants could be awarded as soon as this month.

Chairperson Sanchez stated that the Governor recently signed SB 212, which will require manufacturers and distributors of drugs or sharps to form stewardship programs to operate and pay for take-back programs for drugs and sharps. The law requires CalRecycle to promulgate regulations to implement the law by Jan. 1, 2021.

Chairperson Sanchez explained that the board will be involved with CalRecycle in developing the regulations for SB 212. Staff also said the new law will not change the board's current take-back regulations.

d. Update on the Development of Webinar Course to Satisfy the Education Requirement for Pharmacists to Furnish Naloxone

Chairperson Sanchez explained that naloxone, a prescription drug that reverses opioid overdose, is one of the most effective tools for preventing overdose deaths from opioids. California law authorizes pharmacists to furnish naloxone to patients pursuant to a protocol adopted by the board in California Code of Regulations, title 16, section 1746.3. The protocol requires pharmacists to complete one hour of training in an approved CE course before they can begin furnishing naloxone.

Chairperson Sanchez stated that in February 2018, the board approved a recommendation by this committee to create a webinar course that will satisfy the naloxone training requirement. Pharmacists will be able to access the course on the board's website at their convenience.

Chairperson Sanchez reported that at the Oct. 11 committee meeting, staff reported DCA's SOLID unit is finalizing the voice-over and closed-captioning. In addition, staff has asked SOLID to set up the webinar to prevent users from fast-forwarding through the video to the quiz at the end. The webinar is expected to be complete and available on the website in October.

e. Discussion of Proposal to Establish a Twitter Account for the Board of Pharmacy

Chairperson Sanchez explained that the board's 2017-2021 Strategic Plan calls for the board to "identify and use additional resources for public and licensee outreach services."

Chairperson Sanchez reported that at the Oct. 11 committee meeting, staff proposed using Twitter as a communication tool for outreach to the public. It was noted that the board currently has several channels for communicating directly with licensees – including subscriber alerts, the newsletter, site inspections, etc. – but none that is widely accessible or known to the general public.

Chairperson Sanchez reported that staff gave a brief PowerPoint presentation about how the board could use Twitter effectively to:

- Reach and engage consumers directly.
- Reach news media.
- Deliver timely information immediately.
- Create links with other organizations.
- Promote public awareness of the board's activities and brand.
- Increase public awareness and support for the board's mission and activities.

Chairperson Sanchez noted that staff also discussed types of information the board could communicate to the public via Twitter – including upcoming board meetings and events, recalls, regulations, news releases, and links to consumer resources.

Chairperson Sanchez reported that the committee expressed support for using Twitter as a communication channel with the public. Members noted that millions of Americans currently rely on Twitter to receive news and information, mostly on their cell phones, rather than traditional news media. Twitter messages also can easily be sent out in multiple languages.

Chairperson Sanchez stated that the committee asked about using other social media in addition to Twitter, such as Facebook and Instagram. Staff recommended starting with

Twitter because it is the easiest to use. In addition, staff could collect and present data on its effectiveness to help the board determine whether to add other social media accounts.

Chairperson Sanchez reported that in public comment, speakers said they supported the board using Twitter but expressed concern about how the board would handle hostile messages that target licensees or other individuals. Speakers also asked if private messages sent on Twitter would be subject to Public Records Act requests. Counsel said these issues would require legal research.

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

Committee recommendation: Recommend that the board approve the establishment and use of a Twitter account to communicate with the public and direct staff to report on its usage in the committee's quarterly report to the board. In addition, direct staff to research other social media for possible use.

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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

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

Chairperson Sanchez stated that a major regulation adopted by the board to help pharmacies and clinics prevent drug losses and identify any losses early took effect April 1, 2018.

Chairperson Sanchez explained that the new rule – California Code of Regulations, title 16, section 1715.65 – requires pharmacies to perform a periodic inventory reconciliation for all controlled substances. The regulation also requires a physical hand count of all Schedule II drugs every three months. Many licensees have expressed questions about how to comply with the regulation.

Chairperson Sanchez reported that staff has compiled and posted a list of frequently asked questions (FAQs) and answers on the board's website next to the regulation text. In addition, the FAQs were updated and published in the July 2018 issue of The Script.

Chairperson Sanchez noted that a follow-up FAQ article is planned for the next Script. In addition, staff provided training on the new regulation at a board-sponsored CE forum on Sept. 22 in Buena Park.

g. Discussion and Consideration of Granting CE Credit for Reading The Script

Chairperson Sanchez reported that in November 2017, the board directed the committee to discuss and consider awarding CE credit for reading The Script. At the January 2018 committee meeting, members suggested pharmacists could earn one CE credit for reading each newsletter, up to a maximum of two credits per renewal cycle (every two years).

Chairperson Sanchez stated that at the Oct. 11 committee meeting, staff presented the following possible options for awarding CE for The Script:

1. **Require pharmacists to self-certify reading The Script**. Users could click on a link in the newsletter that would take them to a site to certify they have read the newsletter. This option would require no staff time to prepare and minimal staff time to process the CE. **Estimated staff time to process each CE unit: one minute.**

2. **Require pharmacists to pass a quiz to be included with The Script**. Users would answer multiple-choice or true-false questions based on articles. This option would require staff time to prepare questions and answers for articles. **Estimated staff time to process each CE unit: one minute.**

3. **Require pharmacists to complete learning objectives after reading The Script**. Users would write a brief description of what they learned from reading articles. This option would require more technical capabilities and staff time to review responses. **Estimated staff time to process each CE unit: five to 15 minutes.**

Chairperson Sanchez stated that the committee discussed the amount of staff time required to carry out the program and the need for ensure CE improves the professional competence of licensees. Staff said that developing quizzes for articles would not be an obstacle.

Chairperson Sanchez reported that in public comment, speakers stressed the importance of having CE requirements that improve professional competence. It was suggested that staff invite pharmacy school faculty to write articles and quizzes for the newsletter.

Committee recommendation: Recommend that the board allow pharmacists who pass a quiz based on Script articles to earn one hour of CE credit per newsletter, up to a maximum of two credits per renewal period, as fulfillment of the two units of CE required to be earned from completion of board-provided CE to renew a pharmacist license.

Support: 10 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			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser				x
Wong	x			

h. Update and Discussion of Communication and Public Education Activities by Board Staff

Chairperson Sanchez reviewed the following public outreach activities.

1. The Script
   Staff reported the next newsletter is expected to be published in October. It will include articles about the inventory reconciliation regulation, applying to be an inspector, counseling patients over 50 about opioids, the executive officer's retirement and new board members.

2. News Media
   - **Sacramento News and Review**, Feb. 15: Mike Mott, mandates for safe disposal of drug needles.
   - **KPIX/CBS 5**, Feb. 26: Molly McCrea, PBM gag rules on pharmacists.
   - **Kaiser Health News**, March16: Pauline Bartolone, cease-and-desist order for Pharmedium Services LLC.
   - **STAT**, March 21: Ed Silverman, cease-and-desist order for Pharmedium.
   - **Capital Public Radio**, March 29: Sammy Caiolo, pharmacist use of CURES.
   - **Oakland Tribune**, April 4: Harry Harris, arrest of RPH Jonathan Szkotak on suspicion of armed robbery at pharmacy.
   - **KIQI/KATD**, April 18: Isabel Gutierrez, drug take-back programs.
   - **KGTV/10News**, April 19: Adam Racusin, dispensing error statistics.
   - **Capsa Healthcare**, May 3: Mike Stotz, new inventory reconciliation regulation.
   - **Coach Lynn Radio Show**, May 15: Lynn Johnson, opioid epidemic and online drugs.
   - **NBC4 Los Angeles**, June 1: Eric Leonard, stolen prescription pads from USC student health center.
   - **San Diego Union-Tribune**, Aug. 7: Paul Sisson, lidocaine and drug shortages in California.
   - **Palm Springs Desert Sun**, Aug. 10: Geraldine Estevez, availability of hormonal contraception.
   - **KPIX**, Aug. 23: Julie Watts, Kaiser restriction on EpiPen prescriptions.
   - **STAT**, Aug. 27: Ed Silverman, update on Pharmedium license cancellation.
   - **News 10 San Diego**, Sept. 5: Jennifer Kastner, complaint about improperly stored Kaiser insulin.
   - **Outpatient Surgery Magazine**, Sept. 20: Desiree Ifft, compounding regulations for ambulatory surgery centers.

3. Public Outreach
    - March 5: Inspector Diann Potter presented information about the Board of Pharmacy and pharmacy technician education and regulations to high school students and adults in the Bakersfield Regional Occupational pharmacy technician program.
    - March 14: Executive Officer Virginia Herold presented on pharmacy law, the Board of Pharmacy and corresponding responsibility to Touro University students.
    - March 16: Supervising Inspector Janice Dang presented on the responsibilities of a PIC to fourth-year pharmacy students at Western University School of Pharmacy.
    - March 16: Presentation by Executive Officer Virginia Herold at UOP Legislation Dinner.
    - April 5: Presentation by Executive Officer Virginia Herold at CSHP's Peninsula Pharmacists Association.
    - April 15: Presentation by Supervising Inspector Christine Acosta on California compounding regulations at Controlled Environment Testing Association (CETA)
    - April 17: Presentation by Supervising Inspector Christine Acosta for webinar on implementing compounding regulatory changes for CHA
    - May 3: Inspector Anna Kalantar presented California compounding regulations to San Fernando Valley Society of Health-Systems Pharmacists.
    - May 21-22: Executive Officer Virginia Herold participated in a webinar presentation, "Advancing Quality Compounding – State Perspectives" at USP Workshop on Evolution and Advances in Compounding
    - May 30: Executive Officer Virginia Herold presented a 2018 pharmacy law update to about 100 Ralphs pharmacy managers
    - June 13: Executive Officer Virginia Herold presented the role of the Board of Pharmacy to about 150 pharmacy students at University of the Pacific.
    - July 28: Executive Officer Virginia Herold, Chief of Enforcement Tom Lenox, and Supervising Inspector Tony Ngondara presented CE on Prescription Drug Abuse and Drug Diversion at California Northstate University.
    - Aug. 7: Supervising inspectors Anne Hunt and De'Bora White provided training on 2018 pharmacy laws for the Competency Committee in Ontario.
    - Aug. 14: Supervising Inspector Michael Ignacio presented an overview of the Board of Pharmacy, prescription drug abuse, drug take-back programs and pharmacist consultation to about 60 people at Eskaton Monroe Lodge Retirement Center in Sacramento.
    - Aug. 14: Inspector Manisha Shafir spoke about new pharmacy laws to the Alameda County Pharmacists Association in Fremont.
    - Sept. 5: Executive Officer Virginia Herald presented on the Board of Pharmacy to California Northstate University School of Pharmacy students.
    - Sept. 8: Inspector Tran Song provided training on how to prepare for an inspection to pharmacists and pharmacy owners at the California Council for the Advancement of Pharmacy.
    - Sept. 19: Executive Officer Virginia Herold presented on the Board of Pharmacy to Chapman University students.
    - Sept. 22: Executive Officer Virginia Herold, Enforcement Chief Tom Lenox, Supervising Inspector Tony Ngondara and Inspector Steven Kyle presented on pharmacy law topics, drug diversion, corresponding responsibility and preparing for a board inspection to 167 pharmacists at CE training in Buena Park.
    - Sept. 25-26: Executive Officer Virginia Herold presented regulations of outsourcing facilities and presented information about the FDA's proposed memorandum of

understanding for interstate pharmacy shipments of compounded preparations at the FDA's 50-State Meeting in Washington, DC.

- Oct. 2-3: Executive Officer Virginia Herold represented the board at the NABP Executive Officers Fair
- Oct. 3-4: Executive Officer Virginia Herold attended the .Pharmacy quarterly meeting to discuss ongoing implementation of this internet program.
- Oct. 6: Executive Officer Virginia Herold presented 2019 new laws at the California Society of Health System Pharmacists annual meeting.

i. Review and Discussion of News or Journal Articles

Chairperson Sanchez briefly reviewed the below news articles on pharmacy issues that may be of interest to the board.

Safety Violations Compound Pain Of Painkiller Shortages
California Healthline
April 13, 2018
Safety violations at a major compounding pharmacy are exacerbating hospital shortages of key painkillers. In late March, **California's Board of Pharmacy** barred the distribution of medications — including lidocaine and other local anesthetics — from a Texas factory belonging to the company, PharMEDium**.**

Protecting your family from prescription errors
10 News (San Diego)
April 26, 2018
Team 10 spent weeks sifting through disciplinary and enforcement actions taken against pharmacists and pharmacies. We discovered the **California Board of Pharmacy** issues hundreds of citations to pharmacists each year for dispensing errors, but errors are only what the state knows about.

You can get birth control without a doctor's prescription in California, but there's a catch
Desert Sun
Aug. 21, 2018
When it comes to this service, pharmacists are not obligated to provide prescriptions for contraceptives, but to do so, they must be trained. "The pharmacists have to complete a one-hour course available online, and then they're licensed to do this," said Becca Karpinski, Vice President of Strategy at Planned Parenthood of the Pacific Southwest. Yet this service isn't available in every California pharmacy.

State Board Of Pharmacy Investigating Kaiser EpiPen Policy
KPIX
Aug. 23, 2018
After some parents were outraged at having to pay full price for half of the EpiPens Kaiser was providing to treat food and other allergies, state officials are investigating the situation. According to the FDA, a pharmacist could only reduce a prescription to one pen if that's specifically what the doctor prescribed. "Generally, we would expect the pharmacy to fill it as it is written," said Virginia Herold with the California State Board of Pharmacy.

j. **Future Meeting Dates**

Chairperson Sanchez reported that following committee meeting dates for next year:

- Tuesday, Jan. 8, 2019
- Wednesday, April 10, 2019
- Tuesday, June 25, 2019
- Wednesday, Oct. 9, 2019

The board adjourned for the day at 5:30 p.m.

Wednesday October 24, 2018

President Law called the meeting to order at 9:04 a.m.

Roll call was taken and a quorum was established. Members present: Shirley Kim, Deborah Veale, Maria Serpa, Lavanza Butler, Gregory Lippe, Victor Law, Allen Schaad, Ricardo Sanchez and Valerie Munoz.

Note: Ryan Brooks arrived at 9:08 a.m.

XV. Executive Officer's Report

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

Executive Officer Herold reviewed the exam statistics as provided below. There were no comments from the board or from the public.

CPJE: Overall Pass Rates

	Frequency	Percent
Fail	465	21.8
Pass	1,664	78.2
Total	2,129	100

NAPLEX: Overall Pass Rates

	Frequency	Percent
Fail	95	6.1
Pass	1,461	93.9
Total	1,556	100

5 Year Comparison of CPJE and NAPLEX Pass Rates (Percentage)

Timespan	CPJE Fail	CPJE Pass	NAPLEX Fail	NAPELX Pass

April 2013 – Mar. 2014	19.9	80.1	4.5	95.5
April 2014 – Mar. 2015	21.3	78.7	4.3	95.7
April 2015 – Mar. 2016	21.6	78.4	5.8	94.2
*April 2016 – Mar. 2017	34.6	65.4	10.1	89.9
April 2017 – Mar. 2018	29.7	70.3	7.9	92.1

***New content outline in effect**

b. Update on 2018 Intergovernmental Working Meeting on Drug Compounding

Ms. Herold reported that on September 24 and 25, the FDA convened its annual meeting with state boards of pharmacy and in some cases, the state offices of the department of public health.

The FDA has been convening these meetings since the DQSA was enacted in late 2013. Ms. Herold reported that approximately 30 to 40 states were present. The purpose of the meeting was to share information about the status of sterile and nonsterile compounding, and outsourcing operations in various states and the emerging policies of the FDA in these areas.

Ms. Herold stated that the board was specifically asked to speak in two areas:

1. On a proposed memorandum of understanding between each board and the FDA that would allow a pharmacy to ship 50 percent of its compounded products across state lines instead of the current limit of 5 percent (discussed in item e below).
2. On the board's activities to regulate outsourcers in CA or doing business into CA.

Ms. Herold explained that the board's compounding and outsourcing staff often work closely with the FDA on common interests and inspection issues. This meeting offers the opportunity to liaise and share information with FDA staff from across the US. Both board programs are strong in comparison with activities of other state boards.

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

c. Update on National Association of Boards of Pharmacy Executive Officers' Meeting

Ms. Herold reported that she attended the annual meeting of executive officers of boards of pharmacy on October 1-4, which is convened by the National Association of Boards of Pharmacy. She provided a presentation on state efforts to secure from wholesalers copies of suspicious orders involving controlled substances sales to pharmacies and other wholesalers that under federal law, must be reported to the Drug Enforcement Administration. California is one of several states that recently added similar requirements for reporting to state law.

Ms. Herold stated that she also attended the annual in person meeting of the .Pharmacy executive committee following the executive officers forum while at NABP.

d. Update on the California Society of Health Systems Pharmacists Annual Meeting

Ms. Herold reported that from October 5-7, she attended the CSHP annual meeting in San Diego. Board Members Schaad and Serpa both attended in their private roles.

Ms. Herold stated that during this meeting, which is focused on diverse continuing education topics, the board provided a presentation to a standing room audience of at least 300 people on newly enacted 2019 laws coupled with a question and answer session with herself, Christine Acosta and Tom Lenox. She noted that the three of them also staffed a booth in the exhibit area for three hours on Friday and Saturday to respond to questions from meeting attendees. There were over 2,100 attendees at this meeting.

Ms. Herold stated that while in attendance, the three of them attended various educational sessions including multiple sessions dealing with compounding matters and opioid issues.

Additionally, Ms. Herold noted that she was honored by CSHP with CSHP's 2018 Lifetime Honorary Membership Award.

e. Discussion and Consideration of FDA's Memorandum of Understanding Relating to Regulation of Pharmacy Compounding

Ms. Herold explained that on September 7, 2018, the FDA released a revised *draft* memorandum of understanding. If approved and signed by a state, it would allow compounding pharmacies in the state to ship up to 50 percent of their compounded drug products across state lines – as an alternative to the current limit of 5 percent of such shipments. The state would be required to identify to the FDA which pharmacies are compounding and shipping more than 5 percent of their compounded drug products outside the state. She noted that a month by month calculation would need to be part of the evaluation.

Ms. Herold stated that compounding for animals or by outsourcers is not included in the calculation.

Note: A copy of the revised MOU was provided in the board meeting materials.

Ms. Herold explained that the MOU provides generally that pharmacies and physicians would be subject to the parameters, but the FDA's focus is principally on state regulators of pharmacies to enforce the provisions. By signing the MOU, a state board of pharmacy would:

- Agree to investigate complaints about compounded drugs in the state, including public safety concerns
- Agree to take appropriate action against pharmacies with complaints filed against them
- Notify the FDA within 3 business days of any complaint involving serious product quality or adverse drug effects
- Share results of any investigation with the FDA
- Any compounded drug shipped must be patient-specific
- If complaint involves a physician, the pharmacy board is to notify the regulator, and if serious adverse effects are involved, notify the FDA within 3 business days
- Inordinate amounts would trigger notification to the FDA by the state board of pharmacy and are defined as:
    - If the number of prescription orders for compounded drug products distributed interstate by a compounder during any calendar month is > 50 percent of the number of prescription orders for compounded drug products distributed or dispensed both intrastate and interstate by the compounder. The data would be collected for a year but would involve a month by month accounting reported to the FDA.

- States that sign the MOU agree to:
  - Identify pharmacies annually that distribute inordinate amounts of compounded drug product, labelled for specific patients, and shipped across state lines
  - Notify FDA if the state becomes aware of physicians distributing inordinate amounts
- States will collect information regarding and notify the FDA within 30 days of:
  - Total number of prescriptions for sterile compounded drugs distributed out of state
  - Total number of states in which the compounder is licensed or ships into
  - Results of the last state inspection of the entity

Ms. Herold reported that comments on the draft MOU are due by December 10.

Ms. Herold explained that during the FDA meeting and the following week at an executive officers meeting convened by the National Association of Boards of Pharmacy, not one state indicated a willingness to sign the MOU. California submitted comments to a prior iteration of the MOU several years ago whereby 30 percent of the product would be allowed to cross state lines, which was also not supported by other states.

Concerns expressed by the states include:

- this is a great deal of effort for the states to perform which while it may be a priority for the FDA, is not necessarily that of the boards
- physicians that compound and ship across state lines should be subject to the same requirements
- efforts to compile such a list at the pharmacy level would come at the expense of other board priorities (investigating complaints, performing compliance inspections). In the case of California, this workload would not be absorbable, even if a survey of California's 7,100 pharmacies were done annually instead of inspections to calculate this information.

Ms. Herold noted that the National Association of Boards of Pharmacy plans to work with the FDA on identifying a possible alternative approach. The board will be advised what alternative solutions are developed.

After discussing the concerns raised about the MOU the board decided not to sign the MOU and ask staff to continue to monitor the situation.

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

Ms. Herold reported that the board has been working with the Department of Consumer Affairs to secure the ability to use credit cards by the end of 2018. The department advises that there may be a delay because of a change in the credit card contract regarding business requirements.

Ms. Herold stated that the Board, working with the DCA Office of Information Services, is now advising that there will likely be a delay of up to 60 days.

Ms. Herold provided a brief overview provided by DCA about the status of this project:

1. All activities the board needs to perform are still scheduled for a completion date of

December 2018.
2. DCA will exert pressure on the involved agencies to secure the credit card clearinghouse contract process completed expeditiously.
3. Contract, business, and technical requirements are being developed in concurrently to avoid additional delays.

Ms. Herold explained that one component we are requiring is that a convenience fee will be paid by the licensee, not absorbed by the board.

Ms. Herold stated that this remains a board priority, and we will continue to engage with senior DCA officials to secure this service.

g. Personnel Update

Ms. Herold reported that the board is currently recruiting staff for the following positions:

- One Inspector on the Drug Diversion & Fraud team.
- One AGPA in the Enforcement unit.
- One SSA in the Enforcement unit.
- Two AGPA's in the Licensing unit.
- One SSA in the Licensing unit.
- One Program Technician in the Licensing unit.
- One Office Assistant (General) in Licensing unit.
- One Office Technician in the Administration unit.

h. Update on the Relocation of Board Office

Ms. Herold stated that for the past year, board staff has been working with DCA and the Department of General Services to locate new office space that can accommodate the board's significant growth.

Ms. Herold reported that the board signed a lease for new office space located at 2720 Gateway Oaks Drive Suite, approximately three miles from our current location. Board staff was recently advised that there may be a delay in the approval of the floor plans by the fire marshal. This will likely require that the February 1, 2019, move date be delayed. Board staff will continue to work with DCA and the Department of General Services and will provide updates to Organizational Development committee as more information becomes available.

XVI. Organizational Development Committee

a. Budget Update/Report

Fiscal Year 2017/2018
President Law stated that fiscal year 2017/2018 ended on June 30, 2018. However, the final FY 2017/2018 numbers are still not available. He noted that it is expected that the final budget report for FY 2017/2018 will not be available until after January 2019.

President Law explained that board staff used the available budget reports from the

department and internal tracking information to create a summary of the revenue for FY 2017/2018. The board received $26,386,200 in revenue originating from the following.

Revenue Sources

Source	Amount	Percentage
Licensing	$23,492,100	89%
Citation Fines	$1,983,300	8%
Cost Recovery	$812,200	3%
Interest	$98,600	0%

President Law stated that the board expended $23,380,877. The largest expenditure categories are detailed below.

Expenditures

Source	Amount	Percentage
Personnel	$14,979,161	64%
Prorata	$2,502,679	11%
Enforcement	$4,040,416	17%

President Law reviewed a summary of the fund condition report prepared by the department with the available budget reports. He stated that as indicated in the below table, the board's budget has a structural imbalance that must be addressed.

Fund Condition

Fiscal Year	Fund Balance	Months in Reserve
2016/2017	$8,084,000	4.0
2017/2018	$9,266,000	4.1
2018/2019	$6,601,000	2.9
2019/2020	$3,415,000	1.5
2020/2021	-$321,000	-0.1
2021/2022	-$4,583,000	-1.9

Fiscal Year 2018/2019

President Law reported 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 $25,280,000, which is a 9.3 percent increase from the prior year. This increase includes the following:

- $1,101,000 one-time costs for the relocation of the board's office,
- $685,000 to fund two inspectors and two AGPA's to perform sterile compounding and other enforcement functions,
- $423,000 to fund three positions to implement new legislation including, Statutes of 2017 (AB 401), Chapter 623, Statutes of 2017 (SB 351), and Chapter 647, Statutes of 2017 (SB 443),
- $816,000 in employer retirement contributions and employee compensation,
- $134,000 to fund equipment purchases,
- $264,000 in Pro Rata.

President Law noted that to date the board had not received any budget reports for fiscal year 2018/2019.

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

b. Discussion and Consideration of Board's Fund and Proposal to Amend California Code of Regulations Section 1749, Fee Schedule

President Law explained that in November 2015, the Department of Consumer Affairs completed an analysis of the board's fund condition and fee structure. This analysis was initiated at the request of the board and done in partnership with the board. As indicated in the report, the analysis was to determine the sustainability of the board's fund and to ensure that the board was collecting sufficient revenue to fully reimburse the board for the cost of regulating those individuals and businesses within its jurisdiction. He added that as indicated in the report, the goal of the analysis was to zero base the board's budget down to the services behind processing each initial and renewal application the board is required to process.

President Law stated that the conclusions of the analysis found that the current level of fees was not sufficient to keep the board's fund solvent and that fees needed to be adjusted to reflect the actual cost to the board to provide service and process each license type. As part of the recommendations from this analysis, it was suggested that the set new fee ceilings be set at a rate that would allow the board the flexibility to adjust fees through the regulatory process and maintain the fund's solvency through the next ten years.

President Law reported that after review and consideration of the findings of the analysis, the board pursued a statutory change in 2016 as part of its Sunset Review process to recast its fees. He noted that this recasting resulted in new statutory maximum fees.

President Law stated that the board's new fee structure took effect on July 1, 2017, but not all fees were increased at that time. Specifically of the board's 118 fees, seven application fees and 14 renewal fees were increased. President Law added that three applications fees were reduced.

President Law explained that since completion of the fee analysis there have been major budget adjustments impacting the board. Although final budget figures for FY 2017/18 are not available, preliminary numbers suggest that overall the board's expenditures have increased 30% since FY 2014/15, the largest areas of expenditure growth being a 31%

Increase in personnel expenses and a 62% increase in pro rata (including statewide pro rata and DCA pro rata).

President Law reported that at his request, board staff worked with Vice-President Lippe to assess the current state of the board's fund and determine what, if any, action is necessary. Based on the assessment, it is clear that an adjustment to the board's fees is necessary to ensure the solvency of the board's fund.

President Law stated that it is recommended that the board again consider a conservative approach to raising fees. Staff, along with Vice-President Lippe recommend that the board consider:

1. Raising fees to their statutory maximum levels for all sterile compounding and outsourcing facilities
2. Raise all other fees to the midway point between the statutory minimum and maximum level.
3. Initiate a new fee analysis to determine a long-term sustainable fee structure.

President Law explained that the below table details the projected impact such a change would have on the board's fund should the new fees take effect January 1, 2020.

Fund Condition with Recommended Fee Increase

Fiscal Year	Fund Balance	Months in Reserve
2018/2019*	$8,164,000	3.3
2019/2020	$7,242,000	2.9
2020/2021	$8,746,000	3.4
2021/2022	$9,568,000	3.6

President Law stated that should the board agree with the recommendation the board would need to vote to initiate the formal rulemaking process.

Board Member Veale asked if the increase in personnel was due to raises or the hiring of new staff. Ms. Herold stated that while staff did receive a raise as part of a bargaining agreement with the union, the increase was mostly due to new staff. Ms. Veale clarified that the increase in personnel was mainly due to new staff from newly created licensing programs.
Daniel Martinez stated that CPhA would oppose another increase since the board recently increased the fees. He requested that the board conduct a new analysis, especially focusing on the sterile compounding fees.

Mr. Lippe stated that the cost for sterile compounding have increased considerably and the board will need to increase its fees in order to remain financially stable. Ms. Veale added that since the cost to license a sterile compounder is the most expensive, they will see the biggest increase in their fees.

President Law and Mr. Lippe stated that the board does not want to raise its fees, but as the

costs have increased, the options are limited. President Law added that as the board is reassessing its enforcement and citation and fine programs, there may be even more of a deficit in the future. Mr. Martinez thanked the board for reviewing its enforcement programs and again asked that another fee analysis be conducted before raising the fees. He also recommended advocating receiving funding from the state in light of the opioid crisis. Ms. Herold responded that the board is self-funded and changing that funding structure would be difficult in the current financial climate.

The board agreed to table the motion and asked staff to provide additional information on the proposed fee increase at the next board meeting. Board member Schaad asked that a table be provided showing the past fees, current fees, and proposed fees. Board member Wong asked for information on the Medical Board's fees in comparison with the board's fees.

Note: Ms. Veale left the room at 10:00 a.m.

c. Board Member Reimbursement and Attendance Information

President Law explained that board members may seek reimbursement for travel expenses and per diem payments. It is important to note that these figures only represent hours and travel expenses where reimbursement was sought. He added that it is not uncommon for board members to waive their per diem payments or only request partial reimbursement of travel expenses.

President Law stated that the reimbursements and board member attendance information were provided in the meeting materials. There were no comments from the board or from the public.

XVII. Executive Officer Recruitment

President Law stated that as a result of Ms. Herold's pending retirement, the board began the process to identify a replacement for her.

President Law reported that at the board's September 7, 2018, meeting, the Department of Consumer Affairs' Human Resources Chief, Nicole Le, advised the board about the typical recruitment process for an executive officer (EO). She also presented a draft duty statement and a draft recruitment announcement for the board's review and comment. The board authorized creation of a two-member executive officer selection committee and authorized the board president to appoint himself and another member to the selection committee. The board also offered feedback for suggested changes to the duty statement and recruitment announcement.

President Law explained that since the last board meeting, he appointed Allen Schaad to serve on the selection committee. The department posted the recruitment announcement, initially accepting applications through October 12, 2018. The selection committee since extended the application filing period to November 12, 2018. The recruitment announcement was posted on the state's CalCareer website (jobs.ca.gov), which is also accessible through the department's website (dca.ca.gov), published it in the newspaper *Capital Morning Report*, posted it on social media, and it was made available to industry organizations identified by the selection committee.

President Law stated that the selection committee will conduct preliminary interviews of

qualified applicants and recommend candidates to be interviewed by the full board.

XVIII. Discussion and Consideration of Appointment of Interim Executive Officer

President Law stated that during closed session the board would be considering the appointment of Interim Executive Officer to serve following Ms. Herold's retirement, but before the full recruitment process is complete.

XIX. Legislation and Regulation Committee

Part 1: Legislation for Discussion and Consideration

a. Board Sponsored/Originated Legislation

Chairperson Lippe reported that this year the board sponsored one measure and was the origin of five additional measures. With one exception, all measures were enacted. He noted that unless otherwise specified, the provisions will take effect January 1, 2019.

Chairperson Lippe briefly reviewed each of the bills below. There were no comments from the board or from the public.

1. AB 1751 (Low) (Chapter 478, Statutes of 2018) Controlled substances: CURES database

Board Position: Support
Summary: Allows the Department of Justice (DOJ) to enter into an agreement with an entity operating an interstate data sharing hub for purposes of interstate sharing of controlled substances reporting information. This measure also requires DOJ to promulgate regulations no later than July 1, 2020, outlining access to and the use of information within the Controlled Substance Utilization, Review and Evaluation System (CURES).

2. AB 1752 (Low) Controlled substances: CURES database

Board Position: Support
Summary: This measure sought to expand CURES reporting to also include Schedule V controlled substances and reduce the time frame for reporting to the CURES system to one working day. This measure was held in committee and as such failed passage. It is recommended that the board again seek the changes sought in this measure as reflected elsewhere in this report.

3. AB 2086 (Gallagher) (Chapter 274, Statutes of 2018) Controlled substances: CURES database

Board Position: Support
Summary: Allows prescribers to request a list of patients for whom they are listed as being the prescriber in the CURES database.

Chairperson Lippe reported that as part of the discussion, the committee received public comments inquiring if pharmacists, as prescribers, are required to check the

CURES system similar to a prescriber's obligation. All present were advised that it expected that pharmacist prescribers should be held to the same standard as other prescribers.

4. AB 2783 (O'Donnell) (Chapter 589, Statutes of 2018) Controlled substances: hydrocodone combination products: schedules

   Board Position: Support
   Summary: Reclassifies specific hydrocodone combination products as Schedule II controlled substances, making California law consistent with federal law.

5. AB 2789 (Wood) (Chapter 438, Statutes of 2018) Health care practitioners: prescriptions: electronic data transmission

   Board Position: Support
   Summary: Requires by January 1, 2022, all written prescriptions issued by licensed prescribers in California be issued as an electronic transmission prescription (e-prescription). By January 1, 2022, all pharmacies, pharmacists or other practitioners authorized to dispense or furnish a prescription must have the capability to receive an e-prescription.

   Exceptions include:
   - any medication listed in Health & Safety Code 11159.2. Note: This exemption applies to prescriptions written for hospice or terminally ill patients.
   - technological/electrical failure
   - prescription that will be filled outside of California
   - hospital pharmacies where
     - patient resides outside of CA, or outside the geographical area of the hospital
     - indigent or homeless patients
     - prescription issued when a patient's pharmacy is closed
   - veterinarians
   - eyeglasses or contact prescriptions
   - prescriber and dispenser are the same entity
   - prescription is not covered by National Council for Prescription Drug Programs' SCRIPT standard

6. SB 1447 (Hernandez) (Chapter 666, Statutes of 2018) Pharmacy: automated drug delivery systems

   Board Position: Support/Sponsor
   Summary: This bill is sponsored by the board. This measure replaces the boards current automated drug delivery system (ADDS) registration requirements with a licensing program that recognizes the different uses for such a device. The measure establishes definitions for the two different functions of ADDS, as; automated unit dose system (AUDS), used for administration, and automated patient dispensing system (APDS), used for dispensing directly to the patient, as well as establishes the requirements for each.

Specifically, effective July 1, 2019, this measure prohibits an ADDS from being installed, leased, owned or operated in California unless specified requirements are met. One requirement specifies an ADDS license will only be issued to the holder of a current, valid, and active California pharmacy license. The bill expands the locations for placement and operation of an ADDS to specified locations, including the licensed pharmacy issued the ADDS license, a licensed health facility, a licensed clinic, or a specified medical office. Further, this measure requires the pharmacy issued the ADDS license to own or lease the ADDS machine and own the drugs and devices located within it. This chapter requires the pharmacy to supervise the operation of the ADDS. This measure details specific stocking and transfer requirements for the ADDS, requires the pharmacy issued the ADDS license to provide training on the operation and use of that ADDS to specified individuals, and requires the pharmacy to complete periodic self-assessments. The bill requires additional conditions for APDS that are used to dispense medication to patients. The bill authorizes a pharmacy inspector employed by the board to enter the location, or proposed location, of an ADDS to inspect the location pursuant to these provisions. Lastly, this measure requires the board to report to the legislature regarding the regulations of ADDS machines on or before January 1, 2024.

Chairperson Lippe reported that as part the discussion, the committee heard public comments in support of the legislation. Further, clarification was sought as to how this legislation applies to a prescriber's use of an ADDS as well as clinics use of ADDS. Those present were advised that a prescriber using an ADDS for dispensing to his or her patients directly would not require licensure.

Public comment also asked about why ADDS are not allowed to be used in emergency departments. The committee was advised that one a provision for such an allowance was included in one iteration of the bill but was amended out to address opposition from the California Hospital Association. This may be something that the board can consider again in the future.

b. Chaptered Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

Chairperson Lippe explained that the Governor signed several measures impacting the board's jurisdiction including some measures where the board had an established position. Below is a summary of those bills. Where applicable, the board's position is noted. He added that unless otherwise noted, the provisions take effect on January 1, 2019.

Chairperson Lippe reviewed the below measures. There were no comments from the board or from the public.

1. AB 1753 (Low) (Chapter 479, Statutes of 2018) Controlled substances: CURES database

Summary: Allows for the reduction of authorized security printers approved by the DOJ to three. Further, this measure requires security prescription forms to contain a unique serialized number that must be reported to CURES and establishes reporting requirements by the DOJ on the delivery of security prescription forms to a prescriber.

2. AB 1953 (Wood) (Chapter 383, Statutes of 2018) Skilled nursing facilities: disclosure of interests in business providing services

Board Position: Support if Amended
Summary: Beginning January 1, 2020, requires an applicant for licensure as a skilled nursing facility or a skilled nursing facility licensee to disclose ownership or control interest of 5 percent or more in a corporation, sole proprietorship, or partnership, that provides, or is proposed to provide, any service to the skilled nursing facility.

3. AB 2037 (Bonta) (Chapter 647, Statutes of 2018) Pharmacy: automated patient dispensing systems

Board Position: Support
Summary: Allows a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B and Medi-Cal patients through the use of an automated drug delivery system (ADDS). This measure included an urgency provision and took effect immediately upon signature of the governor on September 21, 2018.

Chairperson Lippe noted that board staff has started working on implementation to be positioned to implement when applicants are ready.

4. AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing boards: denial of application: revocation or suspension of licensure: criminal conviction

Board Position: Oppose
Summary: Beginning July 1, 2020, the measure places restrictions on the convictions, crimes, or dishonesty, fraud, and deceit or other acts the board may consider in order to deny, revoke or suspend a license. This bill requires reporting on the board's website of denial summaries as well as a list of crimes that will be considered for denial and how they substantially relate to the qualifications, functions, or duties of the practice of pharmacy.

5. AB 2256 (Santiago) (Chapter 259, Statutes of 2018) Law enforcement agencies: opioid antagonist

Board Position: Support
Summary: Allows law enforcement agencies throughout the state to acquire Naloxone from a pharmacy, wholesaler, or manufacturer, without a prescription, if it is exclusively for use by employees of the agency who have completed training in administering an opioid antagonist. Further, provisions require that acquisition and disposition records must be maintained by the law enforcement agency for three years.

6. AB 2576 (Aguiar-Curry) (Chapter 716, Statutes of 2018) Emergencies: health care

Board Position: Support
Summary: Authorizes clinics to furnish dangerous drugs to several entities, authorizes pharmacies to dispense drugs without a prescription, and authorizes the board to waive any requirement in the relevant chapter during a declared state of emergency.

7. AB 2859 (Caballero) (Chapter 240, Statutes of 2018) Pharmacy: safe storage products

Board Position: Neutral
Summary: Requires community pharmacies that dispense Schedule II, III, or IV controlled substances (such as opioids) to display safe storage products on the premises and close to the pharmacy. Pharmacies, where a licensed pharmacist is the majority owner and manager, of no more than four pharmacies, are exempt from this requirement. These provisions will remain in effect until January 1, 2023.

Chairperson Lippe reported that as part of the discussion, public comment inquired if pharmacies are required to supply or dispense the products or just display them. The committee was advised that the measure only requires display of the product. It was suggested that this bill is an example of the type of legislation that would be helpful for the enforcement committee to discuss the policy implementation.

8. AB 2863 (Nazarian) (Chapter 770, Statutes of 2018) Health care coverage: prescriptions

Board Position: Support
Summary: Requires a pharmacy to inform the consumer of the lower price of a covered medication, whether that is the retail price or the cost sharing amount unless the pharmacy automatically charges the lower amount.

Chairperson Lippe stated that as part of the discussion, the committee was advised that this measure may create a conflict with a Medi-Cal provision regarding drug pricing relating to Medicare eligible patients. Those present were advised that the next issue of the Script will include an article about the Medicare pricing issue and the required notice. Board staff will be researching the issue and will report back if clarification or amendment to statutes are necessary to harmonize the requirements.

9. SB 212 (Jackson) (Chapter 1004, Statutes of 2018) Solid waste: pharmaceutical and sharps waste stewardship

Summary: Establishes, no later than January 1, 2021, the Pharmaceutical and Sharps Waste Stewardship program in California. This statewide program will be established and funded by the covered entities of covered drugs sold in California, as defined, and will provide convenient receptacles for the return of pharmaceuticals and sharps waste. CalRecycle is required to develop regulations governing this stewardship program no later than January 1, 2021, and the bill's provisions will become effective upon the promulgation of those regulations.

Under this chapter the board is required to develop and maintain a list of all covered drugs sold in California, as defined in the measure. Further, the board is required to review each stewardship plan for compliance with applicable federal and state laws governing drug take back programs. It cannot be known at this time how many stewardship organizations, and resultant stewardship plans will require approval by staff. Board staff will be required to work in collaboration with CalRecycle for the establishment and enforcement of this program.

Chairperson Lippe explained that as part of the discussion, the committee was advised

that the policy goal of the measure was to secure permanent funding for pharmaceutical and sharps waste disposal. Further, it was reiterated that the board's current take-back regulations are included in the measure and pharmacies participating in drug take-back would be required to comply with those regulations. Our committee was advised that the measure will take significant additional resources to implement and that through a funding mechanism established in the bill, the board should be able to recover the costs associated with the additional resources.

Further the committee was advised through public comment about the significant efforts licensees had to undertake when implementing the drug take-back program in Alameda County.

10. SB 1021 (Wiener) (Chapter 787, Statutes of 2018) Prescription drugs

Board Position: Support
Summary: Eliminates the sunset date on provisions of AB 339 (Gordon, Chapter 619, Statutes of 2015) making permanent provisions, capping monthly copays at $250 total per patient. This measure creates the new prohibition for a health care insurance plan with a drug formulary from having more than four tiers. Further, this measure caps the co-pay amount at the retail price if it is lower than the co-pay.

11. SB 1109 (Bates) (Chapter 693, Statutes of 2018) Controlled substances: Schedule II drugs: opioids

Board Position: Neutral
Summary: Requires continuing education for prescribers on the hazards of opioid use. Also requires a specified warning notice to be included on the label or container for an opioid dispensed to a patient for outpatient use.

12. SB 1254 (Stone) (Chapter 697, Statutes of 2018) Hospital pharmacies: medication profiles or lists for high-risk patients

Board Position: Support
Summary: Requires a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission and discharge of the patient. The criteria for determining whether a patient is high- risk will be established by each hospital. Additionally, allows for this duty to be performed by a pharmacy technician or intern pharmacist if they have successfully completed training and proctoring by the pharmacy department and where a quality assurance program is used to monitor competency.

Chairperson Lippe stated that as part of the discussion, the committee heard policy concern about the measure as enacted which still provides allowance for other health care professionals to perform these functions.

13. SB 1442 (Wiener) (Chapter 569, Statutes of 2018) Community pharmacies: staffing

Board Position: Support
Summary: This bill specifies that a community pharmacy shall not require a pharmacist

employee to engage in the practice of pharmacy unless the pharmacist is assisted at all times by another employee as specified.

Chairperson Lippe stated that during the meeting the committee clarified that hospital outpatient pharmacies are exempted from the staffing requirements.

Part 2: Regulations for Discussion and Consideration

Chairperson Lippe briefly reviewed the following regulations. There were no comments from the board or from the public.

Note: the language and the timelines for each regulation were provided in the board meeting materials.

c. Board Approved to Initiate Rulemaking - Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

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

   Summary of Regulation:
   This proposal amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

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

   Summary of Regulation:
   This regulation establishes the regulatory framework for third-party logistics providers.

3. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

   Summary of Regulation:
   This regulation amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

4. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

   Summary of Regulation:
   This regulation establishes regulatory requirements for automated refill programs.

5. Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

   Summary of Regulation:
   This regulation updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements

for abandoning an application and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

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

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

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

   Summary of Regulation:
   This regulation updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms.

8. 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.

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

   Summary of Regulation:
   This regulation updates the renewal requirement language to include all licensing programs and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

10. Proposed Regulations to Amend Title 16 CCR Section 1707.2 Related to Mail-Order Pharmacy Consultation

    Summary of Regulation:
    This proposal amends the board's regulations regarding the duty to provide consultation for mail-order pharmacies.

d. Board Approved to Initiate Rulemaking – Documents Returned to the Board for Corrections to be Made by Staff

Chairperson Lippe reviewed the following regulation. There were no comments from the board or from the public.

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy

Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Summary of Regulation:
This regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

Timeline:
Approved by board: October 26, 2016
Submitted to DCA for Pre-Notice Review: January 23, 2017
Returned to the board: March 28, 2017
Re-submitted to DCA for Pre-Notice Review: August 21, 2017
Returned to the board: February 24, 2018
Modified language approved by board: March 27, 2018
Re-submitted to DCA for Pre-Notice Review: July 11, 2018
Returned to the board: August 20, 2018

e. Board Approved to Initiate Rulemaking – Documents Being Prepared by Board Staff for Pre-Notice Review

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

Summary of Regulation:
This regulation updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

Chairperson Lippe reported that this regulation was approved by the board on November 8, 2017. He noted that board staff anticipates this regulation will be submitted to the department within the next 30 days.

Part 3: General Committee Matters

f. Review of Pending Legislative Proposals Previously Approved by the Board

1. Amend Health and Safety Code Section 11165 to Include Schedule V Controlled Substances in CURES Database and Reduce Reporting Requirement Timeframe to One Day

Chairperson Lippe explained that as indicated previously in this report, Assembly Bill 1752 (Low) failed passage this year. The measure was intended to expand CURES reporting to include Schedule V controlled substances and reduce the time frame for reporting to the CURES system to one working day. AB 1752 can be read here: AB 1752. The board should again advocate for this change.

Chairperson Lippe stated that as part of the discussion, the committee received public

comments suggesting that the board also consider the rescheduling of controlled substances in California to match the federal Schedules. Further public comment suggested that pharmacies that inadvertently report an item that is scheduled in CA but not federally may result in a HIPAA violation. The committee was cautioned about the challenges of attempting to reschedule some controlled substances and learned about some recent experiences in seeking to reschedule hydrocodone containing products. Further, DCA legal counsel clarified that inadvertent transfer of information to CURES does not constitute a HIPAA violation.

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

2. Amend Business & Professions Code Section 4200 Relating to the Examination Score Validity Period for the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chairperson Lippe reported that the board voted at the May 2018 meeting to pursue a statutory change to amend BPC Section 4200 as it relates to the time period that a test score will remain valid for consideration for licensure. Enactment of this legislation would establish that a passing score on NAPLEX or CPJE Pharmacist examinations would be valid for licensure while the occupational analysis that was used to develop that examination is valid or was replaced no more than one year prior.

Note: A summary of the discussion and motion can be found in the board's minutes here: Board of Pharmacy May 2018 Meeting Minutes.

Chairperson Lippe stated that during the committee's discussion, clarification was provided that a pharmacist licensed and practicing in another state would not be required to retake the NAPLEX in the NAPLEX had been taken on or after January 1, 2004.

3. Establish an Advanced Pharmacy Technician (APT) Licensure Program

At its November 2017 meeting, the board voted to pursue a statutory change to create a new licensing category for Advanced Pharmacy Technicians. This proposal establishes APT as a new category requiring licensure, outlines the requirements for licensure, and details the duties that APTs may perform in different settings.

Note: a summary of the discussion and motion can be found in the board's minutes here: Board of Pharmacy November 2017 Meeting Minutes.

There were no board or public comments on this measure.

4. Establish an Advanced Hospital Pharmacy Technician (AHT) Licensure Program

Chairperson Lippe reported that at the February 2018 meeting the board voted to pursue a statutory change to create a new licensing category for Advanced Hospital Pharmacy Technicians. This proposal establishes the licensing and renewal requirements, proposed duties, and requirements of a hospital choosing to utilize AHT personnel.

Note: a summary of the discussion and motion can be found in the board's minutes here:

Board of Pharmacy February 2018 Meeting Minutes.

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

5. Amend Business and Professions Code Section 4163 to Allow a Reverse Distributor to Accept Medications for Destruction in Limited Circumstances from a Previously Licensed Source

Chairperson Lippe explained that during its July 2018 meeting, the board voted to pursue a statutory change that would allow a reverse distributor to accept medications for destruction.

Note: documents pertaining to this discussion may be found in the relevant meeting materials here: Board of Pharmacy July 2018 Meeting Materials.

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

6. Amend Business and Professions Code Section 4400 Relating to Fees for Government Owned Facilities

Chairperson Lippe reported that at its November 2017 meeting, the board voted to pursue a statutory change to amend BPC section 4400 to require an application fee from government owned facilities.

Note: a summary of the discussion and motion can be found in the board's minutes here: Board of Pharmacy November 2017 Meeting Minutes.

Chairperson Lippe explained that as part of the discussion, the committee was advised that initially this proposal was going to be including in a measure this year, however at the request of the administration, the proposed change was postponed until next year.

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

g. Future Meeting Dates

Chairperson Lippe provided the following future committee meeting dates.

- January 30, 2019
- May 7, 2019
- July 24, 2019
- November 5, 2019

XX. Closed Session Matters

The board recessed to closed session at 1:00 p.m.

President Law returned the meeting to open session at 2:05 p.m. and adjourned the meeting at 2:06 p.m.