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

California State Board of Pharmacy
Public Board Meeting Minutes
November 5-6, 2019
DRAFT

DATES: November 5-6, 2019

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Blvd.
Sacramento, CA 95834

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

BOARD MEMBERS NOT PRESENT: Lavanza Butler, Licensee Member
Valerie Muñoz, Public Member

STAFF PRESENT: Anne Sodergren, Interim Executive Officer
Laura Freedman, DCA Counsel
Norine Marks, DCA Counsel
Kristina Jarvis, Deputy Attorney General
Jennifer Niklas, Senior Administrative and Policy Manager
Debi Mitchel, Senior Licensing Manager
MaryJo Tobola, Senior Enforcement Manager
Debbie Damoth, Administration Manager

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

Acting President Greg Lippe opened the meeting at 3:01 p.m.

Mr. Lippe provided the board's strategic plan creates standing committees through which the board establishes its goals and organizes its activities. Each committee is comprised of public and licensee members. The committee structure provides an important venue for ensuring staff and members share information in crafting and implementing objectives. These meetings also provide an opportunity for

stakeholder involvement and public comment is encouraged. Following committee meetings, the chairs from each of the respective committees provide reports to the full board as part of board meetings. Committee recommendations on policy decisions are referred to the full board as the final decision maker. As included on the agenda, during this meeting the board will receive reports from the chairperson of several of the board's committees.

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

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

Steve Gray on behalf of California Society of Health-System Pharmacists (CSHP) read a statement from CSHP's Opioid Stewardship Task Force Co-Chair Sandy Bardas requesting the board post the board's video regarding the use of naloxone targeting teens and young adults.

> *Thank you so much opportunity to tell you about our video regarding the use of naloxone.*
>
> *The video presents the signs and symptoms of an opioid overdose, names of opioid medications and the use of naloxone including calling 911. The target audiences are teens and young adults who would find this teaching format to be more easily watched than reading a pamphlet. It's 3 minutes 27 seconds long and is packed with information for an audience who is often in a position to recognize a friend or family member who is at risk for opioid overdose.*
>
> *We would like this video to be included on the BOP website under important information for consumers. Also, we think it would be beneficial to add it to the Naloxone – Protocol and Training Webinar.*
>
> *The video can be accessed on YouTube at https://www.youtube.com/watch?v=7MJ_-jo-Xqg.*
>
> *The video is free to share and has no copyright restrictions. The music and lyrics are all original and was provided by the California Society of Health-System Pharmacists (CSHP) Opioid Stewardship Task Force.*
>
> *Please do not hesitate to ask me any questions. I really appreciate your willingness to present.*
>
> *Sandy Bardas, co-chair of the CSHP Opioid Task Force*

Danny Martinez of California Pharmacists Association (CPhA) requested the compounding regulations be sent back to committee with a respect letter and changes requested.

Corey Edwards, a pharmacist on behalf of self, asked the board to make information available to the public about operations of the board including budgets, fees paid by licensees, salaries, financial obligations, volume of workload, and how it compares to other boards of pharmacy. Mr. Edwards'

experience with the board was different than other pharmacists' experiences with other state boards of pharmacy. Mr. Edwards was advised the information he requested is available on the board's website specifically for the November 2019 board meeting and at previous board meetings. The information is directly accessible to the public. Mr. Edwards was advised that California is different than every other state, but that the information requested is not hidden and is on the board's website.

III. Approval Board Meeting Minutes

a. July 24-25, 2019 Board Meeting

Motion: Approve the July 24-25, 2019, board meeting minutes.

M/S: Veale/Sanchez

Support: 8 Oppose: 0 Abstain: 0

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

b. September 13, 2019 Board Meeting

Motion: Approve the September 13, 2019, board meeting minutes.

M/S: Sanchez/Schaad

Support: 8 Oppose: 0 Abstain: 0

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

c. October 3, 2019 Board Meeting

Motion: Approve the October 3, 2019, board meeting minutes.

M/S: Veale/Sanchez

Support: 8 Oppose: 0 Abstain: 0

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

d. October 14, 2019 Board Meeting

Motion: Approve the October 14, 2019, board meeting minutes.

M/S: Veale/Sanchez

Support: 8 Oppose: 0 Abstain: 0

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

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

The board recognized Dan Furtado for 50 years of service as a pharmacist.

V. Board Election of Officers

Motion: Elect Greg Lippe as Board President
No public comment on motion.

M/S: Veale/Brooks

Support: 8 Oppose: 0 Abstain: 0

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

Motion: Elect Debbie Veale as Board Vice President

No public comment on motion.

M/S: Lippe/Kim

Support: 5 Oppose: 3 Abstain: 0

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

Motion: Elect Maria Serpa as Board Vice President

No public comment on motion.

M/S: Wong

Support: 3 Oppose: 5 Abstain: 0

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

Motion: To have the terms for President and Vice President go through the end of the terms.

M/S: Brooks/Lippe

Support: 8 Oppose: 0 Abstain: 0

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

VI. Discussion and Consideration of Request from American University of Health Sciences, School of Pharmacy, for Board Recognition Pursuant to Title 16, California Code of Regulations Section 1719

President Lippe noted the request from American University of Health Sciences, School of Pharmacy, for board recognition for the purposes of issuing intern pharmacist licenses pursuant to Title 16, California Code of Regulations section 1719.

Motion: Grant board recognition to American University of Health Sciences, School of Pharmacy, for purposes of issuing intern licenses.

M/S: Sanchez/Veale

Support: 8 Oppose: 0 Abstain: 0

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

VII. Organizational Development Committee

President Lippe provided the report to the board for the Organizational Development Committee.

a. Budget Update/Report

President Lippe reported to the board on the budget. As indicated in the meeting materials, fiscal year-end figures are not yet available for FY 2017/18 and FY 2018/19. Also included in the meeting materials, the board's authorized expenditures for the current fiscal year are about $26 million which represents about an 11 percent increase from the prior year. Mr. Lippe noted preliminary revenue details indicate the board has received over $10 million to date and has expended about $5.3 million.

President Lippe continued that the fund condition report includes estimates that by the end of the fiscal year, the board will have less than 1 month in reserve. However, this will change when the board's fee increase takes effect April 1, 2020.

Vice President Veale added the board is self-funding based on licensing fees. As a result, all funds for the board are a result of fees and the board cannot be given additional funds from the legislature.

b. Board Member Attendance Information

President Lippe provided the board member attendance are included in the board meeting materials.

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

President Lippe provided, as represented in the board meeting materials, data demonstrating the overall renewal payments received online accounts for about one third of renewal payments submitted.

d. Review and Consideration of Draft Sunset Report

President Lippe provided the board will be undergoing the Sunset Review process this fiscal year. A copy of the draft report is included in the meeting materials. The final report is due to the Legislature by December 2, 2019.

President Lippe suggested the board review the draft report to determine if members have comments.

Board Member Brooks left the meeting at 3:35 p.m. and returned at 3:38 p.m. Board Member Schaad left the meeting at 3:38 p.m. Mr. Schaad returned at 3:54 p.m.

Mr. Lippe noted in the cite and fines are about half. Ms. Sodergren indicated this reflects the change in policy to focus on education and remediation. She indicated she will add context to the numbers.

Ms. Veale acknowledged the five most common violations where citations are issued and inquired if there is something similar for the most common reasons for discipline. Ms. Sodergren indicated it can be added. Mr. Lippe stated he liked the idea.

Mr. Lippe commented on the use of board versus staff. Ms. Sodergren indicated board and staff were not delineated. Mr. Lippe asked if the board should state why it isn't being posted on the website. Ms. Sodergren indicated it was an accessibility issue and can be noted.

Ms. Veale inquired about the sections used. Ms. Sodergren provided it is from the report template from Senate Business and Professions and Assembly Business and Professions.

Mr. Lippe inquired if the Consumer Protection Enforcement Initiative (CPEI) goals of 12-18 months goal was being met. Ms. Sodergren indicated that is the goal of CPEI and is not occurring at this time. Mr. Lippe inquired if this should be noted. The report does indicate the board is committed to the intent and spirit of CPEI.

Ms. Sodergren confirmed there were no comments on Licensing.

Dr. Serpa indicated new issues are important and need to be addressed. She inquired if they are included because they were previously discussed, or being addressed now, or if anything has been missed. Ms. Sodergren added that one of the issues noted was completed in April 2016 and has been updated. There will be no outstanding business included.

Ms. Veale inquired about the issue with regulations. Ms. Sodergren indicated she can add a table of the status of regulations if requested by the board. Some of the factors impacting the processing times are outside of the board's control. Ms. Veale and Mr. Lippe want to be reasonable and sensitive but also demonstrate the board's completion as requested.

Dr. Serpa noted some of the current issues like CPJE were mentioned but other issues like board appointments, quorum, having an interim executive officer, etc. Ms. Sodergren requested feedback from the board on issues they would like added or withdrawn. With respect to the interim executive officer, the report notes that the board has completed its recruitment and waiting for approval. Dr. Serpa inquired if USP should be added as it demonstrates California's participation at the national level.

Dr. Serpa inquired if disaster planning/preparation support for pharmacists with just in time information during disasters. Mr. Brooks agreed in this climate. Dr. Serpa added to note the board is being proactive and sending it out to the pharmacists. Mr. Brooks added the board's work with naloxone for the opioid epidemic. Ms. Veale indicated the outreach would be helpful. Ms. Sodergren

suggested an accomplishment's table to highlight at a high level and context throughout the document.

Ms. Sodergren confirmed that the new issues to be added include quorum, hiring executive officer, USP delays, and table of accomplishments. Ms. Veale added natural disasters.

Motion: Approve the draft Sunset Report subject to changes discussed with nonsubstantive changes.

M/S: Veale/Sanchez

The board heard comment that the board should be inspecting the drug supplies in medical offices and clinics.

Mr. Schaad stepped out of the meeting at 4:24 p.m.

Support: 7 Oppose: 0 Abstain: 0

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

Motion: Delegate the authority to the final approval to the Interim Executive Officer, Anne Sodergren and Vice President, Debbie Veale.

M/S: Lippe/Brooks

Mr. Schaad returned at 4:26 p.m.

Support: 8 Oppose: 0 Abstain: 0

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

Board Member	Support	Oppose	Abstain	Not Present
Veale	Support			
Wong	Support			

e. Personnel Update

This item was for information update only. Information can be found in the meeting materials with the update provided to the board.

The board adjourned to closed session at 4:27 p.m.

The board returned from closed session and went into open session at 4:58 p.m.

VIII. Compounding Committee

a. Discussion and Consideration of Draft Policy Statement Regarding Applicability of Board Compounding Regulations and USP Compounding Chapters While Pending Appeals Before USP

Chairperson Serpa provided on September 23, 2019, USP announced a delay in the official date of the of the revised Chapters 795 and 797 and the new Chapter 825 until further notice. The delay results from appeals received on certain provisions of the respective Chapters. Since the beginning of the year the committee has dedicated several meetings to education on the proposed revised and new chapters. Following education, the committee transitioned its work to evaluating regulations necessary to clarify, make more specific and necessary to ensure safe processes consistent with the board's mandate.

Dr. Serpa reported the committee believes it is appropriate to recommend the following policy statement intended to provide clarification to the board's regulated public about the board's intentions to regulate pharmacy compounding of drug preparations during the appeal process. The committee determined the following changes should be added to ensure the message is clear to the public:

- The last sentence in the second paragraph is changed to, "Further, effective January 1, 2020, in addition to the board's compounding regulations, all pharmacies must adhere to current USP Chapters relating to compounding, including Chapters 795 and 797." by adding the phrase "in addition to the board's compounding regulation."
- The last sentence in the fourth paragraph is added, "While the USP appeals are under consideration, where physical construction or alteration is not yet complete, the board will consider mitigation, including a licensee's efforts to achieve compliance."

The board heard comments in support of the policy statement. The board heard comments concerned with incorporating guidelines as part of the board's regulations and going back to lesser and older standards. The board also heard comments indicating some pharmacies do not want to compound because of the rules and regulations.

Committee Recommendation (Motion): Accept the draft policy statement to present to the board and include the amendments discussed about enforcement discretion to be determined and the addition of California regulations to the second paragraph including amendments.

> In light of USP's September 23, 2019, announcement regarding the appeals and postponement of the official dates of the revised Chapters 795 and 797 and the new Chapter 825, the California State Board of Pharmacy (board) wishes to ensure stakeholders have a clear understanding of the legal requirements for pharmacies compounding drug preparations.
>
> At minimum, all pharmacies must adhere to all relevant sections of Pharmacy Law and regulation – including but not limited to the board's current regulations, California Code of Regulations, title 16, sections 1735 et. seq, 1751 et. seq, and 1708.3-1708.5. Further, effective January 1, 2020, in addition to the board's compounding regulations, all pharmacies must adhere to current USP Chapters relating to compounding, including Chapters 795 and 797.
>
> Although USP has indicated that Chapter 800 is informational while USP reviews the appeals of related compounding chapters, the board's current regulations on compounding hazardous drug preparations remain in effect. Like USP, the board encourages utilization of Chapter 800 in the interest of advancing public health.
>
> Waivers previously granted to allow for physical construction or alteration of a facility pursuant to California Code of Regulations, title 16, sections 1735.6 or 1751.4 will not be extended and will sunset on December 1, 2019. While the USP appeals are under consideration, where physical construction or alteration is not yet complete, the board will consider mitigation, including a licensee's efforts to achieve compliance.
>
> Prior to September 23, 2019, the board voted to initiate a rulemaking process to effectuate proposed changes to regulations for pharmaceutical compounding of nonsterile preparations. At this time, the board will delay initiation of the formal rulemaking process until additional information is available from the USP.
>
> Although the board's compounding committee had completed its review of proposed regulations for pharmaceutical compounding of sterile preparations, the board will delay proceeding with any regulation changes until additional information is available from the USP.
>
> The board encourages its licensees to continue efforts to transition to proposed USP requirements that ensure the safety and efficacy of compounded drug preparations and patient safety. The board will continue to communicate with stakeholders as information becomes available.

Support: 7 Oppose: 0 Abstain: 0

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

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

b. Discussion and Consideration of Timing of Formal Rulemaking for Proposed Regulations Relating to Pharmaceutical Compounding of Nonsterile Preparations (Note: Discussion will not address the text of the proposed regulation, only the timing of the rulemaking process.)

Dr. Serpa advised on July 11, 2019, the committee approved proposed regulations to repeal and add new CCR sections 1735 through 1735.15 relating to Nonsterile Preparations, including sections. The board considered the committee's recommendation as part of its July 2019 meeting. The board voted to initiate a rulemaking related to Nonsterile Preparations. At this time, the committee recommends holding the rulemaking process.

Committee Recommendation (Motion): Recommend to the board to hold the formal rulemaking process previously approved by the board relating to pharmaceutical compounding of nonsterile preparations.

Support: 7 Oppose: 0 Abstain: 0

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

c. Discussion of Timing of Committee's Recommendation to Initiate the Formal Rulemaking Process for Proposed Regulations Relating to Pharmaceutical Compounding of Sterile Preparations (Note: Discussion will not address the text of the proposed regulation, only the timing of the rulemaking process.)

Dr. Serpa advised the board, the committee decided to not initiate the formal rulemaking process relating to pharmaceutical compounding of sterile preparations. Counsel Freedman advised a motion was not required.

The board adjourned at 5:09 p.m.

Wednesday, November 6, 2019

President Greg Lippe called the meeting to order at or about 9:05 a.m. Board members present: Ricardo Sanchez, Albert Wong, Greg Lippe, Maria Serpa, Ryan Brooks, Debbie Veale and Allen Schaad. Quorum was established.

IX. Discussion and Consideration of Board Approved Regulations, Comments Pending Review by the Board

a. Proposed Amendments to Title 16 CCR Section 1707.2 Related to Mail Order Pharmacy Consultation

President Lippe provided the proposed language was included in the meeting materials. He noted at the May 2018 meeting, the board approved the text to amend CCR Section 1707.2. The proposed text clarifies and makes specific the consultation requirements for all pharmacies, including mail order pharmacies or pharmacies that deliver medications. Mr. Lippe confirmed board members had an opportunity to review all comments and staff recommendations. He confirmed board members did not have questions about the comments received or staff recommendations.

Motion: Adopt the regulation language as noticed on August 16, 2019, 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: Veale/Serpa

The board heard comments about one of the recommendations where staff left open to the board to make the determination whether nonresident pharmacies were required to have a toll-free phone number on the label. The commenter provided the regulation as proposed does not require a toll-free phone number for mail order pharmacies in the state and there is no requirement under Business and Professions Code (BPC) section 4076 for a phone number to be on the label of a prescription on the vial. The staff recommendation was that the board could require mail order pharmacies in the state but it may have fiscal impact. The commenter requested this be discussed at the board level as residents using mail order pharmacies in California must use a toll line to call the pharmacy for consultation. The commenter requested amending the motion to address this issue.

Board Member Ryan Brooks inquired if the concern was that the phone call would cost the consumer $0.15 for a phone call to the pharmacy. The commenter explained his concern was that seniors typically need consultation for chronic medications and the fiscal impact will be on the individual. Additionally, the intent of the regulation and statutes regarding nonresident pharmacies indicates the board must have consistent policies for pharmacies in state and out of state. This requirement is inconsistent where the nonresident pharmacies have the cost for a toll-free line but the pharmacies in California do not. Additionally, nonresident pharmacies must put their phone number on the prescription label where this is not a requirement for pharmacies in California.

Vice President Veale stated she would like to amend the motion to require all pharmacies to have the toll-free number. Interim Executive Officer Anne Sodergren inquired with DCA Counsel if this was a labeling requirement. If that is the case, she stated this issue is not currently before the board.

President Lippe recommended removing the requirement of the toll-free number being on the prescription label and remove the labeling issue.

DCA Counsel Laura Freedman provided pharmacy law only requires nonresident mail order pharmacies have a toll-free number. There is no requirement that pharmacies within California have a toll-free number. She noted having a toll-free number requirement would apply to all pharmacies including resident and nonresident pharmacies that mail prescriptions and may be considered a burden for those that do not mail many prescriptions. She provided if the board would like to have the phone number on the label and require it for all pharmacies, it could be sent to committee to be discussed on the labeling issue.

Ms. Veale rescinded her amendment to the motion and left the motion as previously presented. Mr. Lippe recommended sending the telephone number/labeling issue to committee for further discussion.

Support: 8 Oppose: 0 Abstain: 0

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

Motion: Refer to Communication and Public Education Committee the requirement of having a phone number on the prescription label.

M/S: Veale/Wong

Support: 8 Oppose: 0 Abstain: 0

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

b. Proposed Amendments to Title 16 CCR Section 1706.2 Related to Abandonment of Applications

President Lippe provided that the board approved the proposed text to amend CCR section 1706.2 during the February 2018 meeting. Mr. Lippe stated the memo board members received with meeting materials included the incorrect summary of the regulation. The proposal updates the application abandonment language to ensure all applicants have appropriate notice about the conditions under which an application is considered abandoned. Mr. Lippe noted no comments were received during the 45-day comment period, August 30 – October 14, 2019.

Motion: Adopt the regulation language as noticed on August 30, 2019, 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: Sanchez/Serpa

Support: 8 Oppose: 0 Abstain: 0

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

c. Proposed Addition to Title 16 CCR Section 1793.9 Related to Remote Dispensing Pharmacy Technicians

President Lippe advised the proposed addition to Title 16, CCR Section 1793.9 would establish the minimum qualifications for a pharmacy technician working in a remote dispensing site pharmacy. Mr. Lippe added during the board's June 2019 meeting, the board deferred action on the regulation due to pending legislation, AB 690, also establishing the minimum qualification. The governor has since signed the legislation. Mr. Lippe stated it appears appropriate for the board to withdraw its rulemaking.

Motion: Withdraw rulemaking regarding the proposed addition to Title 16 CCR Section 1793.9 related to remote dispensing pharmacy technicians.

M/S: Brooks/Sanchez

Support: 8 Oppose: 0 Abstain: 0

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

X. Enforcement Committee

Chairperson Schaad provided an update on the Enforcement Committee Meeting held November 5, 2019.

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

Mr. Schaad provided during the July 2019 committee meeting, the committee discussed CCR Section 1715.65 which establishes the board's inventory reconciliation requirements for controlled substances. As discussed at the last meeting, some language needed to be clarified. Both member and public comment identified several areas where clarification would be appropriate, including the requirements for inventory and reconciliation of ADDS devices used in hospitals for unit dose administration, developing a definition of satellite, establishing a minimum frequency for reconciliation activities for Schedule III-V drugs, and the potential problem to secure initials of all individuals involved in the physical count. Consistent with the committee's action at the last meeting, Mr. Schaad worked with staff and counsel to draft possible amendments to clarify the language of the requirements consistent with the board's policy. The draft language was included as part of the meeting materials for the committee's discussion and consideration.

During the November 5, 2019, committee meeting, public comment included concern with the proposed change related to Schedule III-V and the requirement to perform inventory reconciliation reports versus inventory activities. The committee noted that the proposed change is about consumer safety. The committee contemplated if the reconciliation reports should be provided to the board. The committee determined that may be appropriate as a next step, but would not be pursued as part of this proposal.

Committee Recommendation (Motion): The committee recommends amendment to CCR section 1715.65 as presented. Also, as part of the motion authorize the executive officer, counsel, and the chair to clarify language prior to initiation of the rulemaking consistent with the board's policy.

The committee heard comments requesting empirical data supporting administrative costs required and the impact on the opioid crisis; completion of a financial impact study; and return to committee to target certain drugs within Schedule III-V.

Mr. Brooks requested a list of regulations that are burdensome and not useful. Dr. Serpa recommended a step approach to start with Schedule III. The board agreed to return to committee.

Ms. Veale inquired if an electronic signature can be considered at the committee level. Counsel Freedman added the physical signature was considered when the regulation was developed.

Dr. Serpa expressed concern about sending back to committee with the definition of satellite and use of automatic dispensing machines. Ms. Sodergren recommended communicating the board's intention of the policy while the regulation is in process. Counsel Freedman suggested the board could take an action to send back to committee to specify the board is comfortable with the satellite and ADDS but the board is more interested in feedback on the other three schedules and signature.

Motion: Send back to committee to discuss which Schedules should be part of the reconciliation and review how the report signature is handled and to accept as part of policy language outlined in sections (g) and (h) of the draft proposal.

M/S: Veale/Serpa

The committee heard support in referring the item back to committee for further discussion and cautioned the board on blanket statements regarding types of drugs as well as reminded the board of the federal electronic signature requirements.

Board Member Albert Wong spoke in support of the opioid inventory/reconciliation and stated the PBM reimbursement is the reason for pharmacies closing.

The board heard a request to specify an ADDS location is not a pharmacy satellite location.

Support: 8 Oppose: 0 Abstain: 0

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

Ms. Sodergren provided a subscriber alert is sent with the board's action items after board meetings and indicated could be a way to communicate the policy direction to the public. The board agreed.

b. *Discussion and Consideration of Possible Amendments to Title 16, California Code of Regulations, Section 1715.6, Regarding Reporting Drug Losses to the Board

Mr. Schaad reported it was brought to the board's attention the difference in the Code of Federal Regulations (CFR) requirements and California Code of Regulations (CCR). During the rulemaking process, it was suggested that the board amend its current drug loss requirement (CCR 1715.6) to mirror the Drug Enforcement Administration (DEA) requirements. At that time members were advised that such a change could not be implemented as the language lacked the necessary clarity required to comply with the Administrative Procedures Act. During its last meeting, the committee continued its discussion and contemplated that a threshold for reporting would be appropriate in lieu of the current requirement to report any loss. Subsequent to the meeting, the committee chair provided guidance to staff on development of draft amendments that would create threshold limits for reporting.

c. *Presentation on Routine Pharmacy Inspections

Mr. Schaad reported the committee heard a presentation on routine pharmacy inspections.

d. Discussion and Consideration of Recently Enacted Legislation Impacting the Practice of Pharmacy

Mr. Schaad updated the board on measures that impact the practice of pharmacy or the board's jurisdiction.

1. *AB 528 (Low, Chapter 677, Statutes of 2019) Controlled Substances: CURES Database

   Mr. Schaad provided effective January 1, 2021, AB 528 expands the CURES reporting requirements to also include Schedule V drugs and would reduce the reporting period to CURES to within one business day from the date the prescription was released to the patient. The bill also requires reporting to the CURES system by veterinarians as soon as reasonably possible, but not more than seven days after dispensing, allows physicians that do not possess a DEA registration to enroll in the CURES system, and expands the delegate provisions for individuals working under a prescriber to retrieve data from CURES.

2. AB 690 (Aguiar-Curry, Chapter 679, Statutes of 2019) Pharmacies: Relocation: Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications

   Mr. Schaad stated a copy of AB 690 (Aguiar-Curry, Chapter 679, Statutes of 2019) was provided in the meeting materials. This measure includes the board's provision to create a limited exemption to the licensure transferability requirements for a pharmacy to relocate because of damage caused by a declared disaster. Board staff will need to establish a streamlined process for pharmacies to follow when relocation is allowed under the provisions of the bill. It establishes the requirements for a pharmacy technician working in a remote dispensing site pharmacy are established including:

   - Possession of a pharmacy technician license that is in good standing.
   - Possess and maintain a certification issued by a board-approved pharmacy technician certification program.

- Possess one of the following:
  (A) A minimum of an associate degree in pharmacy technology.
  (B) A minimum of a bachelor's degree in any subject.
  (C) A certificate of completion from a course of training specified by regulations adopted by the board pursuant to Section 4202.
- Completion of a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

The committee discussed how best to implement these provisions.

Committee Recommendation (Motion): Include as part of the application requirement for the remote dispensing site pharmacy application, signed affidavits from pharmacy technicians confirming compliance with the statutory requirements.

Support: 8 Oppose: 0 Abstain: 0

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

3. *AB 973 (Irwin, Chapter 184, Statutes of 2019) Pharmacies: Compounding

Mr. Schaad provided effective January 1, 2020, this measure explicitly states that compounding of drug preparations by a pharmacy must be done consistent with the relevant compounding chapters of the United States Pharmacopeia-National Formulary. The new provision will augment the board's compounding regulations and BPC section 4342 which provides the board authority institute any action it deems necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform with the standard and tests as to quality and strength, provided in latest edition of the USP.

4. *AB 1723 (Wood, Chapter 323, Statutes of 2019) Clinics: Purchasing Drugs at Wholesale

Mr. Schaad provided effective January 1, 2020, this measure will conform the maximum hours of operation (increasing from 20 to 40 hours) for a primary care community or free clinic with the provisions of HSC 1206.

5. SB 159 (Wiener, Chapter 532, Statutes of 2019) HIV Preexposure (PrEP) and Postexposure (PEP) Prophylaxis

Mr. Schaad provided this measure establishes authority for a pharmacist to furnish HIV preexposure prophylaxis and HIV postexposure prophylaxis under specified conditions. The meeting materials detail the specific conditions for both PEP and PrEP and included a copy of the language. Specific to the provisions of the bill, the board will need to have emergency regulations in place by July 1, 2020. Areas for regulation will cover training program requirements and, if new drugs come to market, regulations that identify the additional products that a pharmacist may furnish under the authority established.

During the meeting the committee received significant public comment on the importance of the measure, include a written statement from Senator Weiner, the author of the measure, which was read into the record. A copy of the statement was made available and was provided to members. Mr. Schaad added Dr. Gaspar, who has assisted the board in past with development of training programs, has offered his assistance with implementation as well as several other members of the public.

The committee noted the significance of this legislation and that it appears appropriate for the Communication and Public Education Committee consider an education campaign for both consumers as well as pharmacists.

The committee discussed the need to develop regulations quickly and noted that regulations must be develop with the Medical Board. Board staff will need to coordinate efforts with both the Medical Board, Office of Aids, and other stakeholders.

Committee Recommendation (Motion): The Enforcement Committee determined that such development could be referred to either the Legislation and Regulation Committee or the Licensing Committee as decided by the full board. (Note: The board agreed the Licensing Committee would handle the regulations.)

Support: 8 Oppose: 0 Abstain: 0

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

6. SB 569 (Stone, Chapter 705, Statutes of 2019) Controlled Substances: Prescriptions: Declared Local, State, or Federal Emergency

Mr. Schaad provided as included in the chair report, a pharmacist will have the authority to fill a prescription for a controlled substance that does not conform to the controlled substances security form requirements under the following conditions.

1. The prescription form indicates that the patient is affected by a declared emergency.
2. The prescription is written and dispensed within first two weeks of a notice issued by the board.
3. The pharmacist exercises appropriate professional judgement including reviewing the CURES system prior to dispensing.
4. Limits the dispensing of a Schedule II to no greater than a seven-day supply.
5. Requires confirmation that the patient is otherwise unable to access medications. Verification of residency within an evacuation area is one acceptable form of confirmation.
6. Prohibits the refill of a prescription dispensed under these provisions.

The committee noted that the board routinely issues a subscriber alert when a disaster declaration is made. This alert can serve as the notice required to be issued by the board. Further, it appears appropriate to detail out the provisions of this measure in the alert. During this current declared statewide disaster, the board's website was updated to include a list of resources for consumers and pharmacists. Incorporating this information is appropriate as well. The committee also discussed it would be helpful to provide pharmacies with guidance on possible implementation strategies.

Committee Recommendation (Motion): Authorize board staff to work with the chair to develop guidance strategies to disseminate.

In response to a question from Ms. Veale, Ms. Sodergren provided based on the language in the legislation, this is effective upon notification by the board.

Support: 8 Oppose: 0 Abstain: 0

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

7. *SB 655 (Roth, Chapter 213, Statutes of 2019) Pharmacy

Mr. Schaad provided effective January 1, 2020, this measure makes several technical and other conforming changes to Pharmacy Law. Mr. Schaad noted updates in the law validity period for pharmacy examination scores; pharmacy technician trainee provisions; advanced practice pharmacist renewal requirements; reverse distributor provisions; and government-owned facility fees.

e. Discussion and Consideration of Board's Enforcement Statistics

Mr. Schaad reviewed the enforcement statistics:

- 107 cases under review for assignment, averaging 11 days
- 933 cases under investigation, averaging 178 days
- 297 investigations under supervisor review, averaging 86 days
- 127 investigations under second level review, averaging 53 days
- 255 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 49 days

f. Future Committee Meeting Dates

Mr. Schaad provided the next Enforcement Committee Meeting is January 29, 2020.

XI. Legislation and Regulation Committee

a. *Discussion and Consideration of Board Sponsored Legislation

Mr. Lippe provided updates for the following board sponsored legislation signed by the governor were updated by the Enforcement Committee:

- AB 690 (Aguiar-Curry, Chapter 679, Statutes of 2019)
- AB 973 (Irwin, Chapter 184, Statutes of 2019)
- SB 569 (Stone, Chapter 705, Statutes of 2019)
- SB 655 (Roth, Chapter 213, Statutes of 2019)

b. *Discussion and Consideration of Board Sponsored Legislation

1. AB 528 (Low, Chapter 677, Statutes of 2019) Controlled Substances: CURES Database

   Mr. Lippe provided updates were provided in the Enforcement Committee report.

2. AB 1076 (Ting, Chapter 578, Statutes of 2019) Criminal Records: Automatic Relief

   Mr. Lippe provided this measure requires the Department of Justice (DOJ) to review summary criminal history information and identify individuals who are eligible for automatic relief by having their arrest and criminal records withheld from disclosure. It also requires the DOJ to provide automatic relief to eligible persons.

3. AB 1264 (Petrie-Norris, Chapter 741, Statutes of 2019) Medical Practices Act: Dangerous Drugs: Appropriate Prior Examination

   Mr. Lippe provided this measure specifies that an appropriate prior examination does not require a synchronous interaction between a patient and licensee, provided the licensee complies with the appropriate standard of care.

4. SB 159 (Wiener, Chapter 532, Statutes of 2019) HIV Preexposure and Postexposure Prophylaxis

   Mr. Lippe provided updates were provided in the Enforcement Committee report.

5. SB 601 (Morrell, Chapter 854, Statutes of 2019) State Agencies: Licenses: Fee Waiver

   Mr. Lippe provided this measure requires an individual or business that has been displaced or affected by a declared federal emergency or proclaimed state emergency, to submit an application for reduction or waiver of fees required to renew, activate, or replace a license.

c. *Discussion and Consideration of Board Approved Regulations Undergoing Final Review by the Office of Administrative Law

Mr. Lippe advised the board has one regulation package under final review with Office of Administrative Law to amend Title 16 CCR Section 1749 related to the Board's fee schedule. This proposal updates the board's fee schedule by increasing the board's fees to address the structural imbalance within the board's budget. The regulation package was submitted to OAL for final review September 30, 2019. The board requested an April 1, 2020 effective date.

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

Mr. Lippe stated the board has one regulation package undergoing formal review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency to amend Title 16 CCR 1746.3 related to the naloxone fact sheet. This proposal amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride. The board adopted this on June 21, 2019. Formal post-adoption review began August 28, 2019.

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

Mr. Lippe provided a list of regulations under review are included in the meeting materials. He added the Department of Consumer Affairs has established a dedicated regulation unit within the legal office. Mr. Lippe continued he believed it would be a fair expectation to see progress on many regulations by the next board meeting.

f. *Future Committee Meeting Dates

Mr. Lippe provided the next committee date is January 29, 2020.

The board heard a comment concerning the lengthy naloxone protocol where it is not practical for pharmacists to dispense naloxone.

XII. Licensing Committee

a. Discussion and Consideration of Legislative Proposal to Amend the Requirements to Qualify for an Advanced Practice Pharmacist License in Business and Professions Code Section 4210.

Chairperson Veale provided at the July 2019 board meeting, the board directed the licensing committee to review and discuss the criteria under subsection (a)(2) of section 4210 of the BPC to reassess the requirements to qualify for an Advanced Practice Pharmacist (APH) license. Specifically, when a pharmacist is applying to satisfy the criteria in subsection (A) the earned certification in a relevant area of practice and (B) completion of a postgraduate residency. When assessing applicant information, the board has identified several instances when a pharmacist seeking licensure as an APH is using completion of a single criterion (e.g. a residency program) that included as a condition of completion, a second criterion (e.g. completion of a certification program). Under current law this is considered "double-dipping" and is prohibited.

Ms. Veale reported to remedy this situation, the applicant may seek to meet another criterion, such as completion of the collaborative practice experience pathway. In this instance, the board allows the applicant one year to satisfy one of the other criteria to complete their application, thus keeping the application in pending status.

Ms. Veale noted the committee discussed the underlying policy goal of the legislation and determined changes would be appropriate and if the board agrees, a statutory change would be necessary. The committee also discussed researching the minimum requirements of residency programs established by American Society of Health-System Pharmacists (ASHP) to determine if minimum requirements of collaborative practice are met. The committee agreed ASHP will not be the benchmark but a method of gaining foundational information.

Committee Recommendation (Motion): Direct staff to work with counsel to draft a statutory proposal that would define if completion of one requirement as identified in BPC 4210(a)(2) is subsumed within completion of another requirement specified, such completion would satisfy the requirement of the law in BPC 4210(a)(2). Further, to accept if certification is earned as part of the requirements for completion of a residency or completion of 1,500 hours of collaborative practice experience or a residency is completed that included the 1,500 hours of collaborative practice experience.

Support: 8 Oppose: 0 Abstain: 0

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

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

Ms. Veale provided staff and counsel worked on statutory language for consideration to clarify for the allowance of two items to be completed during one process.

Proposed Statutory Language – Advanced Practice Pharmacist

Business and Profession Code 4210.

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) (A)Satisfy any two of the following criteria:

(~~A~~i) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(~~B~~ii) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(~~C~~iii) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(B) For purposes of this subsection, if, as a condition of completion of one of the required criteria fulfillment of a second criteria is also required such completion shall be deemed to satisfy the requirements of this subsection.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

Motion: Approve the proposed statutory language to amend BPC 4210 as drafted and to direct staff to secure an author to sponsor the statutory change.

M/S: Veale/Schaad

Support: 8 Oppose: 0 Abstain: 0

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

b. Discussion and Consideration of Legislative Proposal Regarding the Use of Automated Drug Delivery Systems

Ms. Veale referenced relevant law included in the materials. She provided the committee discussed the identified settings above as well as including any facility listed in HSC 1250. The committee agreed they cannot limit the expansion to only HSC 1250 as other locations such as psychiatric health facility and jails would not be included. The language would need to be broad enough to encompass locations that have authority to administer drugs and would require the ADDS to be licensed with the board.

Ms. Veale provided the committee noted the board does not want to allow ADDS in locations that are not already handling medications. The committee provided policy guidance to staff noting that members were in support of ensuring there is control over the ADDS to include these other locations and future locations that are identified as well.

Committee Recommendation (Motion): Direct staff to work with counsel and the chair to develop a statutory proposal to expand the locations in which ADDS can be licensed to include all facilities listed in HSC 1250 as well as other locations licensed by the state that as a function of the underlying license are authorized to offer medication services.

The board heard support in this motion and a request for policy with the consideration of adult day health care facilities and certain facilities are registered as primary care clinics. Ms. Freedman added the legislation requires the issuance of a license and so the board cannot use discretion.

Support: 8 Oppose: 0 Abstain: 0

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

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

Ms. Veale provided she worked with staff and counsel on statutory language for consideration.

Proposed Statutory Language – ADDS

Proposal to Amend Business and Professions Code Section 4427.3 to read as follows:

(a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.
(b) An ADDS shall be placed and operated in one of the following locations:
(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.
(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.
(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.
(4) A correctional clinic licensed pursuant to Section 4187.1.
(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.
(6) If the ADDS is an AUDS, in a location as provided in Section 4427.65(a).
(c) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. These policies…

Proposal to Add Section 4427.65 to read as follows:

(a) In addition to the locations authorized in Section 4427.3, an AUDS may also be located and operated in any of the following locations:
(1) Facility licensed by this state with the statutory authority to provide pharmaceutical services.
(2) Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director.
(b) The pharmacy operating the AUDS shall develop and implement, and review annually, written policies and procedures pertaining to the device.
(c) The pharmacy shall operate the AUDS in compliance with the following requirements:
(1) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.
(2) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(3) (A) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(B) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(4) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(A) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(B) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(C) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(5) When used to provide pharmacy services pursuant to Section 4017.3 of, and Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of, the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(A) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(B) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(C) The pharmacy providing services to the facility pursuant to Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(D) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(E) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(F) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(G) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those

systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.

(6) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(A) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(B) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(C) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

(7) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

Motion: Approve the proposed statutory language to amend BPC 4427.3 and add BPC 4427.65 as drafted, to direct staff to secure an author to sponsor the statutory change.

M/S: Veale/Schaad

Support: 8 Oppose: 0 Abstain: 0

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

Ms. Veale reported currently, section 4427.7 and 4119.11 of the BPC requires a pharmacy holding an ADDS license to complete an annual self-assessment, pursuant to Section 1715 of Title 16 of the CCR. However, Section 1715 of Title 16 of the CCR specifies the assessment shall be performed before July 1 of every odd-numbered year.

Ms. Veale provided to clarify BPC 4427.7 requires a "pharmacy holding an ADDS license" to complete the self-assessment. However, licensed acute care hospital facility and acute psychiatric hospital facilities are exempt from licensure if the ADDS is owned/leased by the licensed hospital pharmacy and the drugs are owned by the licensed hospital pharmacy. BPC 4427.2(i) also requires the licensed hospital pharmacy to comply with all other requirements for an ADDS in the article. Although the licensed hospital pharmacy's ADDS are not licensed, they should also complete the self-assessment if they are to comply with all other requirements for an ADDS.

Ms. Veale noted the committee discussed the variances in frequency for completing the self-assessment and the conflict between the ADDS self-assessment and the pharmacy self-assessment frequency and directed staff to provide amended language to align the requirements to the full board for consideration.

Committee Recommendation (Motion): Approve the proposed statutory language to amend BPC 4427.7 and 4119.11 to align the ADDS self-assessment requirements with the pharmacy self-assessment requirement in Title 16 CCR 1715 as drafted, to direct staff to secure an author to sponsor the statutory change.

Support: 8 Oppose: 0 Abstain: 0

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

c. Discussion and Consideration of Legislative Proposal to Amend Business and Professions Code section 4312 to Expand the Provisions to Apply to All Facility Licenses

Ms. Veale reported BPC 4312 authorizes the board to cancel the license of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility if the licensed premises remains closed. The statute does not include all facility licenses issued by the board. Therefore, the law as currently written prevents the board from applying this law to all facility licenses. The committee discussed as the board's regulatory jurisdiction continues to grow, it is imperative that the law is written to allow new and existing license types to be included in this statute.

Proposed Statutory Language – Expand the Provisions of BPC 4312 to All Facility Licenses

(a) The board may cancel ~~the license of~~ a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ <u>license of a</u> facility <u>which</u>

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

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

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

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

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

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal

service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.
(e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120 day period.
(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

Committee Recommendation (Motion): Approve the proposed statutory language to amend BPC 4312 as drafted, to direct staff to secure an author to sponsor the statutory change.

Support: 8 Oppose: 0 Abstain: 0

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

d. Discussion and Consideration of Amendments to Title 16 CCR Section 1709, to Specify Required Reporting Requirements for Individuals vested with Management and Control

Ms. Veale provided the board approved draft language to amend CCR section 1709 to include provisions relating to trust ownership of pharmacies in October 2016. The rulemaking file has been under DCA Pre-Notice Review since August 16, 2018.

Ms. Veale continued effective January 1, 2017, the passage of SB 1193 amended BPC 4201 to include reporting information for any person with management or control over a licensed facility. Given the changes in statute, the committee agreed it is appropriate to pursue additional changes to CCR section 1709. The committee discussed the importance of reporting changes in individuals exercising management and control over a facility license. Members agreed to move forward with incorporating the change to add any person with management and control over the license.

Committee Recommendation (Motion): Direct staff to work with counsel and the chair to incorporate changes into the regulation to require reporting of any person with management and control into Title 16, CCR section 1709 and to incorporate this change into the current regulatory package.

Support: 8 Oppose: 0 Abstain: 0

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

Ms. Veale reported staff and counsel worked on the regulatory language.

Proposed Regulatory Language – To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1709. Names of Owners and Pharmacist In Charge Ownership, Management, and Control of Pharmacies and Other Business Entities.

(a) Each permit license issued by the board to operate a pharmacy shall reflect show the name and address of the pharmacy, the form of ownership (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Bboard within 30 days.

(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest the time the original permit license was issued, The following shall require written notification to the board within 30 days.:

(1) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original license was issued,

(2) Any transfer of the management or control over a business entity licensed by the board to a person or entity who did not have management or control over the license at the time the original license was issued,

(c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership transfer of permit and shall require a new application for a change of ownership licensure:

(1) aAny transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest

in that license. The new owner shall apply to the board for licensure in advance of the proposed transaction taking place.

(d) If any beneficial interest of a business entity licensed by the board is held in trust, the applicant, licensee, or any person with management or control of the business entity, shall do the following:

(1) In addition to the requirements in subdivision (a), as part of their application and renewal, report the name of any other person in any position with management or control of the business entity.

(2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.

(3) As part of the renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.

(4) Include in the application and the renewal, the name, address, phone number and any email address for each grantor, settlor, trustee, and trust protector, as applicable.

(5) The application and renewal shall also include the name, address, phone number and any email address for each named beneficiary of the trust, who is age 18 or older.

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the business entity.

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.

(C) The revocation of the trust.

(D) The dissolution of the trust.

(E) Any amendment to the trust since the original application.

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

(e) An application may be denied, or a license may be suspended or revoked, based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307, or 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4058, 4101, 4110, 4111, 4112, 4113, 4120, 4124, 4130, 4131, 4133, 4141, 4149, 4160, 4161, 4196, 4201, 4207, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.

The board heard comments requesting clarification of management and control and defined beneficial control. The board expressed concern about sending it back to committee and delaying the process.

Motion: Approve the proposed regulatory language to amend Title 16, CCR section 1709 to include any person with management in subdivision (b) and (c) and to incorporate this change into the current regulatory package.

M/S: Veale/Schaad

Support: 8 Oppose: 0 Abstain: 0

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

e. Discussion and Consideration of Legislative Proposal to Standardize the Requirements, including Qualifications, for all Designated Representative Licenses (Business and Professions Code Sections 4022.5, 4022.6, 4022.7, 4053, 4053.1, & 4053.2)

Ms. Veale provided there are inconsistencies in statute regarding different types of designated representative licenses. Staff identified areas within the three designated representative license categories that are inconsistent. As an example, under certain provisions, the law explicitly provides authority for a pharmacist to perform the same functions as a designated representative and serve as the designated representative-in-charge of a wholesaler provider facility. However, this similar provision is not explicitly included for the designated representative-3PL. Additionally, when an entity is located outside of California the law is unclear if a pharmacist needs to be licensed in the home state.

Ms. Veale explained the committee reviewed a summary chart developed by staff detailing the inconsistencies when comparing the three designated representative licensure definitions and qualifications. During the meeting, the committee discussed the discrepancies identified by staff to determine if a policy change should be pursued to amend the statutes pertaining to the designated representative licenses.

Committee Recommendation (Motion): Direct staff to work with counsel and the chair to develop proposed amendments to pharmacy law based on the discussion of the committee to bring to the November board meeting.

Support: 7 Oppose: 0 Abstain: 1

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

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

Ms. Veale reported staff and counsel worked on statutory language.

Proposed Statutory Language – Standardize Designated Representative Statutory Requirements

Proposed Amendments to the following Business and Professions Code Sections 4022.5, 4022.7, 4053, 4053.1 and 4053.2.

4022.5. Designated Representative; Designated Representative-in-Charge
(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.
(b) "Designated representative-in-charge" means a designated representative, ~~or~~ a designated representative-reverse distributor, or a pharmacist licensed in the home state proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

4022.7. Designated Representative-3PL; Responsible Manager
(a) "Designated representative-3PL" means an individual to whom a license has been granted pursuant to Section 4053.1. A pharmacist fulfilling the duties of Section 4053.1 shall not be required to obtain a license as a designated representative-3PL.
(b) "Responsible manager" means a designated representative-3PL or a pharmacist licensed in the home state selected by a third-party logistics provider and approved by the board as responsible for ensuring compliance of the licensed place of business with state and federal laws with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider.

4053. Designated Representative to Supervise Wholesaler or Veterinary Food-Animal Drug Retailer
(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.
(b) An individual who is at least 18 years of age may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall have a minimum of one year of paid work experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(C) Knowledge and understanding of quality control systems.
(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
(E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.
(4) The board may, by regulation, require training programs to include additional material.
(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.
(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.
(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.
(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

4053.1. Designated Representative-3PL to Supervise Third-Party Logistics Provider
(a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The designated representative-3PL shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider's place of business.
(b) An individual who is at least 18 years of age may apply for a designated representative-3PL license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall meet one of the following requirements:
(A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.
(B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug

manufacturer, performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.
(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii) Knowledge and understanding of quality control systems.
(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B) The board may, by regulation, require the training program required under this paragraph to include additional material.
(C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of completion of the training required by this paragraph to the board.
(c) A third-party logistics provider shall not operate without a pharmacist or ~~at least one~~ designated representative-3PL present at each of its licensed places of business as required under Section 4160.

4053.2. Designated Representative-Reverse Distributor – Licensing; Requirements
(a)Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.
(b)An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall meet one of the following requirements:
(A)Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the
distribution, dispensing, or destruction of dangerous drugs or dangerous devices.
(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.
(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3)(A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i)Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii)Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii)Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.
(iv)Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B)The board may, by regulation, require the training program required under this paragraph to include additional material.
(C)The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.
(c)A reverse distributor shall not operate without a pharmacist, ~~at least one~~ designated representative, or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

Relevant Law
4022.6. Designated Representative-Reverse Distributor
"Designated representative-reverse distributor" means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

Motion: Approve the proposed statutory language to amend BPC 4022.5, 4022.7, 4053, 4053.1, and 4053.2 as drafted, to direct staff to secure an author to sponsor the statutory change.

M/S: Veale/Schaad

Support: 8 Oppose: 0 Abstain: 0

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

f. Discussion and Consideration of Proposal to Develop Intern Conferences for Students Recently Enrolled in a California School of Pharmacy and for Students Ready to Graduate from a California School of Pharmacy

Regrettably staff has been unable to further refine this proposal. Staff notes that the concept was discussed with several of the deans of the pharmacy schools. Some of the deans expressed concern with the general concept while others suggested, should the board move forward, the conference should be available through a webinar.

g. Discussion and Consideration of Committee's Strategic Plan Goals

Ms. Veale reported the committee reviewed the strategic goals of the committee's strategic plan. After the discussion, the committee decided to remove two of the current committee goals. The committee did not believe that there were any additional goals to add but did emphasize that its priorities are business modernization and application review.

Committee Recommendation: To remove 1.1 and 1.4 from the strategic licensing goals as identified below.

> **1.1** Research and identify issues that result from unlicensed vendors in the marketplace to proactively maintain patient safety and health.
> **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.

Support: 8 Oppose: 0 Abstain: 0

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

h. Discussion and Consideration of Draft Collaborative Practice Agreement: Pharmacist Protocol for Management of Opioid Use Disorders

Ms. Veale provided the committee heard a presentation from Dr. James Gaspar providing an overview of Medication Assisted Treatment (MAT) and current gaps in treatment access. As part of the presentation Dr. Gasper described how DATA 2000 waivers for prescribers has expanded access

to treatment outside of OTPs by enabling qualified practitioners to provide buprenorphine. The waiver is underutilized as many professionals that have the authority to use the waiver are not either using their waiver or using the waiver far below its capacity. Dr. Gaspar further described pharmacists' role in community pharmacies and emphasized that pharmacists can make or break someone's MAT. Following that meeting, the board identified a three-pronged solution intended to address this current treatment gap, including directing the Licensing Committee to develop a sample Collaborative Practice Agreement (CPA) pharmacist could use in collaboration with a practitioner that has received a DATA 200 waiver.

Ms. Veale explained the committee requested the CPA be approved with the words "electronic" be removed in reference to health records.

Committee Recommendation (Motion): Approve the Collaborative Practice Agreement presented at the November 5, 2019, Licensing Committee Meeting with the removal of the word "electronic" in reference to health records pending review and approval from legal counsel with the Licensing Chairperson approving minor changes. Any resulting major changes would require the Collaborative Practice Agreement to be brought back to the board for approval.

The board heard comments requesting clarification that the protocol reviewed was a sample and not binding or required specific to medication assistance treatment. The Chairperson confirmed.

Support: 8 Oppose: 0 Abstain: 0

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

Committee Recommendation (Motion): Refer to the Communication and Public Education Committee to develop resources identifying treatment options and location services that pharmacies can provide or post around MAT.

Support: 8 Oppose: 0 Abstain: 0

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

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

i. *Review of Licensing Statistics

Ms. Veale reported on statistics for July – September 2019. The goal of the board is for an application to be processed within 30 days for new applications. Most application times have decreased from September 2019 to October 2019.

The board heard a comment on the number of advanced practice pharmacist. Ms. Sodergren referred the commenter to the licensing statistics.

The board recessed to closed session at 10:47 a.m.

The board reconvened in open session at 1:29 p.m. to discuss the remaining items that did not require a quorum denoted with an asterisk (*) in the agenda item.

XIII. Update from the Department of Consumer Affairs

The Department of Consumer Affairs provided a written update distributed at the meeting to board members and the public.

The board took a break at 1:47 p.m. and returned to session at 2:30 p.m.

XIV. Petitions for Reinstatement of Licensure, Early Termination, or Other Reduction of Penalty 2:30 p.m., November 6, 2019

Administrative Law Judge Wim van Rooyen presided over the following petition for reduction of penalties.

- **Glendora Medical Supply, PHY 47517 – Reduction of Penalty**

The board recessed to closed session at 2:48 p.m.

The board returned to open session at approximately 3:00 p.m.

President Lippe adjourned the meeting at 3:00 p.m.