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
Department of Consumer Affairs
Public Board Meeting
Minutes

Date:	January 30-31, 2019
Location:	Embassy Suites 250 Gateway Blvd South San Francisco, CA 94080
Board Members Present:	Victor Law, Licensee Member, President Gregory Lippe, Public Member, Vice President Ricardo Sanchez, Public Member Albert Wong, Licensee Member Stanley Weisser, Licensee Member Maria Serpa, Licensee Member Lavanza Butler, Licensee Member Allen Schaad, Licensee Member Deborah Veale, Licensee Member Ryan Brooks, Public Member
Board Members Not Present:	Shirley Kim, Public Member Valerie Muñoz, Public Member Amjad Khan, Public Member
Staff Present:	Anne Sodergren, Interim Executive Officer Joshua Room, Senior Deputy Attorney General Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel MaryJo Tobola, Senior Enforcement Manager Laura Hendricks, Staff Analyst

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

President Victor Law called the meeting to order at 10:05 a.m. Roll call was taken, and a quorum was established. Board members present: Allen Schaad, Deborah Veale, Ryan Brooks, Maria Serpa, Albert Wong, Lavanza Butler, Gregory Lippe, Victor Law, Stanley Weisser, and Ricardo Sanchez.

President Law observed a moment of silence for Kathy Webster, founding Dean of Keck Graduate

Institute (KGI) who passed away the previous month. Ms. Webster was instrumental in the accreditation process of KGI and was very well respected by students and the profession for her accessibility and cooperation with all professions.

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

Fred Meyer of the California Alliance for Retired Americans and Pharmacists Planning Service, Inc. (PPSI) requested to add "Lizzy Law" for veterinarians as a future agenda item. Additionally, Mr. Meyer requested that the legality of Cannabidiol (CBD) be addressed and discussed by the board. Lastly, Mr. Meyer stated that pharmacists are required to fill too many prescriptions in chain drug stores; he requested that prescription drug errors, in chain drug stores should be an agenda item.

Mark Raus, a pharmacist, requested prescription errors, in relation to staffing, be added to a future agenda.

Danny Martinez of California Pharmacists Association (CPhA) requested that the Legislation and Regulation Committee add to a future agenda, a discussion on Pharmacy Benefit Managers (PBMs), as they do not have a required timeline for finalizing contracts when there is a change in ownership and possible change in statute, which impacts the continuity of care. Supervising Deputy Attorney General (SDAG) Joshua Room added that the Pharmacy Board was specifically removed from the bill regarding the regulation of PBMs. Dr. Steve Gray expressed support for CPhA's agenda item request.

III. Approval of the October 23-24, 2018 Board Meeting Minutes

Ms. Veale noted corrections needed for the Licensing Committee minutes:

- Page 29, end of item d. Ms. Sodergren asked if staff should secure an author to clean up the advanced practice pharmacist. Ms. Veale thought the board voted yes but it didn't see it reflected. Ms. Sodergren indicated the tape can be reviewed and updated as appropriate.

- Page 31, the committee recommendation should be "as well" and not "as wells".

- Page 50, second paragraph, after the fund condition and in the middle where "Debbie" is referenced, should include last name.

Motion: Approve the October 2018 Board Meeting minutes, as amended.

M/S: Weisser/Lippe

Support: 10 Oppose: 0 Abstain: 0

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

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

IV. Approval of the December 14, 2018 Board Meeting Minutes

President Law indicated that that following corrections should be made:

- Page 1: the location needs to be corrected.
- Page 6: Stan Weisser should be noted as present for the vote.

Motion: Approve the December 2018 Board Meeting minutes, as amended.

M/S: Lippe/Wong

Support: 10 Oppose: 0 Abstain: 0

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

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

There were no pharmacists in attendance to recognize.

VI. Enforcement and Compounding Committee Related Items

Chairperson Allen Schaad provided a summary of the committee's efforts at the December 20, 2018 meeting, as well as updates, for discussion and actions. Additionally, Chairperson Schaad reminded the board that the next Enforcement Committee Meeting would be held on March 14, 2019.

Chairperson Schaad stated that at the September Enforcement Committee and October Board meetings members of the public suggested that the legislation passed in this year's legislative session be brought to the committee for discussion.

a. Summary and Discussion of Implementation Strategies for Chaptered Legislation

1. AB 2086 (Gallagher) (Chapter 274, Statutes of 2018) Controlled Substances: CURES Database

Chairperson Schaad provided background information for AB 2086 Controlled Substances: CURES Database. Chairperson Schaad shared that as part of the committee discussion, the committee considered whether a pharmacist working under a collaboration practice agreement may similarly obtain a list of patients where he/she is listed as the prescriber. Additionally, board staff stated that the DOJ CURES database can accommodate such a request, as long as an individual has a DEA number. As part of the public discussion, clarification was sought on whether CURES allows an individual to be both a prescriber and a dispenser. The committee was informed that, historically, prescribers have been unable to obtain a list. Chairperson Schaad stated that board staff will confirm that individuals who are both prescribers and dispensers may obtain a list of patients for whom they are listed as being the prescriber in the CURES database, as long as they have a DEA number. Additionally, staff will ask DOJ if the list will be provided to the requestor by e-mail, postal mail or fax.

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

Chairperson Schaad provided background information for AB 2783 Controlled Substances: Hydrocodone Combination Products: Schedules. Chairperson Schaad shared that as part of the public discussion, the committee was informed that mid-level practitioners, such as physician assistants and nurse practitioners, may not be aware of the changes to Schedule II controlled substances. Additionally, the committee was informed that some nurse practitioners may not know the difference between federal and state schedules. It was stated that pharmacists are filling prescriptions from prescribers who may not have DEA approval to prescribe Schedule II controlled substances. Chairperson Schaad stated that board staff will advise those boards whose practitioners' prescribing abilities are affected by this law.

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

Chairperson Schaad provided background information for AB 2789. Chairperson Schaad shared that the committee discussed who is responsible for ensuring that prescribers provide e-prescriptions to pharmacists. Board staff confirmed that the board would not provide regulatory oversight to prescribers for this new law. The committee also reviewed the list of approved exemptions. Chairperson Schaad stated that as part of the public discussion, the committee was advised that there are concerns regarding a Drug Enforcement Agency (DEA) letter authored in 2017, which would allow pharmacists to forward unfilled electronic prescriptions from pharmacy to pharmacy, including Schedule II drugs, however, there is no mechanism to accomplish that. Board staff requested a copy of the 2017 DEA letter be sent to the board. Additionally, the public sought clarification of the terms "forwarding" and "transferring" as they pertain to CCR section 1717(e). The committee was informed that there are prescribers that have the capability to transfer electronically, but their systems do not meet DEA requirements. Mr. Schaad informed that board that the committee directed board staff to

work with DCA counsel on the limitations that exists within the regulation and bring back a recommendation to the committee.

Mr. Schaad confirmed the committee did not take action on that item.

As part of the public discussion Dr. Gray suggested that in regard to AB 2789, that although the committee reported that the board would not provide regulatory oversight to prescribers for this new law, there are prescribing pharmacists that should also be educated on the requirements of AB 2789. Dr. Gray stated that there is confusion on whether e-prescribing also applies to prescribers in hospitals when a patient is discharged.

Anne Sodergren stated that AB 2789 would be discussed in the upcoming newsletter.

President Law asked whether e-prescriptions could be transferred electronically to another pharmacy. Ms. Sodergren stated that board staff are researching Code of Federal Regulations, coordinating with the DEA, and reaching out to the State of New York since they have already implemented e-prescribing.

Mr. Schaad provided background information for SB 1447 Pharmacy: Automated Drug Delivery Systems and AB 2037 Pharmacy: Automated Patient Dispensing Systems. Mr. Schaad stated that as part of the committee discussion, the committee considered providing more specific storage and recordkeeping requirements. Board staff suggested that the board sponsor legislation to amend this statute in order to tighten the storage restrictions to apply only to an AUDS, not to an APDS. In response, board staff were directed to research options and present policy recommendations to the committee. Additionally, the committee considered whether the board should develop regulations regarding the mandatory reporting of Quality Assurance reports. Mr. Schaad stated that as part of the public discussion there was a request for clear language in the requirements for Quality Assurance reports. Mr. Schaad stated that the committee directed board staff to work with the committee chair in developing regulation language for consideration regarding the mandatory reporting of Quality Assurance reports to the board. Proposed language has been brought to the board today.

Motion: Approve the proposed regulation language for CCR section 1711. Further, direct staff to initiate the formal rulemaking process to amend Title 16, California Code of Regulations Section 1711. Authorize the executive officer to make any clarifying changes consistent with the board's policy to the rulemaking package and provide a 45-day public comment period.

M/S: Lippe/Weisser

Support: 10 Oppose: 0 Abstain: 0

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

Lippe	X			
Munoz				X
Sanchez	X			
Schaad	X			
Serpa	X			
Veale	X			
Weisser	X			
Wong	X			

2. AB 1753 (Low) (Chapter 479, Statutes of 2018) Controlled Substances: CURES Database

Mr. Schaad provided background information for AB 1753 Controlled Substances: CURES Database. Mr. Schaad stated that as part of the committee discussion, the committee was informed that the board requested that DOJ delayed implementation of the provision, since the actual approved forms would not be widely available by the January 1, 2019 effective date. SDAG Room confirmed that printers would not be able to provide compliant forms to prescribers by the effective date. SDAG Room presented the committee with a proposed subscriber alert, which detailed proposed options for pharmacies. As part of the public discussion, a member of the pubic questioned the use of "if applicable" relating to the serialized number provision in the law. SDAG Room clarified that the term "if applicable" is only used in reporting to CURES, not in the prescribing or dispensing requirement. Further, SDAG Room stated that Health & Safety Code section 11164(a) is the provision that requires that as of January 1, 2019, only a prescription with the new security feature is lawful. Additionally, a representative of CRA and NACDS, noted that she has had discussions with the author's office and was informed that it was the intent of the author to allow for a broader application of the "if applicable" and offered to work with board to find a solution. Mr. Schaad stated that in response, Ms. Herold suggested enforcement discretion. SDAG Room supported the Executive Officer's option to not make enforcement of this law a priority for the first 6 months of 2019.

Mr. Schaad informed the board that following the meeting the board released the approved committee statement detailing that the enforcement committee of the board was recommending to the board and the EO to not make investigations into noncompliance security forms, as specified, to be an enforcement priority.

Board staff monitored the implementation and took several steps to assist patients and pharmacist during this transition. Specifically, board staff were redirected to respond to questions both over the phone and in writing. The board released the correspondence from Assembly Member Low (the author of the measure) wherein the intent of the legislation was detailed, and board staff worked with the DOJ and Medical Board to release a joint statement intended to clarify the position of the respective agencies as well as each entities' role in enforcement. In addition, board staff developed FAQ's. The information was sent out via subscriber alerts and posted on the board's website.

Mr. Schaad directed the members to review a copy of the subscriber alert, the joint statement, FAQs, the letter from Assembly Member Low and copy of approved language for AB 1753.

During the meeting Mr. Weisser stated that patients have been very negatively impacted by this legislation.

Joshua Room explained that there was a provision that was removed that would have allowed for delayed implementation.

Ms. Sodergren informed the board that the author's letter, which was disseminated, explicitly stated the policy, their intent and how the author believed the legislation should have been effectuated.

A member of the public stated that despite the letters and notifications there are still pharmacists who are refusing to fill prescription on non-compliant forms. He encouraged more communication from the board to pharmacists and pharmacies.

Danny Martinez of CPhA stated their support of this motion.

Dr. Gray stated to the board that it appears pharmacies will need to change their software in order to comply with this law.

A representative of NACDS and CRA stated that there is still a problem with the new "right" forms which do not have serialized numbers that are compliant with NCPDP system. Ms. Snyder clarified that although the forms are valid, if the pharmacy has to transmit the serialized number there will be a problem in the transmission.

Committee Recommendation (Motion): Ratify the enforcement committee's recommendation clarifying that the board will not consider this an enforcement priority until July 1, 2019.

Support: 10 Oppose: 0 Abstain: 0

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

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

Mr. Schaad provided background information for AB 2138 Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction. Mr. Schaad stated that as part of the committee's discussion, members considered making a recommendation for board staff to begin working with the Office of the Attorney General and DCA counsel to identify next steps, including possible statutory changes that could minimize the impacts of this measure as enacted.

Mr. Schaad stated that SDAG Room informed the committee that this law makes several changes to the types of convictions that can be used as a basis for denial and allows the board to look into the conduct that led to the convictions. SDAG Room clarified that only convictions within the past 7 years to be the most relevant types and any conviction(s) that have been dismissed, pursuant to Penal Code Section 1203.4, in which the individual has successfully completed probation, may, by petition, be dismissed.

Mr. Schaad informed the board that DCA Counsel Laura Freedman informed the committee that her office is actively working on general guidelines for all boards. They are working on model language and will be consulting with the DOJ.

As part of the committee discussion committee asked if DUI convictions would be included in this law. SDAG Room confirmed that the DUI conviction could no longer be considered for license denial if the individual who committed the DUI offense completed probation and petitioned for the conviction to be dismissed. The committee inquired if in the case where an applicant is approved for licensure, may the board then immediately take disciplinary action and place the license on probation. In response, SDAG Room stated that, in theory, the board could approve the application of an individual who has committed an offense that could no longer be considered, then take disciplinary action against that license based on that prior conviction.

Mr. Schaad stated that board staff requested that the committee consider amending this law to allow the board a provision to take into consideration certain convictions or underlying conduct, such as fraud convictions.

Committee Recommendation (Motion): Direct staff to begin working with the Office of the Attorney General and DCA counsel to identify next steps including possible statutory changes that could minimize the impacts of this measure as enacted. Further, it is recommended that staff, in concert with counsel, perform a GAP analysis as the first step towards implementation.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Khan				X
Kim				X
Law	X			
Lippe	X			
Munoz				X
Sanchez	X			
Schaad	X			

Serpa	X			
Veale	X			
Weisser	X			
Wong	X			

4. AB 2859 (Caballero) (Chapter 240, Statutes of 2018) Pharmacy: Safe Storage Products

Mr. Schaad provided background information for AB 2859 Pharmacy: Safe Storage Products.

No comments were made.

5. SB 212 (Jackson) (Chapter 1004, Statutes of 2018) Solid Waste: Pharmaceutical and Sharps Waste Stewardship.

Mr. Schaad provided background information for SB 212 Solid Waste: Pharmaceutical and Sharps Waste Stewardship.

Mr. Schaad stated that as part of the committee discussion, the committee was informed that the board is required to review a list of covered and not covered products for sale in California. Implementation challenges were shared with the committee, for example how covered entities are to provide the information to the board. Board staff noted their preference is receipt of the information in an electronic standardized format. Board staff requested approval to develop regulations for the purpose of standardizing reporting requirements to ensure consistency in the receipt of data. Mr. Schaad stated that as part of the public discussion, a speaker indicated that many of the provisions of the bill are problematic, she expressed concern with pharmacies that are included in the definition of covered entities. Additionally, she highlighted that there is a requirement that 90 days after the effective date of the bill (January 1, 2019), covered entities will have to submit to the board all of their drugs that they distribute into California, and annually, thereafter.

Ms. Sodergren informed the board that CalReycle is in charge of this program. Staff is attending a meeting today where specific requirements will be discussed.

6. SB 1109 (Bates) (Chapter 693, Statutes of 2018) Controlled Substances: Schedule II Drugs: Opioids

Mr. Schaad provided background information for SB 1109 Controlled Substances: Schedule II Drugs: Opioids. As part of the committee discussion, committee members were asked to consider developing a similar requirement for pharmacists who prescribe under a collaborative practice agreement. Members agreed that pharmacists should receive similar CE. As part of the public discussion, it was stated that it was not the authors intent to include pharmacists in this CE requirement. He opined that the author intended to regulate prescribers rather than pharmacists.

Ms. Sodergren informed the board that there will be an article in the Script and the article will include sample labels.

Committee Recommendation (Motion): Direct staff to develop a statutory proposal seeking the CE requirement for a pharmacist operating under a collaborative practice agreement, with the authority to work with the chair of the committee. The proposal will be brought to the board at the January 2019 meeting.

Support: 10 Oppose: 0 Abstain: 0

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

Consistent to the committee's recommendation a draft proposal has been approved by the chair. Should the board agree with the proposed changes, the following motion could be used to initiate statutory change.

Motion: Approve the proposed statutory language for Business and Professions Code section 4052.11 and to direct board staff to secure an author to sponsor the statutory change

M/S: Schaad/Veale

Support: 10 Oppose: 0 Abstain: 0

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

7. SB 1254 (Stone) (Chapter 697, Statutes of 2018) Hospital Pharmacies: Medication Profiles or Lists for High Risk Patients

Mr. Schaad provided background information for SB 1254 Hospital Pharmacies: Medication Profiles or Lists for High Risk Patients. As part of the committee discussion, the committee members determined if field staff should identify hospitals that have chosen to implement medication reconciliation under the purview of the pharmacy. Board staff explained to the committee that data collected from hospitals could help with the development of policy, moving forward. As part of the public discussion a member of the public commented that this is one of the most important bills of the year and encouraged the board to take this opportunity to take a very strong enforcement position on the implementation of this bill.

During the public comment period Mr. Mayer asked why pharmacists are not the only ones who performs the task of obtaining an accurate medication profile or list for a high-risk patient. Ms. Sodergren stated that the Board of Pharmacy was not the sponsor of this bill, but the policy behind it was based on a study done by a hospital in Southern California and that study demonstrated the value and importance of an important medication safety list and who appeared to be appropriately trained to collect that information.

Committee Recommendation (Motion): Direct board staff to collect information on how hospitals are implementing the collection of data pursuant to SB 1254.

Support: 10 Oppose: 0 Abstain: 0

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

The board stopped for a break at 11:42 AM. The board reconvened at 11:45 AM

8. SB 1442 (Wiener) (Chapter 569, Statutes of 2018) Community Pharmacies: Staffing

Mr. Schaad provided background information for SB 1442 Community Pharmacies: Staffing. He shared that as part of the committee discussion, staff was directed to work with counsel to research the DEA requirements and to see if a background check would be required under the Code of Federal Regulations or if the board should develop such a requirement. Staff will

report back with a recommendation at the next meeting. As part of the public discussion, members of the public requested that the board clarify what it means to "assist the pharmacist." An opinion on the intent was provided, which is to identify a staff member, not a pharmacy technician, within the establishment to relieve the pharmacists for short periods of time. In opposition, a different context of the intent was to provide an actual assistant to help with administrative duties. In addition, a member of the public stated there may be staffing issues with separate ownerships between the pharmacy and the retailer. An example he provided is a CVS Pharmacy located inside a Target retail store.

Lavanza Butler stated that in her observation and talks with practicing pharmacist, this law, which became effective in January is not being enforced and pharmacists are not receiving the help required. She encouraged the board to monitor enforcement of this law.

Mr. Wong encouraged the board to determine the source of the problem. Mr. Wong suggested that reimbursements may affect the pharmacies ability to employ a sufficient number of staff.

Mr. Lippe stated that at the Legislation & Regulation Committee meeting it was discussed that the UFCW will be filing a petition to request the board to promulgate regulation on this law. The UFCW will be meeting with the board to provide draft language. DCA Counsel, Laura Freedman clarified that the UFCW would submit proposed draft language to the board for consideration.

During public discussion, the president of the Independent Pharmacist Association stated that leaders of the large chain pharmacies know the law, but they are not meeting the intent of the law. He asked the board to clarify how this will be enforced. Additional public comment stated that there are still not enough staff who are trained to help in the pharmacy. A member of the public encouraged the use of pharmacy technicians to comply with this bill. A representative from the CRA and NACDS stated that they understood that the intent of the bill was to have a cross-trained staff member available, not necessarily a technician. Additional public comment requested enforcement discretion by the board as it will take time to assess the responsibilities and cross-train staff.

Ms. Sodergren stated board staff would research DEA requirements in terms of background checks for people who have access to the controlled substances and that will be reported back to the committee.

As part of public comment, Dr. Gray requested Stone come to speak to the intent of this bill. A representative from the California Growers Association various sections of the store already require specialized training in the stores e.g. food safety, alcohol sales. They are committed to working with the board in the implementation of this bill. Another member of the public urged the committee to recognize that non-licensed staff assigned to work in the pharmacy must be trained thoroughly on the computer system in order to avoid detrimental errors to insurance claims, patient records etc.

9. Chapters Bills Relating to Health Care Coverage: Prescription Drugs
    - AB 2863 (Nazarian) (Chapter 770, Statutes of 2018)
    - AB 315 (Wood) (Chapter 905, Statutes of 2018)
    - AB 1021 (Wiener) (Chapter 787, Statutes of 2018

Chairperson Schaad provided background information for AB 2863, AB 315 and SB 1021. He stated these bills are intended to ensure that patients do not pay more for a drug if they have health insurance, than if they had paid the cash price directly.

He reported that as part of the public discussion, a representative of the California Retailers Association and the National Association of Chain Drug Stores, requested that the board delay enforcement of provisions in AB 2863 and AB 315 which requires a pharmacy to submit a claim, but noted that submission of the claim is a problem because the systems do not allow for such a submission.

DCA Counsel reviewed provisions in AB 2863 and AB 315. She informed the committee that violations of provisions are not enforceable because the law specifically prevents the board from disciplining. Board staff may offer education of pharmacists and consumers or collect data. Provision in AB 315 require, new section 1441 will create requirements for a Pharmacy Benefit Managers (PBMs) to report certain information to healthcare plans or insurers. Since the board is not responsible to license PBMs, the responsibility will fall to another agency and the boards role will be educational. AB 315 created the regulatory body over PBMS but will not implement enforcement until 2020. In the meantime, there is a taskforce specific to the Taskforce on Pharmacy Benefit Management Reporting within the Department of Managed Healthcare (DMHC) which specifically allows other departments to be a part of the taskforce. DCA Counsel informed the board that board staff could reach out to DMHC to participate.

Ms. Sodergren suggested, and the board agreed to the Communication and Public Education Committee look at different education avenues that we can explore.

Mr. Weisser encouraged the board to participate in the Taskforce on Pharmacy Benefit Management Reporting.

CPhA expressed support and encouragement of the Board of Pharmacy's involvement in the taskforce.

Motion: Recommend the Board of Pharmacy participate in the Taskforce on Pharmacy Benefit Management Reporting.

M/S: Wong/Brooks

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			

Khan				X
Kim				X
Law	X			
Lippe	X			
Munoz				X
Sanchez	X			
Schaad	X			
Serpa	X			
Veale	X			
Weisser	X			
Wong	X			

b. Discussion and Consideration of Amendments to California Code of Regulations, Title 16, Section 1713, Related to Automated Drug Delivery Systems

Chairperson Schaad informed the board that recently enacted legislation regarding ADDS alters the condition under which a pharmacy can operate such a device. With the enactment of SB 1447 and AB 2037, the board/committee should consider amending existing regulations for ADDS that dispense medications to patients to reflect current law in this area.

He stated that the committee recommends to the board initiation of a rulemaking to amend Title 16, California Code of Regulations section 1713 and delegate to the executive officer the authority to make technical or non-substantive changes consistent with the board's policy and provide a 45-day public comment period.

DCA Counsel recommended changing the motion to replace the word "technical or non-substantive" with "clarifying".

Committee Recommendation (Motion): Initiation of a rulemaking to amend Title 16, California Code of Regulations section 1713 and delegate to the executive officer the authority to make clarifying changes consistent with the board's policy and provide a 45-day public comment period.

Support: 10 Oppose: 0 Abstain: 0

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

Veale	X			
Weisser	X			
Wong	X			

c. Discussion and Consideration of CURES Reporting Requirement Related to the Dispensing Date

Chairperson Schaad provided background information. He stated currently, all Schedule II – IV controlled substance prescriptions dispensed in California must be reported to the Prescription Drug Monitoring Program (PDMP) known as CURES. Records of dispensing must be sent to CURES within seven days of the dispensing of the controlled substance, but there is currently no requirement to send a void/cancel message for prescriptions that were filled in the pharmacy but never picked up. While the CURES reporting system is administered by the DOJ, actual submissions by pharmacies are transmitted to a third party, Atlantic Associates (AAI). AAI is tasked with data integrity, formatting checks, identifying duplicate entries, and reconciling "near matches." AAI then transmits the data for insertion into the CURES database. Additionally, while some pharmacy systems hold a prescriptions' transmission to CURES until the patient actually receives the filled prescription, most systems do not. Thus, CURES reports may contain medication that, in fact, were never actually dispensed to the patient.

Mr. Robert Stein was invited to provide the committee with a review of the issue.

Mr. Stein stated CURES reports are inaccurate in the reporting of prescriptions received by a recipient. Currently, the CURES system lacks the ability to account for prescriptions that are not picked up by the patient. Mr. Stein explained this problem is not isolated to California; his research has disclosed that other states are experiencing the same challenges with the CURES database.

Mr. Stein presented possible solutions to the problem. Mr. Stein noted that a reverse/cancel transaction obviates the manual processes needed to remove a prescription not provided to a patient from CURES. Second, pharmacies with computer systems that include integrated Point of Sale or "closed loop dispensing" may not require the reverse/cancel functionality if the date of sale, physical dispensing to the patient, becomes the "trigger event" to send a prescription record to CURES. Mr. Stein noted; however, if the "date of dispensing" is considered to be the date of fill in the pharmacy computer system, some prescriptions may be reported to CURES later than the statutory requirement.

Mr. Stein suggested a statutory amendment to Health & Safety Code section 11165 in order to clarify that the time limit to submit the transaction to CURES begins at either the date of prescription processing or the date of actual dispensing to the patient, whichever is later.

Third, pharmacy system vendors should be notified that to comply with California reporting requirements, they must modify their systems to send a void/cancel code to AAI. Fourth, Mr. Stein requested clarifying language throughout statutes and regulations that harmonizes definitions of "fill," "dispense," and "sale" dates.

Mr. Martinez of CPhA stated they are looking forward to working with board on this statutory amendment.

d. Review of Board's Enforcement Statistics

Mr. Schaad provided the following statistical data to the board:

Since July 1, 2018, the board received 1,398 complaints and closed 1,406 investigations. As of December 31, 2018, the board had 1,893 investigations pending.

Since July 1, 2018, 643 investigations were closed without a substantiated violation, including 162 complaints that were determined non-jurisdictional.

Since July 1, 2018, the board issued 709 citations, 107 of which the board offered abatement to either reduce or eliminate the fine. The board referred 125 investigations to the Office of the Attorney General.

Since July 1, 2018, the board resolved administrative cases that resulted in 107 revocations or surrenders of a license, 53 licenses being placed on probation, and issued 20 public reprovals.

e. Future Committee Meeting Dates

Mr. Schaad informed the board that the next committee meeting dates are March 14, 2019, July 2, 2019, and September 25, 2019.

The board stopped for a lunch at 1:00 PM. The board reconvened at 2:04 PM.

Special Meeting

President Law provided the board will hold a Special Meeting as authorized by Government Code sections 11125.3 and 11125.4. The purpose of the Special Meeting is to allow the board to consider proposed legislation about control substance prescriptions and security prescription requirements.

In order to hold a Special Meeting, the board must consider and find the necessity for a Special Meeting by establishing whether the delay necessitated by providing notice 10 days prior to the meeting would cause a substantial hardship on the board or that immediate action is required to protect the public interest.

President Law noted for the board's consideration as earlier discussed by the board's Enforcement Committee report, there is potential for significant public harm resulting in the enactment last year by AB 1753 which altered the requirements for controlled substance security forms but failed to establish a transition period. Since the enactment, the board has communicated the low priority for investigation of pharmacists dispensing based on noncompliant prescriptions; however, a permanent solution is necessary. The board's concern that a patient unable to receive required medication necessitates immediate action by this board to convey the board's position on the proposed legislation and provide further guidance to pharmacists and pharmacies that may be hesitant to provide patient care because liability concerns. Additionally, AB 149 was amended to address this issue after the publication of the board's agenda. The cost of to establish another board meeting for address this issue would be substantial hardship and there is a need to act immediately.

Motion: Sufficient necessity established to hold a Special Meeting.

M/S: Lippe/Weisser

Support: 10 Oppose: 0 Abstain: 0

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

President Law provided the board with the amendments provided by AB 149 as amended January 24, 2019. As amended, AB 149 would delay the requirement for controlled substances security forms to have a uniquely serialized number until a date determined by the Department Justice no later than January 1, 2020. The amendment also establishes specifications for the serialized number. Further, the amendment provides for any prescription written on an otherwise valid prescription form prior to January 1, 2019, is considered a valid prescription that may be filled until January 1, 2021.

Board Member Weiser inquired if this would resolve the issue of the required unique serial number being too long. Interim Executive Officer Anne Sodergren provided as amended in its current form the bill would require that the unique serial number comply with NCPDP standards.

Danny Martinez, California Pharmacist Association (CPhA), provided CPhA supports the bill and testified at the Business and Professions Committee in support of the bill. Mr. Martinez clarified the urgency clause was inserted during the committee process.

Motion: Motion to support AB 149 as amended on January 24, 2019.

M/S: Sanchez/Lippe

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Khan				X
Kim				X
Law	X			
Lippe	X			
Munoz				X
Sanchez	X			
Schaad	X			

Serpa	X			
Veale	X			
Weisser	X			
Wong	X			

Board Member Weiser inquired when this will become effective. DCA Counsel Laura Freedman clarified that Mr. Martinez advised that an urgency clause was added; however, as the bill is written now, it wouldn't become law until January 1, 2020. An urgency clause would mean it would take effect when the legislature passes it. Ms. Freedman advised if the board would like to make a motion on the urgency issue, it may do so as well.

Motion: Motion to support the urgency clause be added to AB 149.

M/S: Weisser/Butler

Support: 10 Oppose: 0 Abstain: 0

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

The Special Meeting was adjourned.

VII. Licensing Committee

The board reviewed a summary of the committee's efforts at the December 19, 2018, meeting, as well as updates, for discussion and action as necessary.

a. Pharmacy Services During a Declared State of Emergency

Chairperson Deborah Veale provided pursuant to Business and Professions Code (BPC) section 4062, a pharmacy may furnish dangerous drugs in reasonable quantities without a prescription during a federal, state or local emergency. This section allows the board to waive application of any provisions of pharmacy law if, in the board's opinion, the waiver will aid the provision of patient care or the protection of public health. Further, under this section, provisions exist to allow for the use of a mobile pharmacy under specified conditions.

Ms. Veale noted BPC section 4064 provides that a prescription may be refilled by a pharmacist without prescriber authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgement, failure to refill the prescription might interrupt the patient's ongoing care.

Ms. Veale reported regrettably in recent years the number of declared state of emergencies in California have grown both in frequency and scope. The board has relied upon both its strong policy and legislative authority during such emergencies to guide pharmacists in helping displaced patients.

Ms. Veale stated when such an event occurs, the board uses its subscriber alert system to remind pharmacists about authorities provided in the law. Further, the board's duty inspector provides real time guidance. During the most recent declared emergency resulting from the Camp Fire, in addition to mandatory evacuations and loss of homes, five pharmacies were closed because the business either burned down or sustained significant fire damage. An additional six pharmacies closed for limited time due to air quality concerns.

Ms. Veale explained board staff also collaborates with other state agencies involved in disaster response, most notably the California Department of Public Health (CDPH) and the Office of Emergency Services. During this most recent emergency, the board disseminated information on a pharmacist's ability to care for patients under emergency conditions via the subscriber alert system. For the first time the board also shared reimbursement procedures for pharmacies providing emergency dispensing through the Emergency Prescription Assistance Program (EPAP).

1. Summary of Presentation by the California Department of Public Health Regarding Provisions

   Ms. Veale provided at the December 2018 committee meeting, Tom Ahrens, a pharmacist contracted with CDPH and currently working for UC Davis, and Mark Chew, pharmacist with Orange County Emergency Services as well as one of the respondents from the California Medical Assistance Team, provided a presentation on the emergency response to the Camp and Woolsey Fires.

   Ms. Veale reported that the relief efforts for the Camp and Woolsey Fires were provided by a combination of groups familiar with providing emergency services and groups trying to help less versed in providing emergency services. As a result, medical supplies and medications provided varied as well.

   Ms. Veale stated sometimes a person impacted by the wildfire would stay with family far away from the fires and so the impact of the wildfire was beyond the geographical area of the wildfire.

   Ms. Veale reported the presentation identified areas where people had difficulties getting prescriptions. During the Camp Fire, a methadone clinic was impacted so the patients were impacted and needed to get their prescriptions to prevent relapse. A pharmacy that was evacuated was worried about vandals stealing the medications. The board also received calls from patients who couldn't receive their mediations because they didn't have the money for co-pays. EPAP is available to assist with covering co-pays but is only available to people without

insurance. During the Camp and Woolsey Fires only 7 people took advantage of the EPAP. The committee discussed override codes available to assist with copays or a fund within the state to handle such a situation.

Ms. Veale commented one of the lessons learned from the fires was the lack of knowledge on the part of the pharmacist to handle such an emergency especially since emergencies are not common. Pharmacists didn't know what to do in the case of an emergency and were hesitant to act.

Ms. Veale reported the committee discussed the need for more education for pharmacists in the area of emergency preparedness and discussed the possibility of a prescription blank for to be used in emergencies similar to what is used for terminally ill patients. The committee referred the issues to the Communication and Public Education Committee.

2. Recommended Statutory Change Related to Controlled Substances Prescriptions

Chairperson Veale reported the committee previously directed staff to work with her to develop a statutory proposal to create an exemption from the security prescription forms requirement for patients unable to access controlled medication as a result of a declared state or federal emergency. The draft language for Health and Safety Code section 11159.25 was provided in the meeting materials.

President Law inquired if the committee has worked to see if the PBMs are willing to disclose patient information during a declared emergency. Often times during emergencies, evacuees only have their personal identification. Ms. Veale noted that by using Surescript, eligibility checks can be run for the patients. Ms. Veale also commented that this was forwarded to the Communication and Public Education Committee to see if best practices can be developed.

President Law asked if there is a central bank for pharmacists to volunteer during emergencies. Ms. Veale added the Communication and Public Education Committee will be working to encourage pharmacists to sign up for the disaster recovery in their respective counties.

Ms. Veale read the draft language provided. Ms. Sodergren indicated declared emergencies can be quite lengthy and policy guidance would be helpful as the proposed language would be appropriate at the beginning of the declared emergency. As access changes, the proposed language may not be needed. Policy direction would be helpful for additional parameters should there be limitations as the declared emergency is resolved. Ms. Veale clarified this is specific for controlled substances.

> Prescription Form Standards for a Controlled Substance During a Declared Emergency – DRAFT language (2019 1 7)
>
> HEALTH AND SAFETY CODE -HSC *DIVISION 10. UNIFORM CONTROLLED SUBSTANCES ACT [11000 -11651] CHAPTER 4. Prescriptions [11150 -11209]*
>
> **ARTICLE 1. Requirements of Prescriptions [11150 -11180]**
> *(Article 1 added by Stats. 1972, Ch. 1407.)*

Proposal to add Health and Safety Code Section 11159.25 as follows

(a) Notwithstanding any other provision of law, if the California State Board of Pharmacy issues an notification pursuant to BPC section 4062, a pharmacist may fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of a declared state or federal emergency, regardless of whether the prescription form meets the requirements of Section 11162.1, if the prescription meets the following requirements:

(1) Contains the information specified in subdivision (a) of Section 11164.

(2) Indicates that the patient is affected by a declared emergency by the words "11159.25 exemption."

(c) A pharmacist filling such a prescription must review the patient's activity report from the Prescription Drug Monitoring Program prior to dispensing the medication.

Committee Motion: Approve the proposed statutory language for Health and Safety Code section 11159.25 and to direct board staff to secure an author to sponsor the statutory change.

Ms. Veale indicated that the motion and language would need to be set aside as a timeline is being added. Ms. Veale asked if board members thought it should be valid for one refill, two-week time period, etc.

Steve Gray, a pharmacist, suggested professional judgement that allows for the prescriber to be reached should be added to mirror federal requirements.

Ms. Veale requested DCA Counsel Freedman's opinion for reasonable time. Ms. Freedman indicated a reasonable time in the pharmacist's professional judgement is an acceptable for statutes but would not be acceptable for regulations.

Dr. Gray commented on the 11159.2 exemption for terminally ill patients, prescribers do not remember code numbers so professional judgement is again appropriate.

Ms. Sodergren commented this is intended for a new prescription and not a refill. Ms. Sodergren mentioned that it may be difficult to get approved by the legislature if it is deemed reasonable based on professional judgement due to the concern of potential abuse. Ms. Sodergren recommended if the board is agreeable, policy direction and authorization to work with Legislation/Regulation or Licensing Chair would be helpful in effectuating the policy goal if it is not a little more specific on the time period.

Ms. Veale asked if the potential author Ms. Sodergren has been in discussions with was concerned with a time requirement. Ms. Sodergren indicated it had not been a concern but there is a concern for creating a loophole for drug seekers.

DCA Counsel Freedman suggested "within the professional discretion of a pharmacist not to exceed ___" as a possible option. Ms. Veale offered "within two weeks" as a suggestion.

Dr. Gray commented a new prescription may be ongoing therapy. Ms. Veale indicated this is focused on controlled substances.

Motion: Amend and approve the proposed language add Health and Safety Code section 11159.25 to include in section (a)(2) specifying the patient is affected by a declared emergency 11159.25 exemption or similar language and add upon pharmacist's professional judgement up to two weeks. Direct board staff to secure an author to sponsor the statutory change.

M/S: Veale/Sanchez

Support: 10 Oppose: 0 Abstain: 0

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

Dr. Gray commented that pharmacists in the surround area of a declared emergency do not know if they are able to help incoming patients from declared emergency areas. Ms. Freedman verified this was considered in the language. Mr. Weisser inquired if there was concern about fraud. Ms. Veale indicated the CURES requirement and 11159.25 exemption is added to combat fraud.

b. Summary of Discussion of Inspections of Sterile Compounding Pharmacies Required as a Result of Remodeling of the Facility

Ms. Veale provided pursuant to BPC sections 4127.1 and 4127.2, a license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance. A fee is assessed for the issuance or renewal of a sterile compounding license.

Ms. Veale noted at the October 2018 Board Meeting, at the recommendation of the Enforcement Committee, the board referred further discussion to the Licensing Committee and requested consideration of inspections for sterile compounding pharmacies that are required after a pharmacy remodel.

Ms. Veale stated while there is no requirement in pharmacy law for the board to conduct an inspection of the sterile compounding pharmacy after a remodel, the board is mandated by law to ensure that sterile compounding pharmacies are in compliance with pharmacy law, and as

such a remodel inspection is conducted to confirm compliance. Such reinspection is necessary to reassess the compounding conditions and compliance with pharmacy law and to ensure that changes do not pose a safety threat to consumers. This process is similar to CETA guidelines that establish recertification of equipment when changes are made to certain types of equipment used. However, under current law, the board does not have the authority to assess a fee for such an inspection. The board must immediately respond to perform such remodel inspections because a delay could impact patient care.

Ms. Veale explained since July 1, 2015, the board has completed approximately 65 sterile compounding remodel inspections. This number is expected to increase as sterile compounding pharmacies remodel for compliance with the new USP chapters. The scope of a remodel ranges from simple projects to a full remodel or an expansion. There are several reasons that a remodel may trigger an inspection such as: unforeseen damage (e.g., flood, fire); planned upgrades (e.g., replacement of a PEC, addition of a PEC, repairing walls, floors, ceilings); and expansion of a facility.

Ms. Veale provided currently, when board staff is notified of a pending remodel to a sterile compounding facility, the board attempts to conduct an inspection as soon as possible after receiving the notification. Most remodel inspection requests are planned projects that the facility is aware of months in advance. Travel costs and inspector time for remodel inspections are currently being absorbed by the board.

Ms. Veale reported the committee discussed the board's mandate to conduct inspections of sterile compounding pharmacies to confirm the facility is in compliance with pharmacy law and agreed that an inspection is required after a remodel. The committee discussed establishing notification parameters for advising the board when a remodel is planned and possible consideration to develop a remodel application for the facility to submit in order to be notified if an inspection will be required at the conclusion of the remodel.

Ms. Veale noted the committee discussion included establishing parameters as well when an inspection fee would be assessed. The committee identified that an inspection is required prior to the expiration of the license as the board is mandated to conduct an inspection of a sterile compounding pharmacy prior to issuance and renewal of the license. The committee noted that the board does not have the authority to postpone conducting an inspection after the expiration date of the license. Additionally, a sterile compounding pharmacy license renewal period runs congruent with the underlying primary pharmacy or hospital license and as such the expiration date for the sterile compounding pharmacy cannot be altered. The committee agreed that placing parameters in law to specify that if a remodel inspection occurs within 90 days of the expiration of the license then the inspection would also serve as the renewal inspection.

Ms. Veale noted the committee requested staff to develop language with legal to establish remodel inspection parameters and fees for review and consideration at the next licensing committee meeting.

Danny Martinez, CPhA, commented on the proposed remodeling fee and noted the recent increases in fees. Mr. Martinez commented that remodeling should be covered by the recent increase in fees.

Ms. Veale indicated there seemed to be calculation errors in the numbers provided by CPhA. Ms. Sodergren added there may have been some assumptions built in and is happy to bring it back to the Licensing Committee. With changes in USP, the board anticipates an increase in remodeling inspections requested in the future.

President Law added there are costs associated with inspections, especially with compounding inspections.

c. Discussion and Consideration of Proposed Regulation Regarding the Self-Assessment Requirement for Automated Drug Delivery Systems

Ms. Veale reported in 2018, Governor Brown signed AB 2037 and SB 1447, both relating to the licensure and use of Automated Drug Delivery Systems (ADDS). Both measures require the operating pharmacy to complete an annual self-assessment to ensure compliance with pharmacy law as it relates to the use of the ADDS.

Ms. Veale explained to facilitate implementation of this requirement, promulgation of regulations is necessary. Similar to the approach the board is taking with the pharmacy self-assessment process, board staff recommends detailing the specific reporting elements in the regulation language while also incorporating a self-assessment form by reference.

Ms. Veale noted the committee discussed and reviewed the proposed draft self-assessment of an ADDS by a pharmacist-in-charge regulation and the proposed draft ADDS self-assessment and made the following changes to the language. The committee added a comma and the word "or" at the end of paragraph (2) of subdivision (b).

> Draft Regulation to read as follows: § 17##. Self-Assessment of an Automated Drug Delivery System by Pharmacist-in-Charge.
>
> (a) A pharmacy holding an automated drug delivery system (ADDS) license as defined under section 4119.11, 4187.5 or section 4427.2 of the Business and Professions Code shall complete a self-assessment of compliance with federal and state pharmacy law for each location where an ADDS license is granted. The assessment shall be performed by the pharmacist-in-charge annually before July 1 of every year.
> (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
> (1) A new ADDS license has been issued, or
> (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge, or
> (3) There is a change in the licensed location of an ADDS to a new address.

Committee Recommendation (Motion): Recommend to the full board to approve the draft language with the addition of the ", or" after (b)(2) and to direct staff to initiate the rulemaking with the intent to have the regulation in place by May 1, 2020.

Support: 10 Oppose: 0 Abstain: 0

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

Ms. Veale reported the committee discussed and reviewed the proposed draft ADDS self-assessment and made the following changes to the assessment.

Draft Automated Drug Delivery System Self-Assessment form

- Include in the assessment form the hours of the ADDS as required in the draft regulation in (c)(1)(D) and add if the hours of the ADDS are different than the pharmacy, what are they and why?
- Need to reference to sign the certification on page 34 for the ADDS listed under sections 4, 5, 6, 7, and 8 after completing the assessment.
- Correct if the ADDS is either an AUDS and/or an APDS in Section 1 and to provide instruction that there are two different types of ADDS.

Ms. Freedman clarified acceptance of the changes to the self-assessment were included in the prior motion.

Motion: Authorize the executive officer to make clarifying changes to the text of the regulation or self-assessment form as needed to be consistent with board policies.

M/S: Veale/Weisser

Support: 10 Oppose: 0 Abstain: 0

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

Lippe	X			
Munoz				X
Sanchez	X			
Schaad	X			
Serpa	X			
Veale	X			
Weisser	X			
Wong	X			

d. Discussion and Consideration of a Policy Statement and Strategic Steps to Authorize a Pharmacist to Provide Medication-Assisted Treatment

Ms. Veale reported there is a huge nationwide opioid crisis. One of the recommended solutions to address the crisis is to provide medication-assisted treatment (MAT) to help wean patients from opioids. There are three main medications used for this -methadone, buprenorphine and naltrexone.

Ms. Veale noted the California Legislature declares pharmacists to be health care providers who have the authority to provide health care services. Pharmacists are medication specialists who are skilled in the assessment and management of substance related disorders such as opioid addiction. Today pharmacists have six to eight years of collegiate education with focused experience in performing medication management. Increasingly this also includes additional residency experience. For a number of years under California law and in conjunction with collaborative practice agreements with prescribers, pharmacists have had the ability to: design treatment plans; initiate medications; monitor patient progress; order and review necessary laboratory tests; coordinate care with other medical providers; and serve as expert consultants to support prescribers in making medication decisions for patients with opioid addiction and co-occurring conditions.

Ms. Veale added pharmacists with this skill set are well positioned to provide direct care to patients with opioid addiction and assist other medical providers in caring for this population, thereby expanding access to treatment for consumers. Additionally, in California, pharmacists with appropriate education and experience may secure an additional pharmacist's license, that of Advanced Practice Pharmacist, which authorizes collaborative practice with primary care providers.

Ms. Veale reported currently, federal laws prevent a pharmacist from prescribing MAT for opioid addiction. A pharmacist is not eligible to obtain a federal DATA 2000 waiver to prescribe buprenorphine. Pursuant to federal regulation, the only health care providers who can obtain this authority currently are physicians, nurse practitioners, and physician assistants. Expanding this authority to pharmacists would allow pharmacists to fully exercise their pharmaceutical education and experience in this area of health care services as a health care practitioner in California. Additionally, expanding this authority to pharmacists increases the number and availability of health care providers for Californians.

Ms. Veale provided during the October 2018 Board Meeting, the board directed staff to draft a policy statement supporting the role of pharmacists in providing MAT services as well as develop options for advocating changes in federal law to allow such services to occur.

Ms. Veale reported the committee discussed the draft policy statement and possible ways to advocate this policy. The discussion included encouraging the National Association of Boards of Pharmacy

(NABP) to adopt this policy as they are the national organization and should be advocating for pharmacists to be a part of the list of providers federally.

Ms. Veale provided the committee also discussed the need to work with a coalition of groups on this policy including: the American Pharmacist Association (APHA), the NABP, the California Healthcare Foundation, the California Pharmacists Association (CPHA), the California Society of Health-System Pharmacists, schools of pharmacy and other interested parties.

Ms. Veale reported the committee heard comment from the public in support of the policy and support for adopting this policy statement and to move forward with legislation at the state level which will ultimately prepare the board to initiate this change once it's approved at the federal level.

Committee Recommendation (Motion): Recommend to the board to adopt this policy statement; encourage the NABP establish this policy language as a model law for all states nationwide; and work with APHA, CPhA and other national organizations to implement this in federal law.

President Law strongly applauded the committee for their work in advocating for pharmacists.

Danny Martinez commented CPhA looks forward to working with the board as well as other national partners.

Dr. Gray, pharmacist, commented he supports the concept and development of the policy to raise to the national level. However, this is a huge patient care issue and shortage of practitioners. Dr. Gray stated he believed the board should sponsor legislation in advance of federal law change.

Board Vice President Greg Lippe asked how many pharmacists would be qualified to do this or would additional training be needed? Dr. Gray stated he believed pharmacists should be ready but would need specialized training to get the DEA approval.

The committee directed staff to work with legal counsel to determine if a change in statute is necessary at the state level. Ms. Freedman stated she did not believe anything would prohibit a pharmacist from doing MAT under the collaborative agreement.

Freddie Mayer, PPSI, commented methadone is easy to control.

Support: 10 Oppose: 0 Abstain: 0

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

Veale	X			
Weisser	X			
Wong	X			

Mr. Weisser inquired where the board was with national partners. Ms. Sodergren indicated before Ms. Herold retired, she reached out to many national partners to let them know this would be before the board. The board has initial national partners and will continue to work with other national partners. The board has also done some research and will be bring more information to the Licensing Committee on other options available before federal law is changed.

e. Review of Licensing Statistics

Ms. Veale reported since December 31, 2018, the board has received 8,992 initial licenses; issued 6,608 licenses; renewed 33,193 licenses; and maintains 140,820 active licensees. Ms. Veale stated the board is consistently working to process an application in 30 days and deficiency mail in 10 days. The board staff is working to triage and meet processing goals.

f. Future Committee Meeting Dates

Ms. Veale reported the next Licensing Committee Meeting dates as April 3, 2019; June 26, 2019; and October 2, 2019.

The board took a break at 3:15 pm and resumed at 3:20 pm.

VIII. Communication and Public Education Committee

The board reviewed a summary of the committee's efforts at the January 8, 2019, meeting, as well as updates, for discussion and action as necessary.

a. Discussion and Consideration of Proposed Language for a Policy Statement by the Board Regarding Warning Labels on Prescription Labels for Oral Chemotherapy Medications

Chairperson Ricardo Sanchez reported in 2017 and 2018, Chapman University pharmacy students and faculty appeared before the committee to discuss proper handling and disposal of oral chemotherapy medications. The group advocated a requirement for pharmacies to place a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs.

Mr. Sanchez noted in October 2018, the committee suggested the group focus on increasing stakeholder awareness rather than seeking a mandated requirement for labels. Members also directed staff to develop a possible board policy statement regarding proper handling and disposal of oral chemotherapy drugs.

Mr. Sanchez reported at the January 2019 meeting, staff presented language for a proposed policy statement regarding a hazardous drug symbol on prescription labels for oral chemotherapy medications.

Mr. Sanchez explained the committee requested a minor word change and clarification regarding an abbreviation for "oral chemotherapy." The committee directed staff to work with the chairperson on

the requested modifications. In addition, the committee voted to recommend the board adopt the statement as modified by the committee.

Committee Recommendation (Motion): Recommend that the board adopt the proposed policy with modifications in verbiage that are acceptable to the interim executive officer, the public information officer and the committee chairperson.

Danny Martinez of CPhA commented on CPhA's support of the policy statement.

Support: 10 Oppose: 0 Abstain: 0

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

b. Summary of Staff Report on the "Ask and Inspector" Program

Mr. Sanchez reported, at the October 2018 committee meeting, the committee requested staff report on the Ask an Inspector program. Specifically, members asked about the number of calls received and the top 10 types of calls. The committee also directed staff to report annually on the program, starting in January 2019.

Mr. Sanchez provided at the January 2019 meeting, staff reported inspectors responded to a total of 3,257 inquiries to Ask an Inspector between Jan. 1 and Dec. 20, 2018. Inquiries were classified into 77 types. The top 10 types of inquiries were provided in meeting materials. The most common topics were controlled substances and pharmacy practice.

Mr. Sanchez reported based on the information provided, staff recommended publishing frequently asked questions (FAQs) in The Script and the website to address the most common questions which could reduce calls to Ask a Pharmacy.

Mr. Sanchez noted staff also provided an overview of the program. Ask an Inspector is staffed by one inspector each week. The duty inspector is available to answer phone calls from 8 a.m. to 4:30 p.m. Tuesdays and Thursdays. In addition, inspectors respond to faxed and emailed questions all week long

and spend an additional two to three days the following week researching and responding to questions.

Mr. Sanchez reported the committee discussed possibly changing the hours inspectors are available to respond to phone calls to fewer hours but more days per week. The committee directed staff to report back on the possibility of extending the program based on available resources.

Ms. Sodergren added staff is looking to see if the program can be changed so someone will be available to answer phone calls daily at a reduced time period. Ms. Sodergren anticipates having a recommendation at the next committee meeting.

Board members commented on their support of daily calls. Ms. Sodergren added that the board will track statistics before and after the change in the program to see if areas of education can be identified. Ms. Veale noted that the Chiefs of Enforcement previously reported after a full day of phone calls, it takes a few days to respond to all of the day's inquiries.

c. Summary of Staff Report on Surveys Performed after Pharmacy Inspections

Mr. Sanchez reported at the October 2018 committee meeting, the committee directed staff to report on follow-up surveys of pharmacies performed after inspections. The committee also directed staff to report annually on the inspections, beginning in January 2019. At the January 2019 meeting, staff reported supervising inspectors surveyed 67 licensees after they were inspected in 2018. The surveys asked pharmacies to rate the inspectors in five areas. The responses were provided in the meeting materials.

Mr. Sanchez stated the surveys also solicited comments from pharmacies on the inspection process. Staff noted that more than 95 percent of survey responses were positive. Copies of the survey form and comments received from pharmacies were provided in the meeting materials. Staff said the surveys are a small sample of the total number of inspections performed annually. Staff explained the surveys are an informal means to get an idea of how inspectors were doing in the field. Moving forward, supervising inspectors plan to build on the program by increasing the number of surveys and collecting more data from pharmacies about the inspection process.

Mr. Sanchez noted staff also suggested creating a fact sheet or brochure about the inspection process that could be given to pharmacies at the time of inspection and posted online. The fact sheet would include information about the inspection process and what is expected of both the inspector and the licensee. It also would provide information on how licensees could contact the board with concerns or feedback about the inspection.

Mr. Sanchez explained the committee asked how negative comments on surveys are followed up. In addition, the committee asked about procedures to enable whistleblowers to voice a complaint without fear of retaliation.

Mr. Sanchez reported staff stated said supervising inspectors review the surveys and address negative comments with individual inspectors. In addition, DCA's website provides information on how to file a complaint about any DCA agency, which would be referred to DCA's Division of Investigations. A link to the DCA complaint process could be added to the board's website. In addition, the board could provide other ways besides inspection surveys to solicit feedback about inspections from pharmacies. This information could be provided in the fact sheet given to pharmacies at the time of inspection.

In response to committee questions, staff collected additional data for a comparison of surveys and inspections in 2018. The surveys were completed between January 1 and November 30, 2018. During that time, a total of 2,448 inspections were completed and 67 surveys were completed.

The board and public discussed the option of having an anonymous reporting mechanism. Board members expressed concern that the results did not match what they were hearing from licensees in the field. CPhA offered assistance. The board discussed a complaint cannot be completely anonymous or it could be heresy, retaliation to the inspector, etc.

d. Discussion and Consideration of Current and Potential Public Educational Materials and Activities in Preparation for 2020 Sunset Review Report

Mr. Sanchez reported the board's Sunset Review Report 2016 discusses key programs for communication and education of the public and licensees. At the January 2019 meeting, in anticipation of the upcoming sunset review in 2020, staff reviewed some of the communication and public education resources currently used by the board. In addition, staff requested feedback on possible additional activities and materials, including: revised/updated brochures– Notice to Consumers, point to your language, etc.; new brochures or videos – How to dispose of unwanted medications, how to prepare for a declared disaster, etc.; additional social media accounts – Facebook, Instagram, YouTube, etc.; additional CE webinars; a PowerPoint overview of the board for public outreach events; and staff presence with consumer brochures and other materials at community health fairs, senior events, other public gatherings.

Mr. Sanchez stated the committee suggested staff work on making the board's website more user friendly and making online materials easier to find. A copy of the Public Information Policies from the sunset report was provided in the meeting materials.

Mr. Weisser asked about the timeline for the Sunset Report. Ms. Sodergren explained she anticipated receiving an invitation to participate and providing the board with a draft report in November 2019.

e. Discussion and Consideration of Steps to Improve Emergency Response during Declared Emergencies

Mr. Sanchez provided on Nov. 8, 2018, Acting Governor Gavin Newsom declared a state of emergency in Butte, Los Angeles and Ventura counties due to wildfires. In Butte County, the Camp fire forced five pharmacies to close because they were destroyed or sustained significant damage. Six additional pharmacies closed temporarily because of poor air quality.

Mr. Sanchez reported on Nov. 9, 2018, the board issued a subscriber alert advising licensees about Business and Professions Code (BPC) sections 4062 and 4064. These provisions are intended to help pharmacists provide essential health care for patients who are displaced in an emergency.

Mr. Sanchez explained on Nov. 20, 2018, the board issued a second alert explaining the board waived pharmacy law requirements that may be impossible to meet in an emergency, including security prescription forms for controlled substances, under BPC section 4062(b). The alert also directed pharmacists to the board's official Disaster Response Policy Statement regarding emergency care for patients in declared disasters.

Additionally, Mr. Sanchez explained the board also issued subscriber alerts Nov. 21 and Dec. 3 about the EPAP, which helps uninsured patients in disaster areas obtain prescription medications at no cost. Board staff also collaborated with other state agencies during the disaster, including the CDPH and the Office of Emergency Services.

Mr. Sanchez continued at the Dec. 19, 2018, Licensing Committee meeting, CDPH staff presented information regarding the provision of pharmacy services during a declared disaster. The Licensing Committee recommended the information also be presented to the Communication and Public Education Committee to consider educational materials to develop and ways to improve the board's communications during a disaster.

Mr. Sanchez reported at the January 2019 meeting, Tom Ahrens of the CDPH Emergency Preparedness Office informed the committee about challenges in providing health care and pharmacy services for residents evacuated during the Camp Fire disaster. Key issues included: residents were forced to evacuate with little time to pack prescription medications; community shelters were not prepared to care for evacuees who were sick or needed prescription medications; evacuees staying in cars, tents, local fairgrounds and other locations did not have access to health care; medical disaster teams and volunteer health-care professionals did not have security prescription forms on hand at evacuation centers; pharmacies in outlying communities mistakenly believed that BPC sections 4062 and 4064 were "optional" or applied only in the disaster area. As a result, they declined to fill noncompliant prescriptions out of fear of being sanctioned by the board; and patients did not have money available or could not afford to cover copays for medications.

Additionally, Mr. Sanchez provided committee members and staff discussed possible solutions and steps the board could take to improve delivery of health care and pharmacy services during disasters, including: create free CE for pharmacists on what to do before and during a disaster; prepare fact sheets for consumers on how to prepare for a disaster; create a specific website section for disaster preparation materials for licensees and consumers; assign a supervising inspector to be available to answer questions from licensees during a disaster; provide complete information in subscriber alerts about BPC sections 4062 and 4064. Remind pharmacies outside the disaster area how to handle nonsecure prescription forms; utilize multiple channels to communicate emergency information – including email, website, newsletter, social media; invite CDPH, Office of Emergency Services and other agencies to add links on their websites to Board of Pharmacy information; and reach out to pharmacy chains and professional organizations to help disseminate information.

Mr. Sanchez advised the board was provided with the following information in the board meeting materials: text of BPC sections 4062 and 4064; copies of four subscriber alerts issued during the recent

declared disaster; an excerpt from the Committee minutes; and a copy of the board's Disaster Response Policy Statement.

Mr. Sanchez reported the committee directed staff to report back with recommendations on implementing improvements to the board's communications during declared disasters.

Board Member Schaad supported the idea of continuing education. Ms. Sodergren indicated it was feasible with assistance by experts.

Board Member Brooks asked if pharmacists may receive continuing education for serving in times of disaster. Ms. Freedman indicated she didn't think the law allowed for it. Ms. Sodergren offered to reach information to see what other states in case of emergencies and develop proposals for consideration.

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

1. The Script

Mr. Sanchez reported the current issue of the newsletter was published online in December 2018. Staff is working on the next issue, which will focus on new pharmacy laws.

2. Projects Update

Mr. Sanchez provided Outfront Media signed a no-cost contract on Jan. 8, 2019, for five billboards about prescription drug abuse. The contract calls for billboards in the Sacramento, Fresno and Los Angeles markets. Specific locations will be determined based on availability. Outfront has informed board staff that Outfront will print and ship the proofs to billboard sites in two to four weeks.

Additionally, the board established its first social media account in December on Twitter. Visitors can view the board's Twitter feed at https://twitter.com/CAPharmBoard.

3. News Media

Mr. Sanchez stated the board's executive officer and public information officer participated in interviews or provided background information in response to media inquiries listed in the board meeting materials.

4. Public Outreach

Mr. Sanchez provided board inspectors and staff provided training at the board's Dec. 8, 2018, CE forum on prescription drug abuse and drug diversion at Santa Barbara Community College in Santa Barbara. A total of 94 pharmacists attended and received CE at the event. The board has tentatively scheduled the next forum for February 23, 2019, in Fresno and is working to schedule another in San Diego in April.

g. Summary of Discussion of News or Journal Articles

Mr. Sanchez provided news articles on pharmacy issues that may be of interest to the board are included in the meeting materials.

h. Future Committee Meeting Dates

Mr. Sanchez noted the following committee dates: Wednesday, April 10, 2019; Tuesday, June 25, 2019; and Wednesday, Oct. 9, 2019.

IX. Organizational Development Committee

a. Budget Update/Report

President Law advised the board on June 28, 2018, the Governor signed the budget for FY 2018/19. The new budget year began July 1, 2018. The board's spending authorization for the year is $26,007,000, which is an 11.3% increase from the prior year. This increase was detailed in the board meeting materials. Significant increases include $1.1 million for one-time costs for relation; $685,000 to fund two inspectors and two AGPA positions to perform sterile compounding and enforcement activities; $423,000 to fund three positions to implement AB 401, SB 351, and SB 443 of statutes of 2017; $816,000 to fund employer retirement contributions and employee compensation as well as increases to fund equipment purchases, pro rata, employer retirement contributions, board and bureaus workload BCP, and other post-employment benefits.

President Law reported there continues to be a delay in receiving budget information from the department due to the newly implemented FI$CAL accounting system. Board staff have been advised that until the FI$CAL system is able to close out the prior fiscal year (FY17/18), no interim budget figures can be produced by the system. We are hopeful that when the prior year closes out we will be able to resume providing the board with current year expenditures. Based on the limited reporting available, the board believes it has received $11,405,300 in revenue originating from Licensing, Citation Fines and Cost Recovery. A summary of the fund condition was provided in the meeting materials assuming new fees will be in place by January 1, 2020. Detailed budget charts for board revenue as well as fund condition were also provided in meeting materials.

b. Board Member Reimbursement and Attendance Information

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

Mr. Weisser expressed concern of attendance of board members and the impact it has on the board. Mr. Weisser asked what the board could do about the lack of attendance for board members. President Law indicated he spoke with two board members about their attendance. Board members discussed having committee meetings condensed and changing the time of the meeting to increase attendance.

Vice President Greg Lippe advised the board that he and President Law have been reviewing and discussing cite and fines with the executive officer and supervising inspectors with the idea of adherence of education versus punishment. Counsel Freedman confirmed with President Law the cite and fines reviewed are not pending. President Law confirmed they were all closed.

Mr. Weisser stated that it is important that the board meetings are held throughout the state but also asked that the board track attendance as there is substantial cost related to having the meetings throughout the state. The board members discussed the merits of having the meetings in Sacramento versus evenly spread throughout the state. President Law indicated that part of the goal of meetings throughout the state was to increase accessibility for licensees. Danny Martinez of CPhA commented that he encourages board attendance.

c. Discussion and Consideration of Change to Board's Current Policy Related to Recognition of Pharmacists with 50 years of Licensure

President Law requested that this item be placed on the agenda so that the board could discuss the current policy of acknowledging pharmacists who have been licensed in California for 50 years. President Law is proposing that the board change its policy to acknowledge pharmacists who have been licensed in California for 40 years.

Motion: Recognize pharmacists after 40 years after instead 50 years.

M/S: Lippe/Butler

Support: 9 Oppose: 1 Abstain: 0

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

X. Interim Executive Officer's Report

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

Interim Executive Officer Anne Sodergren provided to the board an update on the online renewal payment for pharmacy technicians. Ms. Sodergren advised the board pharmacists and advanced practice pharmacists will be added next. Information about the process was provided in the meeting materials. They system being used has some limitations as it is not an intuitive system but rather a system to collect payment.

b. Personnel Update

Ms. Sodergren reported there are 14 vacant positions at the board currently. Many positions are being left vacant to achieve salary savings.

c. Update on the Relocation of Board Office

Ms. Sodergren informed the board there have been significant delays outside of the board's control. The move may be delayed until in fiscal year 2019/20.

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

Ms. Sodergren advised the board that the CURES usage for the past calendar year are provided in the meeting materials. There were 42 million prescriptions for controlled substances last year.

President Law asked if CURES could change the password from 90 days to 6 months. Ms. Sodergren she will forward DOJ the question but indicated it may be because the information contained in CURES is protected. If locked out three times, the pharmacist has to call DOJ to be reset.

e. Update on Legal Status of Products Containing Cannabidiol (CBD)

Supervising Deputing Attorney General presented the letter he wrote about products containing cannabidiol (CBD). Mr. Room informed the board that the legal terrain regarding marijuana/cannabis/hemp/CBD is very complex. Mr. Room provided an overview of the letter. The Board reported it is not an enforcement priority.

President Law inquired about selling CDB oil. Mr. Room indicated this is a policy decision. Mr. Room indicated he was not comfortable going into hypotheticals but confirmed the CBD oil cannot be added to food items or have health claims about it.

Fred Mayer of PPSI provided an article he wrote about 6 people in Marin County who died because of interactions with CBD. Mr. Meyer requested the board read the article and do more education.

Danny Martinez of CPhA asked Mr. Room if pharmacist can sell CDB oil outside of the pharmacy counter but within the pharmacy. Mr. Room provided there is no legal question to this. Mr. Martinez further inquired given the nonenforcement priority of the board, if FDA or CDPH took action would the board be compelled to also take action. Mr. Room indicated the board is never compelled to take action as there is discretion.

The board adjourned at 4:44 pm.

January 31, 2019

President Victor Law called the meeting to order at 9:00 a.m. Roll call was taken, and a quorum was established. Board members present: Allen Schaad, Deborah Veale, Lavanza Butler, Gregory Lippe, Victor Law, Stanley Weisser, and Ricardo Sanchez

XI. Legislation and Regulation Committee

Chairperson Greg Lippe reported the Legislation and Regulation Committee convened a meeting immediately prior to the board meeting on January 30, 2019. The board received a summary of the committee's efforts, as well as updates, for discussion and action as necessary.

Mr. Lippe provided to the board the first item on the agenda provided for items to be added to future agendas. The committee heard from a UFCW representative who discussed SB 1442 and informed the committee UFCW felt the language was too broad. The representative informed the committee UFCW will be filing a petition before the next board meeting requesting the board to promulgate regulation. This issue was also raised at during the Enforcement Committee report the first day of the board meeting. A conclusion was not made but determined to be watched.

Board member Ryan Brooks arrived at 9:15 am.

Board Member Albert Wong arrived at 9:30 am.

Part 1: Legislation for Discussion and Consideration

a. Board Proposed Legislation

1. Amend Health and Safety Code (HSC) Section 11165

Chairperson Lippe advised the board the measure is intended to expand CURES reporting to include Schedule V controlled substances and reduce the time frame for reporting to the CURES system to one working day. Similar changes were sought last year in AB 1752 (Low). That measure failed passage. This measure was approved for sponsorship at the November 2017 Board Meeting.

Steve Gray a pharmacist commented this might be a good opportunity to reconcile the discrepancies between the federal and state controlled substance lists.

Ms. Sodergren advised the board the bill was controversial and limited in scope. Ms. Sodergren recommended to the board to move forward as the proposed language is written and if amendments are needed to include the changes as part of the Sunset Review process.

Robert Stein for CSHP and CPhA advised the bill they are sponsoring and discussed previously to add Schedule V to HSC 11165 does not include the change in reporting time.

2. Amend Business and Professions Code (BPC) 4200

Mr. Lippe advised this measure relates to the time period that a test score will remain valid for consideration for licensure. Enactment of this legislation would establish that a passing score on the NAPLEX or CPJE Pharmacist examinations would be valid for licensure only while the occupational analysis that was used to develop that examination is valid or was replaced no more than one year prior. This measure was approved for sponsorship at the May 2018 Board Meeting.

3. Add BPC Sections 4038.5, 4115.6, 4211

Mr. Lippe explained that this measure would create a new licensing category—Advanced Pharmacy Technician (APT). This proposal would establish the licensing requirements, detail the proposed duties and requirements, and define the conditions a pharmacy must satisfy if using APT personnel. This measure was approved for sponsorship at the November 2017 Board Meeting.

Dr. Gray commented this proposal does not include any continuing education requirements.

Ms. Veale asked this language to be referred back to the Licensing Committee to reevaluate if one or two advanced practice technician licenses are required.

Ms. Sodergren stated that the board does not currently have an author for the legislative proposal. She explained that the board has three options: 1) delay and revisit policy at the Licensing Committee; 2) move forward and negotiate with the author's office; or 3) consider as a provision in the Sunset Review process.

Ms. Veale made a motion to refer the APT and AHT language back to the Licensing Committee so that they can make a recommendation at the May 2019 Board Meeting. Mr. Lippe seconded the motion.

Ms. Sodergren indicated that May would be too late to put significant policy into legislation as there will be numerous stakeholders who will want to provide input.

Danny Martinez indicated that CPhA has concerns about the APT and the AHT license types. He stated that at some point, ratios need to be addressed and the discussion should occur at the Licensing Committee rather than the legislature.

Dr. Gray supported sending the language back to the Licensing Committee and stated that he is against the creation of an advanced pharmacy technician license type. Dr. Gray also expressed concern for a test being required.

Fred Mayer of California Alliance for Retired Americans and PPSI recommended reviewing the

Idaho model with two types of certifications for technicians – one that counts, pours, types and one that can help with immunizations. Fred Mayer requested an article about Albertsons be added into the official records and minutes. Board staff offered to disseminate the articles to the board members following the meeting.

The board asked Ms. Sodergren if the Licensing Committee could consider amendments to the language while an author is being sought. Ms. Sodergren recommended pursuing legislation while the Licensing Committee refines the language.

President Law called for a vote on Ms. Veale's motion.

Motion: Refer the APT and AHT licensing back to the April 2019 Licensing Committee with a recommendation at the May 2019 Board Meeting.

M/S: Veale/Lippe

Support: 2 Oppose: 6 Abstain: 2

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

Following the failed vote Mr. Weisser made the following motion:

Motion: Direct board staff to pursue statutory changes while simultaneously working with the Licensing Committee chair to further refine the language.

M/S: Law/Weisser

Support: 10 Oppose: 0 Abstain: 0

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

Munoz				X
Sanchez	X			
Schaad	X			
Serpa	X			
Veale	X			
Weisser	X			
Wong	X			

4. Add BPC Sections 4038.6, 4115.7, 4211.1 and 4234.5 and Amend BPC Section 4400

   Mr. Lippe advised the issue of this measure to create a new licensing category—Advanced Hospital Pharmacy Technician (AHT) – was addressed with the previous motion. This proposal would establish the licensing requirements, detail the proposed duties and requirements, and define the conditions a hospital must satisfy if using AHT personnel. This proposal was approved for sponsorship during the February 2018 Board Meeting.

5. Amend BPC Section 4163

   Mr. Lippe advised this measure would allow a reverse distributor to accept medications for destruction under limited circumstances. This proposal was approved for sponsorship during the July 2018 Board Meeting.

6. Amend BPC Section 4400

   Mr. Lippe advised this measure would allow the board to assess an application fee from government owned facilities. Further, this measure would clarify the fees for updating a licensing record and the fee to reissue a printed license certificate. The proposal related to government-owned facilities was approved during the November 2017 Board Meeting. The proposal related to updating a license record was approved for sponsorship during the October 2018 Board Meeting.

7. Add BPC Section 4112.5

   Mr. Lipped reported this measure would align establish USP compounding chapters as the foundation for the board's regulation of sterile and non-sterile compounded drug preparations. This measure was approved for sponsorship during the May 2018 Board Meeting.

   Dr. Gray clarified the latest edition of USP was referenced in the meeting materials and advised the board that this may change significantly over time and must be considered as USP in its entirety.

   Ms. Sodergren clarified the proposal the board voted on is very specific to the compounding of drug preparations and separate from USP 800. It is the board's understandings UPS standards

must be complied with regardless if it's in the board's statutes because if it is not compliant with USP, it is considered adulterated and misbranded.

Marie Cottman requested the board delay this legislative proposal due to the financial hardship for those entities adhering to the changes in law at the Legislation and Regulation Committee Meeting on January 30, 2019.

CPhA supported the statutory change in a phased in approach.

These will be considered by the Compounding Committee.

8. Amend BPC Section 4115.5

Mr. Lippe noted this measure would increase the maximum number of hours a pharmacy technician trainee can gain and remove a conflict for completing an ASHP-accredited pharmacy technician training program. This type of training program is currently one pathway to licensure. This proposal was approved for sponsorship during the October 2018 Board Meeting.

9. Add BPC Section 4233.5

Mr. Lippe noted this measure would align the advanced practice pharmacist renewal requirements with the renewal requirements for pharmacists. This proposal was approved for sponsorship during the October 2018 Board Meeting.

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

Mr. Lippe advised the board the legislature reconvened on January 7, 2019. Since that time board staff have been monitoring new legislative proposals to be brought to both the committee and board for consideration. Such proposals generally impact either the board's jurisdiction or board operations. The deadline to introduce bills this year is February 22, 2019. As it is still early in the session, board staff have only identified one measure. A summary of the measure and the full text was provided in the meeting materials. Board staff recommend that the committee monitor the measure but not take a position at this time.

1. Assembly Bill 193 (Patterson) Professions and Vocations

Mr. Lippe noted this measure would require DCA to conduct a comprehensive review of all occupational licensing requirements and identify unnecessary licensing requirements that cannot be adequately justified. DCA would also be required to report to the legislature on its findings. The bill contains additional provisions that either do not apply or impact the board, (e.g. remove tree trimmers from regulation by the Contractors State Licensing Board; remove

shampooing another person's hair from regulation by the Board of Barbering and Cosmetology; remove custom upholsters from regulation by the Bureau
of Household Goods and Services.)

Part 2: Regulations for Discussion and Consideration

c. Board Adopted – Submitted for Administrative Review to the Office of Administrative Law (OAL)

1. Proposed Regulations to Amend Title 16, California Code of Regulations (CCR), Sections 1735.1, 1735.2, 1735.6, 1751.1, & 1751.4 Related to Compounded Drug Preparations

   Mr. Lippe advised this regulation formally amends the board's regulations regarding the establishment of compounding beyond-use dates as it relates to sterile and non-sterile compounded drug preparations. The regulation was submitted to OAL for Final Review on December 14, 2018. OAL must complete its review by January 30, 2019. A copy of the complete timeline for this rulemaking and the board adopted text was included in the meeting materials.

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

Mr. Lippe provided the board with a summary of each of the regulations currently undergoing pre-notice review. The full text and timelines for each of the regulations were included in meeting materials.

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

   This proposal establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians. This regulation was resubmitted to DCA for Pre-Notice Review: October 26, 2018. This regulation is currently undergoing review by DCA counsel.

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

   This proposal amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies. The regulation was resubmitted to DCA for Pre-Notice Review: December 20, 2018. This regulation is currently undergoing review by DCA counsel.

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

   This proposal establishes the regulatory framework for third-party logistics providers. The regulation was resubmitted to DCA for Pre-Notice Review: December 20, 2018. This regulation is currently undergoing review by DCA counsel.

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

   This proposal amends the board's regulations regarding the waiver requirements for offsite storage of records to allow those cited for a records violation to receive a waiver to store records off-site. The regulation began formal DCA Pre-Notice Review: August 20, 2018. This regulation is currently undergoing review by the DCA Legal office.

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

   This proposal establishes regulatory requirements for automatic refill programs.
   This regulation was resubmitted to DCA for Pre-Notice Review: September 20, 2018. This regulation is currently undergoing review by the DCA Legal office.

6. Proposed Regulations to Amend Title 16 CCR Section 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 regulation began the formal DCA Pre-Notice Review: July 2, 2018. This regulation is currently undergoing review by the DCA Legal office.

   The board and members of the public commented on the delays for the naloxone regulation during an opioid crisis.

   The board directed staff to reassess the naloxone protocol and see if there is a better mechanism to help pharmacists provide naloxone at the next Legislation and Regulation Committee.

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

   This proposal updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms. The regulation was resubmitted to DCA for Pre-Notice Review: December 24, 2018. This regulation is currently undergoing review by DCA counsel.

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

   This proposal updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form. The regulation was submitted to DCA for Pre-Notice Review: December 26, 2018. This regulation is currently undergoing review by DCA counsel.

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

   This proposal establishes regulatory requirements for pharmacy technicians working in a remote dispensing site pharmacy. The regulation began the formal DCA Pre-Notice Review: August 29, 2018. This regulation is currently undergoing review by the Business, Consumer Services and Housing Agency.

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

    This proposal updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application. It will also reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established. This regulation began formal DCA Pre-Notice Review: August 3, 2018. This regulation is currently undergoing review by the DCA Legal office.

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

    This proposal updates the renewal requirement language to include all licensing programs. It will also reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established. This regulation began the formal DCA Pre-Notice Review: October 16, 2018. This regulation is currently undergoing review by the DCA Budget office.

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

This proposal amends the board's regulations regarding the duty to provide consultation for mail-order pharmacies. This regulation began formal DCA Pre-Notice Review began: October 1, 2018. This regulation is currently undergoing review by the DCA Budget office.

13. Proposed Regulations 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 began formal DCA Pre-Notice Review began: January 16, 2019. This regulation is currently undergoing review by the DCA Legal office.

e. Future Meeting Dates

Mr. Lippe provided the board with the next Legislation and Regulation Committee meetings as May 7, 2019; July 24, 2019; and November 5, 2019.

Ryan Brooks, Maria Serpa and Albert Wong arrived at the meeting during the course of the committee report and were introduced.

XII. Executive Officer Recruitment – Update on Recruitment Efforts

President Law advised the board the subcommittee consisting of himself and Board Member Allen Schaad have been interviewing for the position of board executive officer. Interviews with the board will be at the March board meeting in closed session. President Law will update the board in closed session.

XIII. Update from the Department of Consumer Affairs

President Law introduced Assistant Deputy Director for Boards and Bureau Services Patrick Le of the Department of Consumer Affairs (DCA) to the board.

Mr. Le provided an overview of 2018 to the board. Nine workgroups were convened across DCA boards and bureaus to share best practices in licensing and enforcement. Three substance abuse coordinate committee meetings were hosted to redefine some of the ways that boards are able to do drug testing for licensee in diversion programs for substance abuse. Four quarterly director's meetings were held for the executive officers to connect directly with the DCA director and executive leadership team. Additionally, two board leadership teleconference calls were hosted for board presidents and vice presidents to connect directly DCA director Dean Grafilo and executive leadership team. All meetings allowed for open dialog and collaborative mission to protect California consumers. DCA is continuously looking for ways to improve and appreciates feedback.

Mr. Le advised the board the DCA Annual Report is available online. The Annual Report provides a comprehensive review and account of achievements for the 38 boards and bureaus within DCA.

Mr. Le updated the board on the transition to a new Governor on January 7, 2019, when Governor

Gavin Newsom was sworn into office. DCA will work with the Governor's Office to further his mission. DCA has been in contact with the transition team. For current gubernatorial appointees there is no action or message at this time other than continuing the great work and service that has been done. DCA will work closely with the transition team on pending vacancies and re-appointments.

Mr. Le reported the Governor's 2019/2020 budget was released on January 10, 2019, based on the driving idea of "California for all" to pay down debts and pension obligations. It continues to build a robust reserve for the state while continuing to invest in housing, child care, health care, preschool and higher education. It also proposes significant changes in the way that the state would purchase prescription drugs. DCA executive team held a telephone conference with board/bureau executive officers the day the budget was released to discuss the budget and pending issues impacting DCA. The DCA budget and fiscal team will follow up with individual boards/bureaus to discuss individual budgets in detail.

Mr. Le provided an update on AB 2138 that limits the board's ability to deny a license based on past criminal convictions. DCA is working with boards and bureaus to help with implementation based on the July 2020 deadline. In order to stay on track, action will be required by all programs by May 2019. DCA will continue to work with the board to help develop model regulations that can be used by the board as a template. Where feasible, DCA will take the lead on collecting data for the reporting requirements and will complete one report to the legislature.

Mr. Le advised the board that the DCA's substance abuse coordinate committee convened the healing arts executive officers to examine the drug testing standards for substance abusing licensees. The committee held three meetings in 2018. Mr. Le advised the board on the two changes made to the Uniform Standard IV that guides all of the protocols for drug testing. The first change adds language to healing arts boards to approve alternative testing locations and testing frequencies for a licensee going on vacation or taking a leave of absence. The change was added to ensure they can still perform drug testing on licensees traveling abroad while considering the varying type of testing available throughout the world. The second change is a policy to allow healing arts boards to lower the drug testing standard from the current standard of 54-104 times a year to not less than 24 times per a year but only if the licensee receives a minimum of 50 percent supervision in the workplace. The change was added to reduce the testing costs for licensees who are already supervised at their place of employment.

Ms. Sodergren clarified the Board of Pharmacy put the request forward as the board's pharmacy technician licensees are supervised in the workplace. Additionally, pharmacists in recovery programs are not allowed work independently. Being supervised daily at work further aids in assessing abstinence during recovery.

Mr. Le reported the committee identified several other standards that may need review. There will be additional committee meetings throughout 2019.

Mr. Le provided an update to the executive officer salary study. DCA retained KH Consulting to conduct the executive officer salary study and is expected to take about six months with an estimated completion of March 2019. The consultants have conducted an initial review of executive officers to identify themes and challenges.

Mr. Books inquired what criteria is being used. Mr. Lee provided items factored include executive officer responsibilities and tasks responsible for performing. The study will also be comparing duties

identified in the 2011 study and identify how the job has changed over time and become more complex based on changes, policy and legislation. Mr. Le added other states will be used as a comparison.

Mr. Books added the compensation for the executive officer is significantly underpaid when compared to the job that is being done. Dr. Wong added the executive officer salary should be more than the deputy salary. Mr. Le indicated the study will assist in getting approval through the various control agencies.

Mr. Le reminded the board that board member orientation training is required to be completed within one year of appointment and re-appointment to a board. Mr. Lee reminded the board to file their annual economic statement of interest known as the Form 700 by April 12, 2019, as required by the Fair Political Practices Commission. Mr. Le provided 2019 is a required and mandatory year for taking the sexual harassment prevention training for the DCA. All DCA staff and board members are required to take this training to promote a safe working environment for all.

Mr. Weisser inquired on the status to update the board's computer system. Mr. Le will forward the question to the DCA's Office of Information Systems.

Mr. Schaad asked about the change in background checks for licenses with the board and will be due in 2020. Ms. Sodergren added the staff was directed to work with counsel at the last Enforcement Committee meeting to conduct a gap analysis to see where changes need to be and whether or not there is an opportunity to do some statutory changes. At the March 2019 Enforcement Committee meeting, there will be an opportunity to discuss this issue.

Dr. Wong requested an update on the delay in relocation. Mr. Le indicated many factors within and outside our control. Mr. Le can provide an update from our Business Services Office.

President Law asked about the regulation review that is taking over six months. President Law asked who is monitoring on the board's behalf. Mr. Le provided it is an extensive process with many layers of review. If there are regulatory packages that need to be expedited and flagged for the legal team, please let Mr. Le know. President Law noted the naloxone regulation has taken since July 2018 to update a fact sheet for naloxone.

Fred Mayer of California Alliance of Retired Americans and PPSI asked about the prudent purchase of drugs. Ms. Freedman added it would have to be added to future agendas.

Steve Gray commented that the scope of the executive officer for California is substantially higher than other boards of pharmacy including cease and desist orders and may need to be a licensed pharmacist. Mr. Brooks indicated he didn't believe a licensed pharmacist was needed for policy and managerial direction needed for the position. As a licensed pharmacist, Mr. Weisser agreed with Mr. Brooks that the executive officer does not need to be a licenses pharmacist.

Mr. Mayer stated that he had news articles he wanted to provide to the board. Board staff distributed the articles to the board members following the meeting.

Dr. Wong would like to add to the next agenda a new possible pathway to become an advanced practice pharmacist.

XIV. Closed Session Matters

The board recessed to closed session at 10:38 am.

XV. Reconvene Open Session

The board recessed to closed session at 12:13 pm.

The board adjourned at 12:13 pm.