California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

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

DATE: April 27-28, 2016

LOCATION: Embassy Suites Anaheim Orange
400 N. State College Blvd.
Orange, CA 92868

BOARD MEMBERS PRESENT:
Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Greg Lippe, Public Member
Stanley Weisser, RPh
Allen Schaad, RPh
Lavanza Butler, RPh
Ramon Castellblanch, Public Member

BOARD MEMBERS NOT PRESENT:
Ricardo Sanchez, Public Member
Ryan Brooks, Public Member
Albert Wong, PharmD
Gregory Murphy, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Janice Dang, Supervising Inspector
Desiree Kellogg, Deputy Attorney General
Carolyn Klein, Staff Manager II
Lori Martinez, Staff Manager
Debbie Damoth, Staff Manager
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting may be found at:
http://www.pharmacy.ca.gov/about/meetings.shtml

Wednesday, April 27, 2016

Call to Order 9:08 a.m.

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

President Gutierrez called the meeting to order at 9:08 a.m.

President Gutierrez conducted a roll call. Board members present: Gregory Lippe, Deborah Veale, Amy Gutierrez, Stanley Weisser, Allen Schaad, Ramon Castellblanch, Victor Law and Lavanza Butler.

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

A member of the public asked the board to consider changing the law from mandatory consultation to "offer to consult." He also stated that the board needs to implement an online renewal system.

III. Approval of the February 24-25, 2016, and March 28, 2016, Board Meeting Minutes

Note: The February minutes will be approved at the June 7-8, 2016 board meeting.

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

Motion: Approve the March 28, 2016 board meeting minutes.

M/S: Weisser/Lippe

Support: 7 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch			x	
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

IV. Recognition and Celebration of Pharmacists Licensed In California for 50 Years

The board recognized James Pontello, Norman Willis and Richard Fond for 50 years of service as pharmacists.

V. Board Officer Elections

Motion: Nominate Amy Gutierrez for Board President.

M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

The board thanked Dr. Gutierrez for her leadership.

Motion: Nominate Deborah Veale for Board Vice President.

M/S: Butler/Lippe

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

Motion: Nominate Victor Law for Board Treasurer.

M/S: Butler/Weisser

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			

Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

President Gutierrez thanked Ms. Veale and Mr. Law for their work as board officers.

VI. Organizational Development Committee

a. Budget Update/Report

1. Budget Report

President Gutierrez reported that the new budget year began July 1, 2015. The board's spending authorization for the year is $19,770,000 which is a 3 percent increase from the prior year. She added that as of March 31, 2016, the board has expended $15,119,992 and taken in $15,742,900 in revenue.

President Gutierrez explained that as it has for the past few years, budget projections for the remainder of the fiscal year indicate that the board will again need to seek a midyear augmentation to its budget to secure the necessary funding to cover the enforcement related costs incurred by services provided by the Attorney General's Office as well as the Office of Administrative Hearings. She stated that this augment is necessary to ensure continuing services from both offices through the fiscal year. As enforcement activities are the core of the board's consumer protection mandate, it is essential that this be pursued.

Ms. Herold noted that the board will be securing a fee increase that will take effect in July 2017, as part of SB 1039.

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

2. Fund Condition Report

President Gutierrez reviewed the board's fund condition as provided in the meeting materials. She reported that the board will need to pursue a fee increase to sustain operations. President Gutierrez explained that as a precursor to making such a determination, a fee analysis was conducted and the results of that analysis were used to determine the new fees.

The board asked if there are any consequences if the board over expends its fund. Ms. Herold responded that as the executive officer she is held personally responsible

for the board's finances. She also explained that the board could secure a short term loan in order to maintain operations.

Dr. Castellblanch asked if the board still planned on conducting inspections of all California pharmacies every four years and if additional funding would be needed to achieve this. Ms. Herold responded that the goal will be to use existing staff to conduct the routine inspections. She added that once the board secures the fee increase they can submit a budget change proposal to obtain additional funding if needed.

Stan Goldenberg, pharmacist, asked the board to consider not increasing the fees for licensees that do not make as much money. Ms. Veale responded that the board conducted a fee analysis to determine the actual cost to deliver services to each license type. Ms. Veale stated that the board takes fee increases very seriously and carefully considered its options before making the decision to raise fees.

3. Governor's Proposed Budget for 2017/18

President Gutierrez reported that on January 7, 2016, the governor released his proposed budget for FY 2016/17. Included in this proposal was funding to make several limited term positions permanent (listed below).

Cures – Combating RX Drug Abuse	AGPA (1.0); Research Program Specialist (1.0); Inspector (5.0); Sup. Inspector (1.0)
SB 294 – Sterile Compounding	AGPA (1.0); SSA (0.5); Inspector (4.0)
Total Positions	**12.5 positions**

President Gutierrez reported that Ms. Herold has been providing testimony on the need for permanent funding for these positions when the board's budget and funding requests are discussed during legislative hearings.

Dr. Castellblanch asked how many pharmacists are enrolled in CURES. Ms. Herold responded that approximately 66 percent of pharmacists are enrolled in CURES.

Mr. Law stated that the new CURES system is much easier to access than the old system.

The board asked if the new system still requires pharmacists to log-in every six weeks to keep their account active. Ms. Herold responded that she would clarify this with the DOJ.

Ms. Herold noted that the board would be mailing postcards to licensees to remind them that they must register for CURES by July 1, 2016.

b. National Association of Boards of Pharmacy 2016 Annual Meeting in San Diego

President Gutierrez reported that the National Association of Boards of Pharmacy is holding its annual meeting in San Diego May 14 -17.

President Gutierrez announced that Mr. Weisser was awarded the Lester E. Hosto award for his work as Board President. The board congratulated Mr. Weisser for being awarded the prestigious award.

c. Board Member Reimbursement Information

President Gutierrez reviewed the board member reimbursement information as provided in the board meeting materials.

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

d. Personnel Update

Ms. Herold provided an overview of the board's recent vacancies and hires.

President Gutierrez thanked board staff for working to decrease application processing times.

At the request of the board Ms. Herold briefly reviewed the duties of the board's public information officer and the prescription drug abuse team.

Ms. Butler thanked board staff for implementing the *Ask Inspector* program and asked if the program would be increased to have an inspector available via phone three days a week. Ms. Herold responded that currently inspectors and the enforcement unit are focusing on decreasing enforcement times.

e. Future Board Meeting Dates

President Gutierrez announced the following future board meeting dates.

1. <u>Remaining Dates Established for 2016</u>
   - June 7 & 8, 2016
   - July 27 & 28, 2016
   - October 26 & 27, 2016

2. <u>Proposed Dates for 2017</u>
   - January 24 & 25, 2017
   - May 3 & 4, 2017
   - July 25 & 26, 2017
   - November 7 & 8, 2017

Dr. Steve Gray, pharmacist, stated that a few of the proposed dates may conflict with pharmacy association dates. He also suggested that the board consider adding an additional board meeting between January and May to handle legislative items. Dr. Castellblanch agreed with the proposal to add an additional board meeting and asked board staff to review the proposed dated for any potential conflicts.

f. Discussion and Consideration of Sunset Review Process and Actions

1. Board Written Responses Provided in Response to Sunset Issues Identified by the Joint Committee

President Gutierrez stated that as part of the Sunset Review process, the Joint Oversight Committee (comprised of members of the Senate Business, Professions, and Economic Develop and members of the Assembly Business and Professions Committee) identified issues that it would like the board to respond. These issues are identified in a committee background paper. Note: board members were provided with a copy of the committee background paper on March 15, 2016.

President Gutierrez explained that board staff worked with the board president and vice president to provide written responses to each of the issues. A copy of the final response was provided in the board meeting materials.

Dr. Steve Gray, as an individual, stated that the board should change the statute to add a board member who has experience working as an advanced practice pharmacist. Dr. Castellblanch agreed with Dr. Gray's suggestion.

2. Legislative Proposals Resulting from Sunset Review

President Gutierrez explained that as part of the Sunset Review process, the board has the opportunity to identify legislative proposals. She noted that staff worked on each proposal with the Organizational Development Committee.

- **Technical Changes to Statutes**

Ms. Sodergren reviewed the proposed technical changes. She noted that many of the changes were conforming changes intended to make the code sections consistent.

Note: a detailed list of the technical changes was provided in the board meeting materials.

Motion: Approve the technical changes.

M/S: Lippe/Weisser

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

- **Proposal to Add Section 4105.5 to the Business and Professions Code Relating to the Registration of Automated Delivery System**

  President Gutierrez reported that during the February 2016 board meeting, the board considered a draft proposal to establish a registration requirement for pharmacies that use automated delivery systems. Subsequent to that meeting, staff worked with the board president and vice-president to refine the language (provided below).

  Ms. Sodergren explained that currently the board knows that automated drug delivery systems are being used, however the board does not know the locations of the systems or the actual number in use. She noted that the proposed language is designed to require the registration of automated drug delivery systems and to provide guidelines to entities who utilize them.

  Proposal to Add Section 4105.5

  (a) For purposes of this section, an automated drug delivery system includes a device as defined in Health and Safety Code Section 1261.6(a)(1).

  (b) Every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall provide the board in writing with the location of each device within 30 days of installation of such a device, and on an annual basis as part of the license renewal. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

  (c) Every pharmacy that uses such a system may only do so if all of the following conditions are satisfied.

  1. *Use of the device is consistent with legal requirements.*
  2. *Policies and procedures include appropriate security measures and monitoring of the inventory to prevent thefts and diversion. <u>The inventory shall be done at least quarterly.</u>*
  3. *Drug losses from the device are reported to the board as required by law.*
  4. *The pharmacy license is in good standing with the board.*
  5. *<u>The device is located within a seventy-five mile radius of the pharmacy</u>.*

(d) The board may prohibit a pharmacy from using a system if it determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal such a decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) A device used in a licensed hospital for doses administered in the hospital is exempt from subdivision (b).

The board discussed the proposed language and expressed concern with the level of security that the board should require for the locations of the machines, especially if the machine will be located 75 miles from the pharmacy.

Supervising Inspector Janice Dang explained how the automated drug delivery systems are used in skilled nursing facilities and noted that in rural areas the machines may actually be located farther than 75 miles from the pharmacy.

Stan Goldenberg, pharmacist, spoke in support of the use of automated drug delivery systems and noted that the board may be surprised how many are currently being used.

The board determined that requiring the registration of the automated drug delivery systems would provide the board with important information regarding the use of the machines; however, they elected to send the proposed language back to the Enforcement Committee so that sections C and D (which detail the specific requirements for the use of the machines) could be further vetted.

Motion: Approve sections A, B and E. Send the proposed language to the Enforcement Committee for further discussion.

M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

The board recessed for a break at 11:20 a.m. and resumed at 11:37 a.m.

- **Proposal to Add Section 4083 to the Business and Professions Code Relating to Recall Notices for Compounded Drug Products**

  President Gutierrez reported that recently board staff was alerted to a pharmacy that was performing general compounding in an unsafe fashion. In this case, two MedWatch reports were submitted and ultimately the FDA required the pharmacy to recalls the compounded product.

  President Gutierrez explained that when staff evaluated the scenario, it was determined that the board should receive notification of MedWatch reports as well as recall notices for compounded drug products. Provided below is the draft proposal that could be used to facilitate such notification requirements.

  Add Section 4083.1
  (a) A pharmacy that issues a recall notice regarding a nonsterile compounded drug product shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply:
  (1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
  (2) The recalled drug was dispensed, or is intended for use, in this state.
  (b) A recall notice issued pursuant to subdivision (a) shall be made as follows:
  (1) If the recalled drug was dispensed directly to the patient, the notice shall be made to the patient.
  (2) If the recalled drug was dispensed directly to the prescriber, the notice shall be made to the prescriber, who shall ensure the patient is notified.
  (3) If the recalled drug was dispensed directly to a pharmacy, the notice shall be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber shall ensure the patient is notified.
  (c) In cases where patient harm has occurred resulting from use of the compounded product, the event shall be reported to MedWatch within 72 hours of the pharmacy being advised.

  President Gutierrez stated that if the board votes to pursue the draft proposal, board staff will request that the provisions be included in the board's sunset extension bill.

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

  Motion: Approve the proposed language.

  M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

3. Next Steps in Sunset Review

President Gutierrez reported that the board's sunset extension provisions are contained in Senate Bill 1193. She noted that this measure passed out of Senate Business, Professions and Economic Development Committee on April 18, 2016 and was referred to Senate Appropriations.

President Gutierrez stated that the board's fee proposal, which is contained in Senate Bill 1039, passed out of committee as well and was referred to Senate Appropriations.

Ms. Herold asked the board to support SB 1039.

Motion: Support SB 1039.

M/S: Lippe/Weisser

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

g. Discussion and Consideration of Implementation of Assembly Bill 15 (Chapter 1, Statutes of 2015-16 Extraordinary Session) End of Life Option Act

President Gutierrez reported that on October 5, 2015, Governor Brown signed the End of Life Option Act (Act). The provisions take effect June 9, 2016. She noted that this new law may impact pharmacists who may be asked to assist patients in this process in a very prescribed manner.

President Gutierrez explained that very generally, to qualify for a prescription for medication under the End of Life Option Act, a patient must be:

- A resident of California (specific qualifying criteria are provided in the law);
- 18 years of age or older;
- Mentally competent, i.e., capable of making and communicating your health care decisions; and
- Diagnosed with a terminal illness that will, within reasonable medical judgment, lead to death within six months.
- The patient must be able to self-administer and ingest the prescribed medication.
- Two physicians must determine whether all these criteria have been met.

President Gutierrez stated that the attending physician, if he or she possesses specified criteria and with the consent of the qualified individual (the patient), may contact a pharmacist, informing the pharmacist of the prescriptions and delivering to the pharmacist the written prescriptions personally, by mail or electronically. The pharmacist may dispense the drug to the qualified individual, the attending physician or a person expressly designated by the qualified individual and with the designation delivered to the pharmacist in writing or verbally.

President Gutierrez reported that the law requires that a specified request form for an aid-in-dying drug include, among other things, the following statement:

> *I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.*

President Gutierrez explained that the law also requires that a person who has custody or control of any unused aid-in-dying drugs prescribed pursuant to the Act after the death of the patient shall personally deliver the unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances, or – if none is available – the person shall dispose of it by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program.

The board asked how conscientious objectors should handle a request for end of life services. Ms. Freedman explained that the law is very clear that pharmacists are not required to participate and should inform their employer that they conscientiously object to providing end of life drugs.

Tony Park, representing CPhA, asked the board to clarify in future educational materials that pharmacists are not required to participate.

President Gutierrez asked board staff to provide information for pharmacists regarding the new law on the board's website.

Ms. Herold noted that she had spoken with the Governor's office regarding concerns they had with the disposal and reporting of any unused medications.

Dr. Steve Gray, representing Kaiser, stated that Kaiser is preparing to offer the service to their patients and noted that they do not expect to see a large demand.

Stan Goldenburg, pharmacist, reported that in Oregon approximately 30 patients per year choose to use the service. He added that there are two or three pharmacies who work with physicians to furnish the medication.

VII. Proposed Regulations to Add Title 16 CCR sections 1776 et seq. related to Prescription Drug Take-Back

President Gutierrez reported that at the January 2016 Board Meeting, the board approved proposed text to add Sections 1776 et seq of Title 16 CCR, related to Prescription Drug Take-Back Programs. The 45 day comment period began on February 12, 2016 and ended March 28, 2016. Two regulation hearings were held on April 13, 2016 (one in Northern California and one in Southern California).

President Gutierrez stated that the Board received numerous comments during the comment period and at the regulation hearings.

President Gutierrez explained that she and Ms. Veale worked with board staff to draft language that incorporated some of the comments received during the comment period. Note: this language was posted on the board's website, provided to the board and the public at the meeting and is provided immediately following these minutes.

President Gutierrez explained that the word "voluntary" was removed from the language; instead the pharmacist-in-charge (PIC) is given the authority to use their professional judgement to determine if it is appropriate for their pharmacy to host a take-back bin. She added that a pharmacy cannot participate in the program if they are on probation with the board.

Dr. Castellblanch asked in what situations a pharmacist could use their professional judgment to decline hosting a take-back bin. President Gutierrez explained that the PIC may determine that it would be a safety risk because they are located in a high-theft area or that there is not adequate room in their pharmacy for the bin. She noted that the language only allows the PIC to decline to have a tack-back bin; they could still be required to provide mail-back envelopes.

Dr. Castellblanch asked if an entire chain could decline to participate. President Gutierrez stated the each individual PIC must make the determination based on their individual pharmacy.

The board discussed that need to prevent patients from putting medications on top of or next to the receptacle when the pharmacy is closed. A representative from Walgreens reported to prevent people from leaving medication when the pharmacy is closed they are implementing take-back receptacles mostly in their 24-hour stores.

Motion: Approve the draft language as provided at the board meeting (and following these minutes) and initiate a 15-day comment period.

M/S: Weisser/Lippe

Jen Jackson, representing the Department of Environment, San Francisco, stated that there are many sections in the language that create requirements above and beyond the DEA requirements. She asked the board to remove the physical barrier requirement and the list of prohibited items from the language. Ms. Jackson also expressed concern with the vagueness of the term "professional judgement" and asked the board to define the circumstances that a pharmacist could use their professional judgement to decline a take-back bin.

Dr. Castellblanch expressed concern that a PIC could use their professional judgement as an excuse to decline participation for reasons other than patient safety. Ms. Veale and Mr. Weisser spoke in support of allowing the PIC to us their professional judgement to determine if it is appropriate for the pharmacy to host a take-back bin.

The board recessed for a break at 1:00 p.m. and resumed at 1:45 p.m.

Representatives from the California Alliance for Retired Americans (CARA) expressed concern that the board's regulations could negatively impact local ordinances' take-back programs. They also asked the board to include the disposal of sharps in the regulation.

Thomas Hare, representing the City of Santa Rosa, thanked the board for their work and stated that there are improvements in this new draft. Mr. Hare expressed concern with the vagueness of the "term professional judgment" and recommended that the board clarify that the PIC can decline to participate for safety reasons. Mr. Hare asked the board to remove the physical barrier requirement and the language on medical waste in section 1773.6 (h). He also asked the board to remove the phrase "within the pharmacy premise" from section 1776.3(b). Mr. Hare concluded that he would submit detailed comments on his recommended changes during the comment period.

Missy Johnson, representing CPhA, thanked the board for allowing the PIC to use their professional judgement. She provided her strong support of the language as presented and asked the board to approve it without amendments.

Tony Park, from CPhA, also spoke in support of pharmacists using their professional judgement. He recommended that the board state in the regulation that participation in take-back programs shall not be mandatory.

The board discussed how skilled nursing facilities are allowed to dispose of their unused medications according to the DEA requirements.

Manuel McDrano, representing Chula Vista, supported the comments made earlier by the representatives from San Francisco and Santa Rosa.

Patti Toews, representing San Luis Obispo, stated that their program has been in place for over one year and it has been running smoothly. She reiterated the concerns raised by the representatives from San Francisco and Santa Rosa.

Dr. Gray, pharmacist, asked the board to clarify the definition of a licensed premises. Dr. Gray spoke in support of allowing PICs to use their professional judgement and asked the board to allow the pharmacy permit holder to also make the decision to host a bin.

Lori Hensic, from Kaiser, expressed concern with the use of the term "vigilant" and the discrepancy it might create with the requirements in section 1776.1(e)(1)

Ms. Freedman stated that she had some suggested modifications to the language. The board asked her to work with staff to incorporate her changes into the language as part of the comment period.

President Gutierrez called for a vote on the motion made by Mr. Weisser.

Motion: Approve the draft language as provided at the board meeting (and following these minutes) and initiate a 15-day comment period.

M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

The board recessed for a break at 3:50 p.m. and returned at 4:03 p.m.

VIII. Proposed Regulations to Amend Title 16 CCR section 1760 related to Board's Disciplinary Guidelines

Chairperson Law reported that at the February 2016 Board Meeting, the board adopted the final text to amend Section 1760 of Title 16 CCR and the disciplinary guidelines. While preparing the final rulemaking documents, board staff determined that several documents needed to be added to the rulemaking file, which requires a 15-day public notice period.

Chairperson Law stated that the 15-day public notice period began on April 6, 2016 which ended on April 21, 2016.

Ms. Sodergren reported that no comments were received during the 15-day comment period.

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

Motion: Adopt section 1760 as noticed. Delegate authority to the executive officer to make any technical or non-substantive changes required to complete the rulemaking file.

M/S: Veale/Lippe

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

IX. Proposed Regulations to Add Title 16 CCR section 1746.5 related to Travel Medications

President Gutierrez reported that at the March 28, 2016 Board meeting the board approved a modified text and initiated a second 15 day comment period, which began March 28, 2016 and ended April 12, 2016.

President Gutierrez noted that during the comment period one comment was received from Dr. Goad. President Gutierrez reviewed the Dr. Goad's comment for the board and the public.

Ms. Herold noted that this regulation had been discussed in detail at multiple committee and board meetings and had been open for multiple comment periods.

After review the board decided not to modify the regulation based on Dr. Goad's comment as it would further delay the implementation of the regulation.

Motion: Adopt the language as provided in the board meeting materials without modifying it in response to the comment received during the comment period.

M/S: Lippe/Law

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

Motion: Delegate authority to the executive officer to make any technical or non-substantive changes required to complete the rulemaking file.

M/S: Lippe/Weisser

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

X. Proposed Regulations to Amend Title 16 CCR section 1744 related to Drug Warnings

President Gutierrez reported that at the April 2015 Board Meeting, the board approved proposed text to amend Section 1744 of Title 16 CCR, related to Drug Warnings. The 45 day comment period began on September 25, 2015 and ended November 9, 2015.

Ms. Martinez reported that the Board received one comment during the comment period from CVS Health asking the board to modify the language as provided below.

> (b) Because the following classed of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall ~~provide a written warning notice on the label to~~ include a written label on the drug container to alert the patient about possible potentiating effects

The board considered if the modification was necessary, as making the change would require another comment period.

Dr. Steve Gray, representing Kaiser, explained that the change was intended to make the language match Business and Professions Code section 4074 (b) which used the term container. He also noted that if the warning was required to be placed on the label it would prevent pharmacies from affixing auxiliary warning labels to the container.

The board decided to amend the language based on the comment and initiate a 15-day comment period.

Motion: Modify the language and initiate a 15-day comment period. If no negative comments are received delegate authority to the executive officer to make any technical or non-substantive changes necessary to complete the rulemaking file.

M/S: Lippe/Law

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

XI. Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient-Centered Labels

President Gutierrez reported that at the January 2015 Board Meeting, the board approved proposed text to amend Section 1707.5 of Title 16 CCR, related to Patient-Centered Labels. The 45 day comment period began on October 23, 2015 and ended December 7, 2015.

Ms. Martinez reviewed the comments for the board's consideration as follows.

Denise McAlliser submitted a comment asking the board to remove the "generic for" statement from the patient centered section of the label. After discussion the board decided that the generic information is important for patients, especially if they take more than one medication, and decided to reject Mr. McAllister's comment.

Motion: Reject the comment submitted by Mr. McAllister.

M/S: Veale/Lippe

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

Mary Staples, for NACDS, submitted a comment stating that the wording of 1707.5(a)(1)(B) is confusing as written. The board agreed and elected to remove the phrase "into the parenthesis" to simplify the language and provide clarity to the section.

Motion: Remove the phrase "into the parenthesis" from 1707.5(a)(1)(B).

M/S: Gutierrez/Veale

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			

Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

Lauren Berton, from CVS Health, submitted a comment asking the board to consider when the generic name for the drug must be provided in the patient centered label. The board discussed the fact that after a certain amount of time the brand name is no longer commonly used and therefor the information would no longer be useful to the patient. Ms. Veale recommended allowing the pharmacist to use their professional judgement to determine when the generic and brand name should be included in the patient centered label.

Motion: Allow the pharmacist to use their professional judgement to determine if the band name and generic name should be included in the patient centered label.

M/S: Veale/Law

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

The board reviewed the remaining comments and elected to reject them.

Motion: Incorporate the changes made during the meeting and initiate a 15-day comment period. If no negative comments are received adopt the text and delegate the authority to the executive officer to make any technical or non-substantive changed necessary to complete the rulemaking file.

M/S: Lippe/Law

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x

Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

XII. Legislation and Regulation Committee

Part 1: Legislation for Discussion and Consideration

a. Board-Sunset Legislation

SB 1193 (Hill) California State Board of Pharmacy: Executive Officer

Chairperson Lippe reported that as introduced, the measure would extend the operations of the California Board of Pharmacy and the board's authority to appoint an executive officer until January 1, 2021.

Chairperson Lippe stated that recently, the bill has been amended to incorporate additional provisions that would:

- Establish the regulatory framework for the licensure of resident and nonresident outsourcing facilities (board-sponsored provisions)
- Require the issuance of a clinic license within 30 days of a completed application, as specified,
- Add licensed pharmacists as one of the individuals that are authorized to be in a professional medical corporation
- Authorize the board to issue a cease and desist order for unlicensed activity, as specified, and
- Require a health facility to register the use of the automated drug delivery system with the board, as specified.

Ms. Herold noted that the bill had been amended since the committee reviewed it.

There were no comments from the public.

Motion: Support Senate Bill 1193.

M/S: Butler/Veale

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

b. <u>Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction</u>

1. AB 45 (Mullin) Household Hazardous Waste
Version: January 21, 2016 Amended
Location: Senate Environmental Quality Committee
Position: Oppose Unless Amended (Ver: 4/30/15)

Chairperson Lippe reported that the bill adds Article 3.4 "Household Hazardous Waste Collection and Reduction" to the Public Resources Code and would require the Department of Resources Recycling and Recovery (CalRecycle) to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste (to include home-generated pharmaceutical waste), and then post the ordinance(s) on CalRecycle's web site. Thereafter, a local jurisdiction that provides for the residential collection and disposal of solid waste that proposes to enact an ordinance governing the collection and diversion of household hazardous waste may adopt one of the model ordinances posted by CalRecycle.

Chairperson Lippe explained that the bill establishes various definitions, including but not limited to "comprehensive program for the collection of household hazardous waste," "household hazardous waste," and "home-generated pharmaceutical waste."

Chairperson Lippe stated that AB 45 requires CalRecycle to determine whether a nonprofit organization has been created and funded to make grants to local jurisdictions for specified purposes related to household hazardous waste disposal. He added that this bill would specify if CalRecycle makes no such determination by December 31, 2018, then the provisions of the bill are repealed on January 1, 2019.

Ms. Klein noted that since the committee last reviewed the bill it has been amended. She added that staff is recommending maintaining the oppose unless amended position.

Motion: Maintain position of Oppose Unless Amended for the January 21, 2016 version.

M/S: Law/Butler

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

2. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
Version: July 1, 2015 Amended
Location: Senate Appropriations Committee (July 2015)
Position: Oppose Unless Amended

Chairperson Lippe explained that AB 1069 would expand the provisions under which a county-established repository and distribution program allows the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

Chairperson Lippe reported that board staff has worked with the author's office to secure amendments to address many of the legal conflicts the measure initially contained, but there are still some concerns with the bill in its current form.

Chairperson Lippe stated that currently, the bill would remove a pharmacist from several aspects of the redistribution program of prescription drugs; would allow a "participating entity" to transfer drugs like a distributor without appropriate licensure and control; and would permit what is currently unlawful repackaging and co-mingling of previously dispensed medications, including donated medications from various sources, all to the detriment of patient safety. .

Board staff recommended maintaining the oppose unless amended position.

Motion: Oppose unless amended.

M/S: Law/Veale

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

Note: Mr. Schaad left the room at 4:50 p.m.

3. AB 1386 (Low) Emergency Medical Care: Epinephrine Auto-Injectors
Version: January 13, 2016 Amended
Location: Senate Health
Coauthors: Assembly Members Chang, Daly and Wilk, and Senator Huff

Chairperson Lippe reported that this measure would amend Pharmacy Law and other provisions of the Civil Code and Health and Safety Code to authorize a health care provider to issue a prescription, and a pharmacy to furnish, epinephrine auto-injectors to an authorized entity, as defined. The bill calls for specific labeling on any epinephrine auto-injectors dispensed pursuant to the bill's provisions. Authorized entities include any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course, as defined.

Chairperson Lippe reported that the committee concurred with comments from proponents that believe Advanced Practice Pharmacists would be well positioned to furnish the auto-injectors, thereby expanding access to those who need them.

Committee Recommendation (motion): Support AB 1386, and offer amendments to allow pharmacists to provide the auto-injectors.

Support: 7 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x

Sanchez				x
Schaad				x
Veale	x			
Weisser	x			
Wong				x

4. AB 1977 (Wood) Health Coverage: Abuse-Deterrent Opioid Analgesics
Version: As Amended April 13, 2016
Location: Assembly Health

Chairperson Lippe reported that as amended, AB 1977 makes declarations regarding the abuse and misuse of opioids. He added that the bill would create the Opioid Abuse Task Force that would require health care service plans and health insurer representatives, in collaboration with advocates, experts, health care professionals, and other entities and stakeholders to convene a task force, develop recommendations regarding the abuse and misuse of opioids, as specified, and requires the task force to report its findings to the Governor and specified Legislators and committees on or before December 31, 2017.

Dr. Castellblanch asked staff why the bill had such a late hearing date. Ms. Sodergren explained that the bill had been amended significantly.

The board did not take a position and asked staff to watch the bill and report new developments to the board.

5. AB 2144 (Rodriguez) Pharmacy: Prescriptions

Version: March 18, 2016
Location: Assembly Health

Chairperson Lippe reported that AB 2144 would amend section 4074 of the Business and Professions Code to specify that a health facility shall require each patient to acknowledge in writing that a patient has received specified drug warning, storage and other specified information at the time of discharge.

President Gutierrez noted that hospitals already provide this information to patients upon discharge.

Ms. Klein stated that the bill requires the patient to receive the information in writing and to sign their acknowledgement of receiving the documents. Dr. Castellblanch noted that he personally had been involved in hospital discharges where no information was provided by the hospital.

Dr. Gray, representing Kaiser and CSHP, stated that hospitals have expressed concern with who will sign the acknowledgement if the patient is unable.

Committee Recommendation (motion): Support AB 2144

Support: 6 Oppose: 1 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez		x		
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad				x
Veale	x			
Weisser	x			
Wong				x

Note: Mr. Schaad returned to the meeting at 5:04 p.m.

6. AB 2592 (Cooper) Prescriptions

Version: April 11, 2016 Amended
Location: Assembly Appropriations

Chairperson Lippe reported as amended this measure will require the Department of Public Health, if funding is available, to create a pilot program to award grants to combat opioid abuse through the safe prescribing of opioids. He added that the measure would specify that a pharmacy that applies for and receives a grant shall offer all patients who are prescribed an opioid with a medicine locking closure package if a patient consents.

Chairperson Lippe stated that the committee reviewed the prior amended version, but did not recommend a position.

Ms. Klein reported that the author of this bill is a company that manufactures the locking packages. Ms. Klein briefly described the locking packages to the board.

The board did not take a position on the bill and asked staff to continue to monitor its progress.

7. SB 482 (Lara) Controlled Substances: CURES database

Version: As Amended April 7, 2016
Location: Assembly Rules Committee

Chairperson Lippe stated that this measure would require a prescriber to access the CURES system under specified conditions, to include checking the system before

prescribing a Schedule II or Schedule III medication for the first time and at least annually.

Chairperson Lippe reported that this measure was amended after the committee meeting. He explained that recent amendments to this measure include additional conditions under which the provisions to check the systems do not apply. Such conditions include specifying that a prescriber is not required to check the system if it is not available, if the patient is in hospice and if the prescription is for use as part of a medical procedure.

The board spoke in support of this bill.

Committee Recommendation (motion): Support SB 482.

M/SL Law/Butler

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

Note: President Gutierrez left the room at 5:15 p.m.

8. SB 1217 (Stone) Healing Arts: Reporting Requirements: Professions Liability
Version: April 12, 2016
Location: Senate Business, Professions and Economic Development
Status: This measure failed in committee on April 18, 2016. Reconsideration was granted.

Chairperson Lippe explained that as initially introduced this measure would have increased the mandatory reporting from $3,000 to $10,000 where there is a judgment or settlement requiring the licensee or licensee's insurer to pay damages for any claim that injury or death was proximately caused by the licensee's negligence, error or omission in practice, or rendering unauthorized professional service.

Chairperson Lippe stated that this measure was recently amended and now only applies to the Board of Pharmacy.

Chairperson Lippe reported that at the committee meeting the vote was a split decision and therefore there is no position from the committee.

Ms. Herold reported that most of the settlement information the board receives are for amounts over $10,000. She added that she plans on meeting with the author of the bill in the coming week.

Ms. Butler stated that the board should support the bill as it would encourage pharmacists to be included on healthcare teams.

Ms. Veale expressed her concern that raising the threshold would prevent the board from finding out about claims where patients were harmed.

Ms. Herold reported that over four years the board took 562 actions based on reports received.

Mr. Weisser asked if it was common for pharmacists to be excluded from medical teams because of their lower reporting requirement. Dr. Gray, representing Kaiser, stated that the bill is intended to make the reporting requirement consistent with other healthcare practitioners.

Motion: Oppose SB 1217.

M/S: Veale/ Castellblanch

Support: 2 Oppose: 5 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler		x		
Castellblanch	x			
Gutierrez				x
Law		x		
Lippe		x		
Murphy				x
Sanchez				x
Schaad		x		
Veale	x			
Weisser		x		
Wong				x

Motion: Support SB 1217.

M/S: Weisser/Butler

Support: 5 Oppose: 2 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch		x		
Gutierrez				x
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale		x		
Weisser	x			
Wong				x

Note: President Gutierrez returned to the meeting at 5:23 p.m.

9. SB 1229 (Jackson and Stone) Home-Generated Pharmaceutical Waste: Secure
Version: Amended March 28, 2016
Location:Senate Floor
Hearing: Do Pass From Senate Environmental Quality

Chairperson Lippe stated that the bill in its current form includes legislative findings and declarations surrounding the disposal of unused medications, including controlled substances and actions taken by the Drug Enforcement Agency. Further this measure provided legislative intent to encourage good faith participation in drug take-back programs and provides the liability protections for specified entities that that provide drug take-back bins on its premises if the entity under specified conditions. He added that the provisions apply to pharmaceutical products including prescription and over-the-counter human and veterinary drugs.

Chairperson Lippe explained that the committee did not have a recommendation on this measure as the amendments were not available at the time of the committee meeting.

Dr. Castellblanch noted that this bill provides protection for pharmacies and pharmacists who participate in take-back programs and stated that the board should support the bill. Ms. Freedman confirmed that this bill creates civil liability protection for pharmacists who participate in take-back programs.

Motion: Support SB 1229.

M/S: Castellblanch/Veale

Support: 7 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez			x	
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

10. SB 1230 (Stone) Pharmacies: Compounding

Version: February 18, 2016 Introduced
Location: Senate Business, Professions and Economic Development

Chairperson Lippe stated that board staff has been advised that this measure was held in committee at request of the author's office.

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

11. SB 1346 (Allen) Pharmacists: Drug Labeling: Medication Guides: Electronic Delivery

Chairperson Lippe reported that board staff was advised by the author's office that this measure will not be moving as it was determined that legislation isn't necessary. The author's office requested that the board complete some education of our licensees about this issue.

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

12. SB 1454 (Stone) Pharmacy

Chairperson Lippe explained that this measure was amended March 31, 2 016 and now relates to pharmacy benefit management.

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

c. <u>Legislation Impacting Board Operations</u>

1. AB 12 (Cooley) State Government: Administrative Regulations: Review

Version: August 19, 2015
Location: Last location was Senate Appropriations / Held under submission
Position: Oppose (4/22/15 text version)

Chairperson Lippe reported that AB 12 would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018, and establish reporting requirements. He added that the bill was amended on August 19, 2015, but there are no substantive differences from the prior version.

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

Committee recommendation (motion): Maintain oppose position.

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

2. SB 1155 (Morrell) Professions and Vocations: Licenses: Military Service

Version: As Amended March 28, 2016
Location: Senate Appropriations
Hearing: April 25, 2016

Chairperson Lippe stated that this bill would require every board within the Department of Consumer Affairs to grant a fee waiver for the application and for the issuance of an initial license to an individual who is an honorably discharged veteran.

Chairperson Lippe reported that the committee did not discuss this bill.

Ms. Klein explained that the waiver would be a one-time waiver that could be used across all DCA boards and bureaus.

Mr. Weisser and Chairperson Lippe expressed their desire to see information on the fiscal impact of this bill. Dr. Castellblanch noted that DCA estimates that it will cost the department $1.2 million. Ms. Sodergren responded that the board does not receive a significant amount of military applications, so she expects that the cost to the board would not be significant.

Ms. Veale made a motion to support the bill but did not receive a second.

3. SB 1195 (Hill) Professions and Vocations: Board Actions: Competitive Impact

Version: As Amended April 6, 2016
Location: Senate Business, Professions and Economic Development
Hearing: April 18, 2016

Chairperson Lippe explained that this bill would grant authority to the DCA director to review a decision or other action, except as specified, of a board within the DCA to determine whether it unreasonably restrains trade and to approve, disapprove, or modify the board decision or action, as specified. It clarifies when a judgment or settlement for treble damages antitrust award would be granted for a member of a regulatory board; and provides for an additional standard for the Office of Administrative Law to follow when reviewing regulatory actions of state boards.

President Gutierrez explained that this bill was developed in response to the North Carolina ruling and recommended that the board not take a position on the bill until after Ms. Freedman's presentation.

Part 2: Regulations for Discussion and Consideration

a. <u>Newly Effective Regulation</u>

Chairperson Lippe provided a brief report on the status to the regulations listed below. There was no action taken by the board on any of the pending regulations. Detailed information on each regulation was provided in the board meeting materials.

President Gutierrez noted that she is working closely with board staff to monitor the progress of pending regulations.

- Title 16 CCR section 1746.1 related to Self-Administered Hormonal Contraception
- Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) Sections 1715 and 1784 related to Self-Assessment Forms for Community Pharmacies/Hospital Outpatient Pharmacies (17M-13), Hospital Pharmacies (17M-14), and Wholesalers (17M-26)
- Proposed Regulations to Add Title 16 CCR section 1746.4 related to Vaccinations
- Regulations to Amend Title 16 CCR section 1735 and 1751 et seq. related to Compounding
- Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists
- Proposed Regulations to Add Title 16 CCR section 1730.2 related to Advanced Practice Pharmacists – Certification Programs
- Proposed Regulations to Amend Title 16 CCR sections 1732.05, 1732.2, and 1732.5, related to Continuing Education
- Proposed Regulations to Amend Title 16 CCR section 1703 related to Authorities Delegated to the Executive Officer

- Proposed Regulations to Amend and/or Add Title 16 CCR section 1702, 1702.1, 1702.2, and 1702.5, related to Renewal Requirements
- Proposed Regulations to Amend Title 16 CCR sections 1780 – 1784, et seq, related to Third Party Logistics Providers

The board recessed for a break at 5:51 p.m. and resumed at 6:04 p.m.

XIV. Presentation on the North Carolina State Board of Dental Examiners v. Federal Trade Commission United States Supreme Court Ruling

Ms. Freedman explained that in addition to the in-person training that DCA provided to all board presidents and executive officers, each board is dedicating time at their meetings to discuss the North Carolina ruling.

Ms. Freedman provided an overview of the ruling.

Ms. Freedman advised the board that they must always be cognizant of the fact that they have been appointed to the board to protect the consumers of California.

Ms. Freedman explained that when the board makes decisions that could limit or infringe on the ability of others to practice or join the field, they must be particularly vigilant in documenting the consumer protection that is offered by the decision being made.

Dr. Castellblanch asked what steps the board should take moving forward. Ms. Freedman explained that all DCA attorneys will be monitoring board discussion and action to ensure that they are following their consumer protection mandate.

Mr. Weisser stated that many members could potentially have conflicts of interest because of their work in the healthcare industry. Ms. Freedman explained that members must remember that when they are working as a board member each decision they make must be based on protecting the consumers of California.

Ms. Freedman concluded that she would keep the board updated on any new information regarding the ruling.

Note: Additional information regarding the ruling may be found using the links below.

- The decision on the North Carolina State Board of Dental Examiners v. Federal Trade Commission United States Supreme Court ruling: http://www.supremecourt.gov/opinions/14pdf/13-534_19m2.pdf

- California's AG Opinion on this case: https://oag.ca.gov/system/files/opinions/pdfs/15-402_0.pdf

- FTC Guidance: https://www.ftc.gov/system/files/attachments/competition-policy-guidance/active_supervision_of_state_boards.pdf

Upon conclusion of Ms. Freedman's presentation the board returned the discussion to SB 1195 (Hill).

Ms. Freedman explained that this is the first version of this bill and she expects to see further amendments. She explained that the bill gives the DCA director and the Office of Administrative Law significantly more authority to review regulations for antitrust issues.

Ms. Herold noted that the bill could potentially open up the board's disciplinary decisions for review by the DCA director.

Ms. Freedman explained that goal of the bill is to establish active state supervision; however, the bill still needs fine tuning to achieve this.

Ms. Herold recommended that the board not take a position on this bill until it is further discussed and amended. The board agreed with Ms. Herold's recommendation.

Dr. Gray, pharmacist, stated that the North Carolina ruling would be discussed at the upcoming NABP annual meeting.

President Gutierrez adjourned the meeting for the day at 6:48 p.m.

Thursday, April 28, 2016

XV. Call to Order and Establishment of Quorum

President Gutierrez called the meeting to order at 9:05 a.m.

President Gutierrez conducted a roll call. Board members present: Gregory Lippe, Deborah Veale, Amy Gutierrez, Stanley Weisser, Allen Schaad, Ramon Castellblanch, Victor Law and Lavanza Butler.

XVI. Development of Guidance Document for Pharmacies Implementing Self-Administered Hormonal Contraception Provisions

President Gutierrez reported that during the February 2016 Board Meeting, the board discussed the development of guidance documents to assist licensees with implementation on several provisions of Senate Bill 493. This matter was referred to the Communication and Public Education Committee.

President Gutierrez explained that with the recent approval of the Self-Administered Hormonal Contraception Provisions, the board's website has been updated. A webpage is dedicated that includes links to the protocol and underlying statute as well as the Summary Chart of U.S. Medical Eligibility Criteria (USMEC) for Contraceptive Use. President Gutierrez added that the webpage also contains the patient-self-screening tool, which is provided in

seven languages.

The board discussed the need for pharmacists to document their consultation with patients regarding hormonal contraception (i.e. the self-screening tool). The board also highlighted the fact that pharmacist must notify the patient's primary care provider if they provide the patient with contraception and must document that the notification occured.

Dr. Dang explained the procedures that pharmacies currently use to document immunizations and stated that she would expect pharmacies to implement similar procedures for hormonal contraception.

The board asked the Communication and Public Education Committee to discuss creating guidance documents for pharmacies that will be providing hormonal contraception as well as other SB 493 services.

XVII. Discussion and Consideration of Statement Released by the Endocrine Society Related to Compounding Bioidentical Hormones in Endocrinology Practice

President Gutierrez briefly reviewed the statement released by the Endocrine Society.

She explained that the Endocrine Society's concluded that due to the widespread availability of FDA-approved bioidentical hormones produced in monitored facilities demonstrates a high quality of safety and efficacy in trials; there is no rationale for the routine prescribing of unregulated, untested, and potentially harmful custom compounded bioidentical hormone therapy.

Mr. Schaad expressed significant concerns with the validity of the document and stated that the author has an inherent conflict of interest that is not disclosed.

Marie Cottman, pharmacist, also expressed her substantial concerns with the statement released by the Endocrine Society. Dr. Cottman also provided her detailed comments in writing, a copy of which can be found following these minutes.

President Gutierrez asked the Enforcement Committee to review the statement to ensure that it doesn't contain any information that might be relevant to the board's compounding regulations.

XVIII. Proposed Regulations to Add Title 16 CCR section 1715.65 related to Reconciliation and Inventory of Controlled Substances

President Gutierrez reported that this regulation was being sent back to the Enforcement Committee for further vetting.

XIX. Enforcement Committee Related Items

Part 1: Enforcement Matters

a. Update on the University of California, San Diego's Pilot Program to Permit Patients to Access Medications from an Automated Storage Device not Immediately Adjacent to a Pharmacy

President Gutierrez stated that the Enforcement Committee received an update from the University of California San Diego, regarding the automated storage device pilot program which began launched on January 20, 2016.

Dr. Castellblanch asked if the board would continue to receive updates on the program. President Gutierrez confirmed that the Enforcement Committee will continue to receive updates and report the information to the board.

b. Discussion and Update to the Board's Procedures to Waive Requirements During a Declared Emergency Pursuant to Business and Professions Code section 4062

President Gutierrez reported that on September 15, 2015, the board held an Emergency Board meeting in response to the wildfires in Lake and Napa counties. In light of the recent use of the policy it was brought to the Enforcement Committee for evaluation and assessment to determine if changes to the policy are necessary.

President Gutierrez explained that at the December 15, 2015, Enforcement Committee meeting, the committee recommended that the board modify the policy to delegate its authority pursuant to Business and Professions Code section 4062 to the board president for a period of 30 days. This was ratified by the board at its February 25, 2016 meeting.

President Gutierrez reported that at the March Enforcement Committee Ms. Freedman further clarified the board's intent with the policy language and indicated that for clarity the policy should be slightly modified to read as:

> In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, the board president may, on behalf of the board, exercise the powers ~~delegated to full board~~ pursuant to Business and Professions Code section 4062 for a period of 30 days.

There were no comments from the board.

Dr. Gray, pharmacist, stated that in the event of another emergency the board should ensure that any emergency provisions approved by the board are applied state-wide as people who are displaced by the emergency may have to re-locate all over California.

c. Data Describing Duty Inspector Activities

President Gutierrez reported that from July 2015 through January 2016, the Complaint Unit resolved 166 *Ask the Inspector* inquiries. This is an average of 23 resolutions per month. In addition, the Complaint Unit has screened 916 *Ask the Inspector* inquiries

before escalating them to the weekly duty inspector for a response. This is an average of 130 inquiries per month.

Note: additional statistics on the *Ask the Inspector* inquires can be found in the board meeting materials.

The board thanked staff and the inspectors for implementing the program and reported that they have received positive feedback. Ms. Butler noted that she had called with a question and was pleased to receive a response very quickly.

Ms. Herold noted that board staff and legal counsel are working to place FAQs on the board's website.

d. Automated Dispensing Machines – Available Drug Diversion Tools, Assessing Features Available, Training Provided to Pharmacy and Health Facility Staff. Summary of Presentations by:

1. Kaiser Permanente
2. BD CareFusion/Pyxis & Rx Auditor
3. Omnicell/Aesyent
4. Cerner Automated Cabinets
5. Talyst

President Gutierrez reported that the committee heard presentations from the organizations listed above, that provided information on the secured log-on features as well as the various types of reports that are available with each device.

Members of the Enforcement Committee stated that they found the presentations to be very informative.

There were no comments from the public.

e. Discussion on the Proposed Reconciliation and Inventory Report of Controlled Substances Regulation, Proposal to Add Title 16 California Code of Regulations Section 1715.65

President Gutierrez stated that the committee did not discuss this item at their meeting due to time constraints. She added that it would be placed on a future agenda.

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

f. Enforcement Statistics

President Gutierrez stated that the meeting materials included the third quarter report of the Enforcement Statistics, SB 1441 Program Statistics and Citation and Fine Statistics for review by the board members and the public.

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

Part 2: Compounding Matters

a. Update on the Status of the Sterile Compounding Regulations, Title 16 California Code of Regulations Sections 1735 et seq., and 1751 et seq.

President Gutierrez reported that the rulemaking file was submitted to DCA legal for review on March 10, 2016.

President Gutierrez stated that the board has set January 1, 2017 as the date for implementation of the regulation. She suggested that facilities conduct a gap analysis to determine what physical changes will be required by the new regulations.

Ms. Herold reported that Supervising Inspectors Christine Acosta and Michael Ignacio have been reviewing the waivers that facilities can submit to the board to seek additional time to complete physical changes. President Gutierrez recommended looking at how Florida implemented their regulations and the waivers that they used.

There was no comment from the public.

b. Summary of Presentation on FDA-Approved Alternative Testing Technologies to Assess Sterility and Potency in Compounded Medications in Use by Drug Manufacturers

President Gutierrez reported that the committee heard a presentation by Dr. Tony Cundell on the Alternative Sterility Testing of Compounding Sterile Preparations. She noted that Dr. Cundell stated that alternative sterility testing methods for compounded sterile preparations, when properly validated, are supported by both the FDA and USP and their use will promote the safety compounded products and benefit the public health.

Ms. Herold stated that the alternative testing methods must be approved by the FDA before the board can approve them for use.

Dr. Gray, representing CSHP, stated that there are many facilities that are already using these testing methods. He asked the board to reach out to the FDA to discuss the use of alternative testing methods. Dr. Gray added that when used properly, the alternative testing methods are beneficial to patients.

Mr. Weisser and Ms. Herold expressed concern that without FDA approval the board would have no means to determine if the alternative testing methods are valid.

President Gutierrez stated that this issue would continue to be discussed by the Enforcement Committee.

c. Future Committee Meeting Dates

President Gutierrez announced the following future committee meeting dates.

- June 1, 2016
- August 31, 2016

The board recessed for a break at 10:35 a.m. and resumed at 10:44 a.m.

XX. Communication and Public Education Committee

a. Update on the Redesign of the Board's Website

Chairperson Veale reported that she and Dr. Castellblanch continue to work closely with board staff to improve the board's website and are looking forward to rolling out the new site in the near future.

b. Update on Communication to Licensees about CURES 2.0

Chairperson Veale reported that the Department of Justice (DOJ) recently released a CURES 2.0 registration tip sheet to help individuals register or access the system. On April 4, 2016, the board issued a subscriber alert announcing the tip sheet as well as a reminder that all pharmacists with active California licenses need to be registered to access CURES 2.0 by July 1, 2016. Note: a copy of the tip sheet was added to the board's website and can be found in the board meeting materials.

Chairperson Veale stated that in February 2016, the board mailed out a reminder postcard to pharmacists to register for CURES 2.0 by July 1, 2016, and will send another postcard as the July 1st deadline approaches. She added that questions regarding these changes should be directed to cures@doj.ca.gov.

Dr. Gray, pharmacist, stated that many pharmacists, particularly those who live out of state, still do not know that they are required to register for CURES. Ms. Herold responded that many pharmacists do not update their address of record when they move. She added that another postcard would be mailed to pharmacists reminding them to register and an article would be included in the next issue of *The Script*.

Chairperson Veale noted that postcards are easily lost in the mail. Ms. Herold responded that staff would research alternative mailing methods (i.e. letters or brightly colored postcards).

The board noted that email may be a more effective way to contact licensees. Ms. Herold explained that currently the board does not require licensees to provide the board with their email. The board asked the Communication and Public Education Committee to research what the board would need to do to collect and utilize licensees' email addresses.

c. Update on The Script Newsletter

Chairperson Veale reported that board staff wrote the Winter issue of *The Script* newsletter - which will now be the Spring 2016 issue.

Ms. Herold noted that the articles are still under legal review.

d. Update on Media Activity and Public Outreach Activities Conducted by the Board

Chairperson Veale stated that the board's public outreach and media activities were provided in the meeting materials for review by the board members and the public.

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

e. Future Committee Meeting Dates

Chairperson Veale reported the following future committee meeting dates.

- May 25, 2016
- July 6, 2016

XXI. Licensing Committee

a. Discussion of Pharmacy Technician Licensure Requirements and Practice

1. Overview of Pharmacy Technician Discipline and Applicant Denials

Chairperson Weisser reported that at prior meetings, the committee was provided information on the number of pharmacy technician application denials and licensee discipline for a 4-year period (FY 11/12 – FY 14/15) and determined that during that period – and of those pharmacy technicians that had been disciplined – a large percentage had qualified for licensure by completing a training program. Those numbers, however, did not reflect the overall populations of those denied and disciplined during that period.

Chairperson Weisser reported that the committee reviewed the tables provided below at the March committee meeting which reflect a comparison of pharmacy technician applicants denied, as well as pharmacy technician licensees revoked for the same 4-year period. He added that for further comparison, staff provided the same for pharmacist exam applicants and pharmacist licensees.

Applicant Population: Denied

Pharmacy Technician	FY 11/12	FY 12/13	FY 13/14	FY 14/15
Application Received	9491	8741	8211	7151
Applications Denied	89	101	45	56
Percentage	0.94%	1.16%	0.55%	0.78%

License Population: Revoked

Pharmacy Technician	FY 11/12	FY 12/13	FY 13/14	FY 14/15
License Population	72338	73994	73558	74586
Licenses Revoked	99	85	170	169

Percentage	0.14%	0.11%	0.23%	0.23%

Applicant Population: Denied

Pharmacist	FY 11/12	FY 12/13	FY 13/14	FY 14/15
Application Received	2467	2487	2682	3122
Applications Denied	7	9	8	9
Percentage	0.28%	0.36%	0.30%	0.29%

License Population: Revoked

Pharmacist	FY 11/12	FY 12/13	FY 13/14	FY 14/15
License Population	38526	39793	41176	42521
Licenses Revoked	11	12	21	15
Percentage	0.03%	0.03%	0.05%	0.02%

Chairperson Weisser explained that with the exception of the pharmacy technician applicants in FY 2012/13, less than one percent of applicants or licensees were denied or revoked for both pharmacist and pharmacist technicians. He noted that during FY 2012/13, just over one percent of pharmacy technician applications were denied.

President Gutierrez asked why a pharmacist would have their license application denied. Ms. Herold explained that usually applications are denied for prior discipline, a prior conviction or discipline in other states.

2. Presentation by the Pharmacy Technician Certification Board (PTCB)

Chairperson Weisser explained that pursuant to Business and Professions Code section 4202(a)(4), certification by the Pharmacy Technician Certification Board (PTCB) is one method to qualify for licensure in California as a pharmacy technician.

Chairperson Weisser reported that the committee heard a presentation on the PTCB by CEO Everett McAllister; Levi Borne, PhD; and Miriam Mobley-Smith, PharmD. The presentation included an update on PTCB program changes, as well as new certifications that are in development. Chairperson Weisser briefly reviewed the presentation which was provided in its entirety in the board meeting materials.

Chairperson Weisser noted that currently the board does not require pharmacy technicians to maintain their certification (or to recertify with the PTCB). President Gutierrez asked how many states require technicians to maintain their certification. Mr. McAllister responded that it varies from state-to-state and added that some employers require them to maintain certification.

Mr. Lippe asked why the board does not require recertification. Chairperson Weisser explained that the committee had discussed this and would continue to

consider the issue as the discussion on technicians continues.

3. Comparison of the PTCB and ExCPT Certifications

Chairperson Weisser explained that the committee reviewed a comparison chart created by board staff which illustrated the eligibility requirements to apply for both PTCB and ExCPT certifications.

The board asked if ExCPT exam is a national exam. Mr. McAllister noted that the ExCPT exam was established in 2006 and is accepted in some, but not all states.

Ms. Veale asked if the new standards that PTCB will be implementing in 2020 would be cause a shortage of pharmacy technicians. Mr. McAllister explained that PTCB worked with ACPE and ASHP to ensure that the new standards ensure that technicians are properly qualified while not creating a significant barrier to entry for technicians. He added that discussion is being had at the national level regarding the job duties of pharmacy technicians and whether it would be prudent to create different levels of pharmacy technicians.

4. Discussion and Consideration of Possible Requirements for Applicants Enrolling in a Pharmacy Technician Training Programs

Chairperson Weisser reported that in September 2015, the committee made a recommendation to the board to change the minimum educational requirements for licensure as a pharmacy technician. After reaching consensus to increase pharmacy technician knowledge, the board in October 2015 re-referred the review back to the committee for further vetting and discussion. He noted that the committee was asked to consider various topics, including but not limited to: discussion on whether education level correlates to the likelihood of discipline; feedback on pharmacy technician training programs; increasing requirements may have unintended consequences; and considering different levels of pharmacy technician licensure (i.e., hospital, compounding, community, etc.).

Chairperson Weisser stated that in January 2016, the committee put forth a recommendation that the board modify Title 16 CCR section 1793.6 to require all pharmacy technician programs prior to enrolling students into the program to:

(1) conduct a criminal background check;
(2) administer drug and alcohol testing;
(3) be at least 18 years of age; and
(4) require the individual to pass a final examination administered by the provider, and to provide proof of successfully passing the final examination to the board.

Chairperson Weisser reported that in February 2016 the board requested that the committee vet this issue further.

Chairperson Weisser stated that at the March 2016 committee meeting, the

committee reviewed draft proposal language provided by staff based on the committee's recommendations at its January 2016 meeting (provided below).

Draft Proposal to Amend Section 1793.6

1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2)
is:
(a) Any pharmacy technician training program accredited by the American Society of Health--System
Pharmacists,
(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or
(c) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(1) Knowledge and understanding of different pharmacy practice settings.
(2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.
(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.
(8) Include a final examination that demonstrates students understanding and ability to perform the provisions in paragraphs (1) through (7) above.

(d) In addition to the content of coursework specified in subdivision (c) the training program must also satisfy the following:

(1) Prior to admission, the program must conduct a criminal background check
(2) Administer at least one drug and alcohol screening
(3) Require students to be at least 18 years of age.

Chairperson Weisser reported that the committee discussed their concerns pertaining to the training requirement outlined in 1793.6(c). He added that after discussion and hearing public comment, the committee requested staff to gather information on the ASHP and military training program requirements and update the draft proposed language to incorporate the committee discussion.

Dr. Castellblanch asked what type of convictions would disqualify someone from licensure. Ms. Herold explained that staff reviews each applicant's case individually and considers the number of convictions, the type of convictions and how long ago the convictions occurred.

President Gutierrez noted that currently the language does not specify what the school must do if a student has something come up in their background check. Ms. Freedman stated that the committee discussed this issue and explained that this was one of the reasons the committee wanted to further vet the language.

Mr. Lippe asked how much the average pharmacy technician makes per hour. Ms. Butler responded that the most experienced technicians make approximately $21 per hour.

President Gutierrez asked if it is possible for technicians to become licensed with the board by only taking the PTCB exam (i.e. they have never stepped foot in a pharmacy). Ms. Herold responded that people can qualify solely by taking the PTCB.

The board thanked the Licensing Committee for their continued work on this important issue.

5. **Pharmacy Technician Duties, Functions and Licensure Requirements. The Board may discuss the licensure requirements, functions, roles and responsibilities of the pharmacy technician as well as possible changes**

Chairperson Weisser explained that Business and Professions Code section 4115 specifies that a pharmacy technician may perform packaging, manipulative, repetitive or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. Further, Title 16 California Code of Regulations section 1793.2 specifies specific duties that may be performed by a pharmacy technician, as listed below.

- Removing the drug or drugs from stock
- Counting, pouring, or mixing pharmaceuticals
- Placing the product into a container
- Affixing the label or labels to the container
- Packaging and repackaging

Chairperson Weisser noted that pharmacists can also employ non-licensed individuals to handle administrative tasks such as data entry.

Chairperson Weisser explained that currently the ratio is one technician for each pharmacist. Ms. Herold stated that during inspections the board has found pharmacies that are violating this ratio.

Dennis McAllister, Arizona Board of Pharmacy member, reported that twenty states have eliminated the technician ratio.

Lugena Mendez-Harper, New Mexico Board of Pharmacy member, explained that in New Mexico the pharmacist-in-charge determines how many technicians they can safely oversee.

Stan Goldenberg, pharmacist, recommended that the board consider how the process of filling of prescriptions has evolved over the years.

The board asked the Licensing Committee to discuss the pharmacy technician ratio at a future meeting.

b. Discussion and Consideration of Senate Bill 952, Anderson (Pharmacy Technicians: Licensure Requirements)

Chairperson Weisser explained that currently, Business and Professions Code section 4202(a)(4) only allows for a pharmacy technician applicant to earn a certification from the Pharmacy Technician Certification Board (PTCB). SB 952 would amend Business and Professions Code section 4202(a)(4) to specify "Is certified by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies (NCCA) that is approved by the board", which will allow other agencies with proper accreditation to provide the pharmacy technician exam certification.

Chairperson Weisser reported that SB 952 was introduced by Senator Anderson on February 4, 2016. SB 952 passed out of the Senate policy committee on April 5, and was re-referred to Senate Appropriations. Note: a copy of the bill and the author's Fact Sheet was provided in the board meeting materials.

Dr. Gray, representing Kaiser, recommended that the board ask the author to amend the bill allow the board to approve other accrediting agencies if they arise. Ms. Herold stated that no other accrediting agencies have approached the board to inform them that they will be accrediting pharmacy technician exams. She added that the board had already vetted the NCCA as part of establishing the APP licensure program.

Mr. Lippe stated that the board should give themselves flexibly to approve other accrediting agencies in the future and asked if there would be any concerns in light of the North Carolina ruling. Ms. Freedman and Ms. Kellogg stated that as this is a statutory change there would be no antitrust issues.

Dr. Castellblanch and Chairperson Weisser expressed concern with asking the author to amend the bill without further researching other potential accrediting agencies.

Mr. McAllister, representing PTCB, stated that currently there are very few accreditation agencies working in this area.

Motion: Support SB 952. Ask the author to amend the language to add the ability for the board to approve other accrediting agencies.

Support: 7 Oppose: 1 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch		x		
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

c. Demonstration of the Video Instructions for Pharmacy Technician Applications

Chairperson Weisser reported that the committee viewed a video that was produced by board staff to provide instructions to pharmacy technician applicants.

It was noted that board staff would send a link to the video to the board members.

d. Consideration of Proposal to Allow Automated Dispensing Machines to Replenish Medications Administered by Fire Departments and Other Emergency Medical Services Personnel

Chairperson Weisser reported that for over two years, board staff has been discussing possible options for refilling the ambulances operated by fire departments, and more recently emergency medical services (EMS), from a stock of drugs that would be stored in an automated drug storage device. The drugs would be owned by the fire department or EMS agency.

Chairperson Weisser explained that since the last time this issue was discussed, the committee learned that the fire departments and EMS have found a solution to this issue and the board no longer needs to be involved at this time.

A representative from the Department of Public Health explained how fire departments currently oversee their automated drug devices and the drug inventory.

Dr. Gray, pharmacist, noted that each location where one of the devises is being used must be registered with the DEA.

e. Discussion and Consideration of Ownership Structures for Pharmacies, including Trusts

Chairperson Weisser reported that the board tracks the beneficial interest of business

owners for pharmacies, whether they be natural persons or entities. Board regulation specifies the reporting of a transfer in the beneficial interest in the business and specifies the threshold as to when a change of ownership must be submitted to the board.

Chairperson Weisser explained that Business and Professions Code section 4035 defines a "person" as follows: *"Person" includes firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision.*

Chairperson Weisser stated that when processing a pharmacy application, the board identifies and records all levels of ownership of the applicant business. This is done through a careful analysis of all information submitted in support of the application, and often times identifies inconsistencies with respect to the ownership reported. For some, what is initially reported as (what appears to be) a simple, two- or three-level ownership structure, often turns out to be multiple levels of ownership with multiple stakeholders when staff uncovers details and facets of ownership.

Chairperson Weisser explained that board staff has also identified applications where (revocable or irrevocable) trust(s) is/are reported as owners of the applicant business. Pharmacy Law does not currently recognize a "trust" as a person to which the board is authorized to issue a license; however, in researching older licensing records, some trusts have been found to be on record as holders of the beneficial interest in some existing licenses.

Chairperson Weisser reported that at the March 2016 committee meeting, the committee discussed and considered appropriate ownership structures for pharmacies, to include whether or not a trust should be recognized within the ownership structure and determined that more information on trusts is needed prior to making a recommendation to the board.

Ms. Kellogg explained that as with other ownership structures, trusts can be used as a legitimate form or ownership, however they can be manipulated to hide ownership. She recommended that the board carefully consider this issue and determine if they want to allow trusts to own pharmacies and if so what information should be reported to the board.

Ms. Herold explained that a statutory change would be required if the board decided to change its ownership requirements to allow trusts to own pharmacies.

The board asked if there are any pending applications with trust ownerships. Ms. Herold stated that there are twelve pending applications that are being held while the board considers the issue.

Chairperson Weisser stated that Matthew Heyn from the Department of Justice will be attending the next Licensing Committee meeting to provide the board with additional information pertaining to trusts.

f. Discussion and Consideration of Allowing Pharmacists to be Shareholders, Officers or Directors of Professional Corporations, Medical or Otherwise, Pursuant to the Moscone-Knox Professional Corporation Act

Chairperson Weisser explained that as part of the board's sunset review, a Background Paper was prepared for the Joint Oversight Hearing held March 14, 2016, wherein staff for the Senate Committee on Business, Professions and Economic Development and the Assembly Committee on Business and Professions identified issues and provided recommendations regarding the Board of Pharmacy.

Chairperson Weisser reported that one of the issues identified in the oversight committee's Background Paper (Issue #7) questions whether or not pharmacists should be included on the list of individuals that may be a shareholder, officer, or director of a medical corporation.

Chairperson Weisser stated that at the March 2016 committee meeting, the committee made the following motion to bring forward to the board.

Committee Recommendation: Pharmacists should be added to the list for medical corporations. In addition, the Board should examine the other professional corporations authorized by the Moscone-Knox Professional Corporation Act and determine whether there are others to which it makes sense for pharmacists to be added as officers, shareholders, or directors.

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

Committee Recommendation (motion): Pharmacists should be added to the list for medical corporations. In addition, the Board should examine the other professional corporations authorized by the Moscone-Knox Professional Corporation Act and determine whether there are others to which it makes sense for pharmacists to be added as officers, shareholders, or directors.

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

g. Licensing Statistics

Chairperson Weisser briefly reviewed the licensing statistics as provided in the board meeting materials.

Dr. Castellblanch asked how many pharmacies the board licenses. Ms. Herold responded that there are approximately 7,100 licensed pharmacies.

h. Competency Committee Report Including Semi-Annual CPJE Examination Statistics

Chairperson Weisser reported that the Competency Committee held two meetings in the winter of 2016 to continue examination development.

Chairperson Weisser stated that the competency committee continues to recruit for pharmacists specializing in institutional or community practice to serve as subject matter experts and assist the board with examination development activities. He noted that interested individuals are encouraged to submit an application.

Semi-Annual CPJE Examination Statistics

Chairperson Weisser explained that examination scores for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and North American Pharmacist Licensure Examination (NAPLEX) are released twice a year, generally in spring and fall.

Chairperson Weisser reported that the semi-Annual CPJE statistical report for October 1, 2015, through March 31, 2016, reflects the overall pass rate for the CPJE was 65.3%. The pass rate for graduates from the California Schools of Pharmacy was 72.7%. The overall pass rate for the NAPLEX was 89.6%.

The board briefly discussed the exam statistics.

Dr. Gray, pharmacist, asked the board when the new content outline would be implemented. Ms. Herold responded that the board began using the new content outline on April 1, 2016.

Ms. Butler stated that board previously asked the Competency Committee to consider adding more law questions to the exam. Mr. Law reported that the committee had taken this into consideration during their exam development meetings.

i. Future Committee Meeting Dates for 2016

Chairperson Weisser announced the following future committee dates. He noted that the May meeting could potentially be re-scheduled.

- May 26, 2016
- September 1, 2016

XXII. Closed Session

President Gutierrez adjourned the meeting to closed session at 12:42 p.m.

XXIII. Reconvene Open Session

Vice President Veale returned the meeting to open session at 2:40 p.m. and adjourned the meeting at 2:43 p.m.