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: February 24-25, 2016

LOCATION: Department of Consumer Affairs
1st Floor Hearing Room
1625 North Market Blvd
Sacramento, CA 95834

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
Albert Wong, PharmD
Gregory Murphy, Public Member (2/24 only)
Ryan Brooks, Public Member (2/25 only)
Ramon Castellblanch, Public Member (2/25 only)
Ricardo Sanchez, Public Member

BOARD MEMBERS NOT PRESENT:

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Janice Dang, Supervising Inspector
Joshua Room, Deputy Attorney General
Laura Hendricks, Staff Analyst

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

Wednesday, February 24, 2016

Call to Order 10:05 a.m.

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

President Gutierrez called the meeting to order at 10:05 a.m.

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

II. Public Comments on Items Not on the Agenda

Victor Law asked the board to research ways that the board can work with technology companies to standardize various forms and labels used in pharmacies. The board decided to place this item on the next Communication and Public Education Committee agenda.

Dr. Albert Wong asked board staff to determine (via survey or inspection) how many consumers are using the call-in translation services used in pharmacies.

Dr. Steve Gray, from Kaiser, asked the board to look at the method that the Board of Registered Nursing uses to notify employers when a nurse is disciplined. Ms. Herold noted that they are using a different information system than the board currently uses.

III. Approval of the October 28-30, 2015, November 11, 2015, and January 19, 2016, Board Meeting Minutes

Motion: Approve the October 28-30, 2015 minutes.

There were no comments from the board or the public.

M/S: Weisser/Veale

Support: 9 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: Approve the November 11, 2015 minutes.

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

M/S: Veale/Weisser

Support: 9 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 noted that there was a typo on page thirteen of the January 19, 2016, minutes.

Motion: Approve the January 19, 2016 minutes.

M/S: Lippe/Weisser

Support: 9 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			

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

There were no 50-year pharmacists in attendance.

V. Update from the Department of Consumer Affairs

Christine Lally, Deputy Director of Board and Bureau Relations, provided the board with an update on the BreEZe system. She reported that with Release Two there are now 18 programs using the BreEZe system. Ms. Veale asked how many more programs need to be added to the BreEZe system. Ms. Lally reported that there are still 22 programs that need to be added, including the Pharmacy Board.

Ms. Lally explained that this year the department is submitting the annual Form 700's using an online system. She asked members who had not already done so to submit their Form 700's using the online system.

Ms. Lally noted that the DCA director is attending the Little Hoover Commission meetings on behalf of DCA board's and bureaus. She added the next meeting will be held March 30 in Cover City and stated that the department will update the board on the activities of the commission.

Ms. Lally reported the following appointments to the Department of Consumer Affairs.

- Tracy Montez – Chief of Programs and Policy Review.
- Veronica Harms – Deputy Director of Communications
- Lori Ajax – Chief of Medical Marijuana Bureau

Mr. Greg Lippe asked if the department expects there to be crossover between the board and the Medical Marijuana Bureau. Ms. Lally responded that at this time the bureau has been charged with developing the program and regulations relating to medical marijuana.

Ms. Lally reminded the board that there is required training all board members must complete. President Gutierrez asked board staff to notify members of any outstanding training.

VI. Discussion and Consideration of the Effective Date for the Approved Amendments the Compounding Regulations

President Gutierrez reported that at the January 19, 2016, Board Meeting the board adopted the proposed regulatory changes to the long-pending compounding regulation (Title 16 CCR sections 1735 et seq., and 1751 et seq.). She added that the board also delegated the authority to the executive officer to make technical or non-substantive changes as may be required to complete the rulemaking file.

President Gutierrez stated that staff is currently compiling the rulemaking file for final review by the administration and anticipates this will be completed by early March 2016.

President Gutierrez explained that no effective date for the regulation was previously discussed or set by the board. She explained that typically, following approval by the Office of Administrative Law regulations become effective at the next of the following dates: January 1, April 1, July 1 or October 1.

Ms. Herold stated that because of the importance and impact of the regulation the board is being asked to select the effective date. Options Include:

1. Immediately upon approval by the Office of Administrative Law (this is being done for the SB 493 regulations).
2. At the next quarterly implementation date (January 1, April 1, July 1 or October 1).
3. A specific date established by the board.

Ms. Veale stated that the regulation has taken so long to finalize that she would like the regulation to take effect immediately upon approval by the Office of Administrative Law.

Motion: Make the compounding regulation effective immediately upon approval by the Office of Administrative Law.

M/S: Veale/Weisser

Ms. Herold stated that due to the complexity of the regulation the board should consider if an immediate effective date is in the best interest of the profession and consumers.

President Gutierrez asked board staff to create a guidance document to clarify the more complex sections of the regulation.

Mr. Weisser stated that when past regulations took effect staff used discretion to determine if a licensee needed to be educated on the new regulation in order to come into compliance, or if discipline should be taken against the licensee. Ms. Herold explained that inspectors are always looking to bring licensees into compliance with the law in order to protect consumers. She added that inspectors use their professional judgement to determine if the licensee can

be educated and allowed to correct the violation, or if the violation is so egregious that discipline is required.

Ms. Freedman stated that if the board believes that licensees need to be educated on the new compounding regulation, she would recommend delaying the implementation date to allow for the education to occur.

Ms. Veale asked if delaying the implementation date would harm consumers. Ms. Herold responded that the board has been able to use existing law to regulate sterile compounding. She added that the board can order an immediate cease and desist if it discovers compounding practices that will cause public harm.

Dr. Steve Gray, representing Kaiser, asked the board to set an implementation date in the future (not immediately upon approval by the Office of Administrative Law) to give licensees time to make changes to their current practices to come into compliance with the new regulation. He also asked the board to set a specific effective date because it will allow hospitals to secure the funding to begin construction on any structural changes required.

Brian Warren, representing the California Pharmacist Association, recommended the board make the effective date January 1, 2017, to allow board staff to educate licensees and to give pharmacies time to come into compliance with the new regulation. Ms. Herold noted that it would likely take the Office of Administrative Law until October 2016, to approve the regulation.

Robert Ratcliff, pharmacist and former board inspector, recommended setting a specific effective date to allow the board's staff to educate licensees.

Mr. Law stated that the board has been working on this regulation for a long time and licensees should have already begun working towards compliance with the new law. He recommended setting the effective date for 30 days after the regulation is approved by the Office of Administrative Law.

Ms. Butler stated that she would support setting the effective date for January 1, 2017.

Supervising Inspector Janice Dang stated that the board can educate licensees by creating guidance documents, publishing articles in the *Script* newsletter, posting information on the board's website and providing presentations to licensees on the new regulation.

The board elected to change prior motion to set the effective date of the regulation to January 1, 2017.

The board heard comments from the public supporting a January 1, 2017 effective date.

Motion: Set the effective date for the compounding regulation for January 1, 2017.

M/S: Veale/Weisser

Support: 9 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 11:15 a.m. resumed at 11:37 p.m.

VII. Consideration of Proposed Changes to the Board's Disciplinary Guidelines and Title 16 California Code of Regulations Section 1760

Chairperson Law explained that Title 16, California Code of Regulations section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action.

Chairperson Law reported that Business and Professions Code (B&PC) section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The committee was charged with formulating uniform and specific standards in several areas for dealing with substance-abusing licensees.

Chairperson Law stated that in early 2011, the board directed staff to restructure and update its Disciplinary Guidelines. Subsequent to this, in April 2011, the uniform standards required in B&PC section 315 were finalized. Over the course of the next year, the board initiated a rulemaking to update the disciplinary guidelines and incorporate the SB 1441 uniform standards as it deemed appropriate considering comments from counsel and staff on how best to proceed.

Chairperson Law explained that in addition to the standards themselves, the board also received opinions on what was required to implement the uniform standards. The board was provided a copy of a legal opinion from the Legislative Counsel Bureau, executive summary issued by the Office Of the Attorney General as well as an implementation memo from Doreatha Johnson, Deputy Director of Legal Affairs, DCA. The opinions provided did not

provide consistent guidance and as such the board requested a formal legal opinion from the Office of the Attorney General in January 2013. He noted that the board received a response to this request on April 8, 2015.

Chairperson Law reported that during the April 2015 Board Meeting, the board briefly discussed the new legal opinion and was advised that the new opinion provides for some discretion by the board. This is contrary to prior guidance provided to the board. As such, members were advised that staff and counsel would work on implementation options and discuss the issue during the June Meeting.

Chairperson Law explained that during the June Board meeting, an ad hoc committee was established to allow a complete review of the proposed implementation strategy. He noted that the ad hoc committee met on two occasions and made recommendations.

Chairperson Law stated that following the work of the ad hoc committee, during the July Board meeting, the board was presented with recommended changes to the guidelines. He explained that the proposed changes included three types of changes:

1. Consolidation of license types within the guidelines to improve ease of use.
2. Revisions to implementation of/or modifications to conform with the standards
3. Revisions to improve our ability to monitor licensees on probation with the board.

Chairperson Law reported that after discussion the July meeting, the board voted to initiate the 45-day comment period.

Chairperson Law stated that during the October Board Meeting, the board reviewed the comments received during the 45- day comment period as well as recommendations provided from staff. Based on the board's discussion, the board voted to make additional changes to the guidelines in response to comments received and recommendations offered and directed staff to initiate a 15-day comment period.

Chairperson Law explained that the 15-day comment period concluded on January 6, 2016, and three comments were received in response to the comment period. Chairperson Law noted that board staff has reviewed the comments and does not believe that additional changes are warranted for the reasons stated below.

Note: a summary of the comments received are provided below.

1. Comments submitted by R. Marks were previously considered by the board during the October Board Meeting. The board amended the guidelines to address one of the comments, but rejected the additional comments.
2. Comments offered by CVS are outside the scope of the 15-day comment period.
3. Comments offered by Ms. Harwood could be considered outside the scope of the 15-day comment. Further, the comment offered by Ms. Harwood (which staff believes is

actually included in term 27) provided for specific prescription coordination requirements. A separate term that the board could use if it deemed such provisions were necessary.

The board briefly discussed the comments received and determined that the language did not need to be amended based on the comments.

Motion: Adopt the amendments to the regulation and Disciplinary Guidelines as presented at the October 2015 Board meeting.

M/S: Veale/Murphy

Support: 9 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			

VIII. Licensing Committee

Chairperson Weisser provided the board with a summary of the committee's efforts at the January 6, 2016, meeting as follows.

a. Discussion of the 2014 National Pharmacist Workforce Study Conducted by the Midwest Pharmacy Workforce Research Consortium

Chairperson Weisser explained that the Midwest Pharmacy Workforce Research Consortium (MPWRC) completed the 2014 National Pharmacist Workforce Study. He explained that the purpose of the study was to determine contemporary demographic practice characteristics and quality of work-life of pharmacists in the United States.

Chairperson Weisser reviewed some of the statistics on pharmacists' satisfaction as provided in the report and recommended that board members take time to review the report in its entirety.

The board discussed the fact that in the report pharmacists note that many of the duties and quotas pharmacists are required to meet adds stress to pharmacists. It was also noted that stress levels differ based on the practice setting.

Dr. Albert Wong noted that the board needs to keep in mind the pharmacists' stress levels when the board creates new regulations that will place more responsibility on the pharmacists. President Gutierrez noted that the board only promulgates regulations that are necessary for consumer protection.

The board recessed for a break at 12:00 p.m. and resumed at 12:36 p.m.

b. Discussion of Pharmacy Technician Licensure Requirements and Practice

1. Pharmacy Technician Duties and Functions. The Board may discuss the 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. He noted that 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

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

2. Discussion of the Evaluation for the PTCB and ExCPT Examinations by the DCA Office of Professional Examination Services

   Chairperson Weisser explained that the Department of Consumer Affairs' Office of Professional Examination Services conducted a comprehensive review for the Pharmacy Technician Certification Board's (PTCB) Pharmacy Technician Certification Exam (PTCE) and the National Healthcareer Association's (NHA) Exam for the Certification of Pharmacy Technicians (ExCPT).

   Chairperson Weisser reported that the committee discussed the pathway of qualifying for licensure under Business and Professions Code section 4202(a)(4) to be certified by the Pharmacy Technician Certification Board and the OPES

comprehensive review between PTCB and ExCPT. Chairperson Weisser noted that based on the comprehensive review by OPES the committee believes the ExCPT has demonstrated that it meets the requirements to provide the pharmacy technician certification examination. However, the only pathway identified in statute at this time is the PTCB.

Everett McAllister, CEO of the PTCB, stated that the PTCB will be attending the next Licensing Committee meeting to provide a presentation on the PTCB exam.

Pat Whalen, representing the ExCPT exam, thanked the Licensing Committee for their guidance as they looked for ways to add the ExCPT exam in statue. He added that to do this they sponsored SB 952 which will be discussed during the Legislation and Regulation Committee report.

3. Presentation by the National Healthcareer Association (NHA) on the ExCPT Examination and Its Pharmacy Technician Workforce Study

Chairperson Weisser reported that the committee heard a presentation from the National Healthcareer Association (NHA) that administers the Exam for the Certification of Pharmacy Technicians (ExCPT). NHA provided an overview of the ExCPT examination including information regarding prerequisites for taking the examination, statistics on pass rates, comparison to the PTCB examination, and other information. Additionally, NHA provided information on its Pharmacy Technician Workforce Study.

President Gutierrez asked if the PTCB and ExCPT exam plan to expand the training provided to pharmacy technicians as the role of pharmacy technicians evolves. Mr. Whalen responded that the ExCPT exam tests to the requirements for technicians in each state and they are always updating their exam based on evolving practice. Mr. McAllister explained that recently the PTCB added training on sterile compounding and is constantly reviewing their exam for necessary updates.

At the request of the board Mr. Whalen and Mr. McAllister provided the board with high-level information on their respective exams, including qualification requirements, pass rates and the number of questions on each exam.

4. Employer Based Pharmacy Technician Training Programs and Impact of the New American Society of Health-System Pharmacists (ASHP) Accreditation Curriculum

Chairperson Weisser stated that the committee heard presentations from CVS and Walmart on their pharmacy technician training programs and the impact of the new American Society of Health- System Pharmacists Accreditation Curriculum.

Mr. McAllister reported that the PTCB has been working with the chain drug stores to ensure that their programs can meet the accreditation standards, thus allowing their trainees to take the PTCB exam.

5. Pharmacy Technician Qualifications and Requirements for Licensure. The board may discuss current qualifications and requirements for licensure as well as possible changes

Chairperson Weisser explained that the board has discussed at several meetings different facets of the pharmacy technician program in an effort to raise the bar for pharmacy technician applicants.

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

Chairperson Weisser noted that in the past, the committee received public feedback in support of increasing the knowledge base of pharmacy technicians, but not necessarily by increasing the minimum statutory educational requirements.

Chairperson Weisser stated that the committee discussed assessing the pharmacy technician licensure requirements and practice and will continue to review data provided by staff in regards to the pharmacy technician applications and will have further discussion at its next committee meeting on whether to develop additional education requirements for licensure.

Chairperson Weisser explained that the committee's recommendation to the board is to move forward with modifying existing Title 16 CCR 1793.6 pharmacy technician training programs to include requiring criminal background checks of new students. Chairperson Weisser read the committee recommendation as provided below.

Committee Recommendation:
To modify California Code of Regulations section 1793.6 to require all pharmacy technician programs prior to enrolling students into the program: 1) conduct a

criminal background check; 2) administer drug and alcohol testing; 3) be 18 years of age; 4) require to pass a final examination administered by the provider; and 4) provide proof to the board of the above.

Ms. Sodergren clarified that prior to enrolling a student into the training program the program must conduct a criminal background check, administer a drug/alcohol test and ensure the student is 18 years of age. The program must also administer a final exam that the student must pass prior to applying to licensure with the board.

President Gutierrez asked if the committee discussed specific requirements for the drug and alcohol screening. Mr. Room explained that this motion would allow staff to begin drafting the regulation language, which would include the specific requirements.

Dr. Steve Gray, representing Kaiser, spoke in support of requiring a final exam and requiring applicants be 18 years old. He offered his assistance as the board begins drafting regulation language.

A representative from a pharmacy technician school discussed the variations between pharmacy technician programs in the private sector and provided the board with information on the cost to complete a training program.

Mr. McAllister, representing PTCB, supported that board's proposal to require background checks prior to enrollment in a training program.

President Gutierrez asked if this regulation would only apply to applicants who completed their training in California. Ms. Freedman explained that the board staff would have to verify that the out-of-state training program met the requirements as set forth by the board.

Ms. Freedman noted that when drafting the regulation language the board would need to determine what it means to "pass" a background check.

Brian Warren, representing the California Pharmacists Association, asked if the requirements would apply to all types of training programs, i.e. ASHP accredited training programs, military training programs, and chain store training programs. Ms. Freedman stated that this would apply to all the training programs.

Mr. Warren asked the board to consider the fact that pharmacists and other healthcare providers do not have to complete drug and alcohol screening prior to licensure. He noted that defining drug and alcohol screening would be difficult.

President Gutierrez stated that the committee would need to determine what

convictions on a background check would be grounds for denying someone from enrolling in a program.

Committee Recommendation (Motion): Modify California Code of Regulations section 1793.6 to require all pharmacy technician programs prior to enrolling students into the program: 1) conduct a criminal background check; 2) administer drug and alcohol testing; 3) be 18 years of age; 4) require to pass a final examination administered by the provider; and 4) provide proof to the board of the above.

Support: 9 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			

6. Frequently Asked Questions (FAQs) on Criminal Convictions That Could Result in Denial of a Pharmacy Technician Application

Chairperson Weisser explained that the board's Criminal Conviction Unit (CCU) reviews criminal offender record information (CORI) received on applicants and licensees. This unit also responds to calls from applicants and licensees on what impact, if any, a particular conviction or act may have on the person's ability to receive or maintain a license. Anecdotally, the CCU indicates that the majority of callers are pharmacy technician applicants and licensees.

Chairperson Weisser reported that a copy of a draft document "FAQs for Applicants with Criminal History" is provided in the meeting materials. The document addresses the majority of the questions this unit receives. The board currently has various FAQ documents on its website for applicant references, such as FAQs for site applicants, FAQs for Pharmacy Technician Applicants, etc. He noted that staff has recommended that the committee consider making this FAQ document available on the board's web site as well.

Chairperson Weisser reported that the committee reviewed and recommends the

board to approve posting the criminal conviction FAQs on the board's website.

Chairperson Weisser stated that staff recently sent a notification to pharmacy technician training programs instructing the training programs to provide prospective students with information regarding criminal history reviews prior to enrolling a student in their pharmacy technician training program.

Note: A copy of the letter sent to the Pharmacy Technician training programs was provided in the meeting materials.

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

7. Development of Video for Pharmacy Technician Applicants

Chairperson Weisser explained that in an effort to address deficiency rates of pharmacy technician applicants, the board has tried various approaches to educate applicants, and to keep the pharmacy technician application up to date. To further these efforts, board staff has been working with the Department of Consumer Affairs to make a video designed to assist pharmacy technician applicants with the application process.

Chairperson Weisser reported that after drafting a script, the department filmed on two occasions in December; several board staff played roles in the video. He noted that board management reviewed the video and provided feedback to the DCA.

Ms. Sodergren noted that board staff who are involved in the processing of pharmacy technician applications were actors in the video.

Ms. Herold explained that once the video has been finalized, it will be available to post on the board's website and on the departments YouTube channel.

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

8. Overview of Board Discipline of Pharmacy Technicians

Chairperson Weisser reported that board staff reviewed pharmacy technician licenses over a four year period (FY2011/2012 through FY 2014/2015) and found that of those pharmacy technicians that had been disciplined, over 80 percent had qualified for licensure by completing a training program.

Chairperson Weisser noted that due to system limitations, the board's electronic records cannot parse out (of the "training program qualification") the various methods of qualification outlined in board regulation (16 CCR 1793.5). Staff

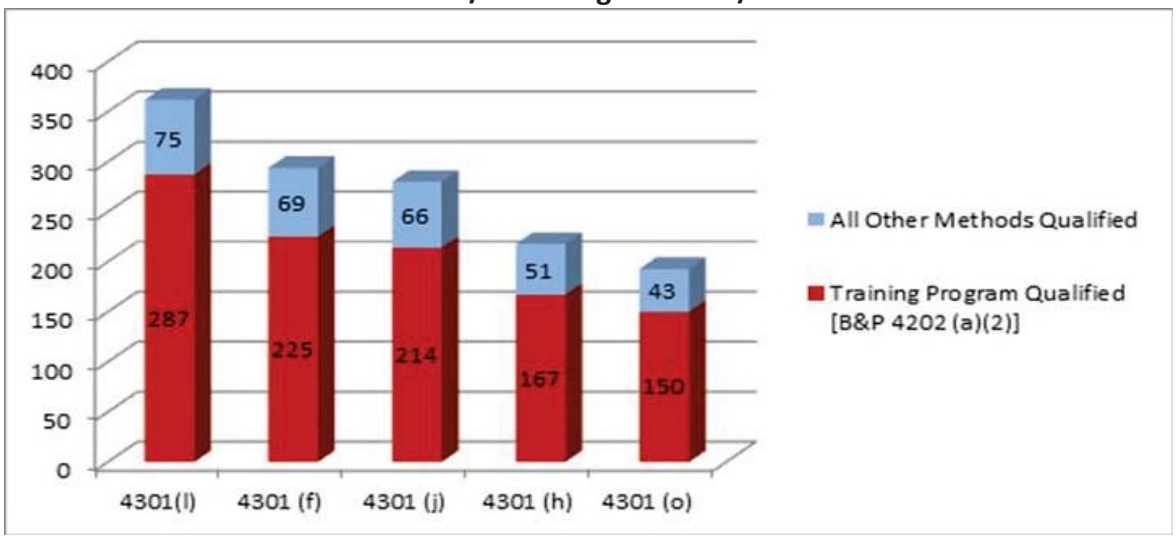
manually pulled pharmacy technician files to determine the type of training program the disciplined pharmacy technicians had to initially qualify for the license.

Chairperson Weisser explained that the charts below depict the top five (5) violations for which a pharmacy technician license was revoked during the four year period.

Note: The first table differentiates which of the licensees qualified for the license by meeting the training course provisions specified in Business and Professions Code section 4202(a)(2) versus all other methods of qualification for a license (B&PC 4202(a)(1), 4202(a)(3) and 4202(a)(4)).

Top 5 Violations for Which a Pharmacy Technician License was Revoked

FY 2011/12 through FY 2014/15



Legend: All references are to the California Business and Professions Code and all are deemed Unprofessional Conduct.

Section 4301(l) –Crime substantially related to the qualifications, functions and duties of a licensee.

Section 4301(f) – Commission of any act involving moral turpitude, dishonesty, fraud, deceit or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

Section 4301(j) – Violation of any of the statutes of California or of any other state, or of the United States regulating controlled substances and dangerous drugs.

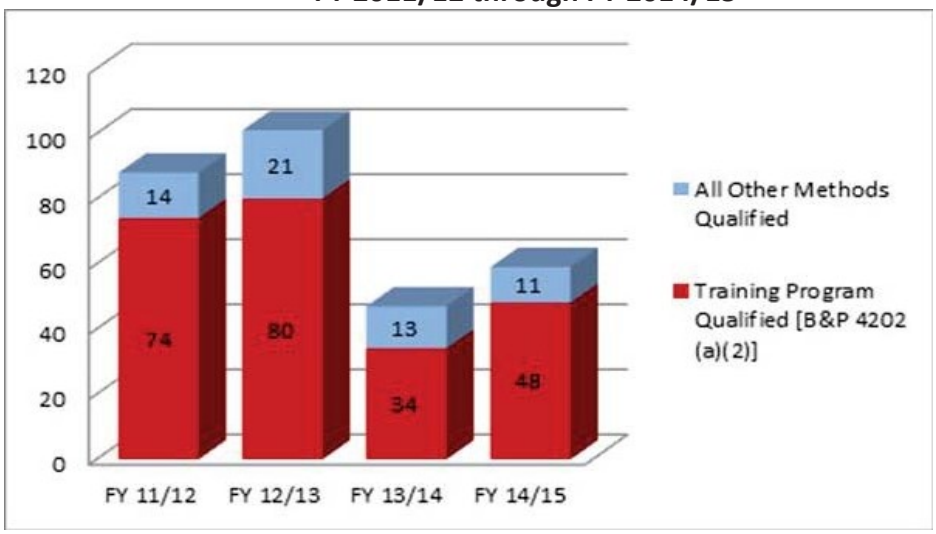
Section 4301(h) – Self-administration of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license

under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

Section 4301(o) – Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

Note: The chart below shows – of the 295 applicants the board denied – the method by which they were seeking to qualify for the license.

Denied Pharmacy Technician Applicants – Qualifying Methods
FY 2011/12 through FY 2014/15



The board discussed the statistics provided above.

President Gutierrez asked how many pharmacy technicians qualify through a training program. Ms. Herold responded that the majority of technicians qualify through a training program; she noted that staff would bring this information to the next committee meeting.

Robert Stein, from KGI School of Pharmacy, suggested that the board clarify the dollar amount threshold for traffic violations that would require applicants to disclose the violation to the board. Ms. Freedman noted that the dollar amount is specifically stated in regulation.

9. Update on the California Pharmacists Association (CPHA) and California Society of Health-System Pharmacists' (CSHP) Workgroup on Pharmacy Technician Job Duties

Brian Warren, with the CPhA, and Jonathan Nelson with CSHP, reported that since the Licensing Committee meeting the workgroup has met and begun analyzing pharmacy technician job duties. They noted that they will continue to report their progress to the board.

There were no comments from the board.

c. Competency Committee Report

1. Update on the Transition to the New Content Outline

Chairperson Weisser explained that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the CPJE examination. To complete this analysis, the committee recently developed a job analysis survey with the board's contracted psychometric firm. The survey was offered to specific, randomly selected California pharmacists (via postcard and a link to the board's Web site) in June 2014. There were 524 pharmacists who provided responses.

Chairperson Weisser stated that the survey resulted in the need to slightly change the content outline of the CPJE to ensure it remains valid for California. Under the leadership of the board's psychometric consultant, the Competency Committee revised the content outline.

Chairperson Weisser reported that the new content outline will be used to develop examinations administered after April 1, 2016. In order to provide for a seamless transition to the new content outline, the board developed a communication plan to ensure all impacted CPJE candidates are made aware of the upcoming change.

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

2. Committee Activities

Chairperson Weisser reported that the competency committee held two meetings in the fall of 2015 to continue examination development activities as well as implement the new CPJE Content Outline. Meetings are schedule for 2016 as well. 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. Subject matter experts primarily provide development and oversight of the CPJE. The CPJE consists of 90 multiple-choice items that tests competency in patient communication skills, pharmacy law and clinical knowledge.

Chairperson Weisser stated that practicing California pharmacists licensed within the last five years are particularly encouraged to apply to serve in this capacity. Experts generally meet five times annually for two days session. Attendance at each meeting is crucial. Experts are approved by the board and generally serve in this capacity for four years; however, individuals can serve in this capacity for a longer duration with approval of the board.

Chairperson Weisser explained that interested individuals are encouraged to submit an application including their curriculum vitae, a cover letter describing the applicant's pharmaceutical experience or practice, and three letters of reference from pharmacists familiar with the applicant's work. Please submit your applications to the board's address at the attention of CPJE Subject Matter Expert Recruitment.

Mr. Law asked President Gutierrez to consider finding another board member to replace him Competency Committee. President Gutierrez responded that she would take his request under advisement.

There were no comments from the public.

d. Implementation of Legislation that Impacts the Board's Licensing Operations Including Updates to Individual Licensing Applications in Response to SB 1159 (Individual Tax Identification Number) and AB 258 (Military Veterans)

Senate Bill 1159 Professions and vocations: license applicants: Individual Tax Identification Number

Chairperson Weisser reported that SB 1159 became effective on January 1, 2015, which requires licensing programs under the Department of Consumer Affairs (DCA) to begin accepting individual tax identification numbers (ITIN) no later than January 1, 2016, for applicants that cannot provide a US social security number.

Chairperson Weisser explained that the board has already been accepting applications with ITINs. Additionally, the following individual licensing applications have all been updated to include the ITIN and are available on the board's website as of December 30, 2015.

- Intern Pharmacist
- Pharmacist Examination
- Designated Representative
- Designated Representative-3PL
- Pharmacy Technician

Assembly Bill 258 State agencies: veterans

Chairperson Weisser reported that AB 258 became effective on July 1, 2014, which requires every state agency to include the question "Have you ever served in the United States military?" on its written forms.

Chairperson Weisser stated that the required information is on all the individual applications and the online renewals, but the board will have to update the pharmacy technician application through the rulemaking process to include this information. Until such time the rulemaking package is complete and approved the question is included as a separate insert for the pharmacy technician application.

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

e. Licensing Statistics

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

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

f. Future Committee Meeting Dates for 2016

Chairperson Weisser reported the following Licensing Committee dates for the remainder of 2016.

- March 30, 2016
- May 26, 2016
- September 21, 2016

The board recessed for a break at 2:00 p.m. and resumed at 2:18 p.m.

IX. Organizational Development Committee

a. Budget Update/Report

1. Budget Report for 2015/2016

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.

President Gutierrez explained that as of December 31, 2015, the board has expended $11,389,691 and taken in $12,797,258 in revenue.

President Gutierrez stated 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 explained 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. She noted that the board does not anticipate a decrease in these enforcement related costs in future years. The midyear augment will serve as a temporary fix until a more permanent solution is achieved.

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

2. Fund Condition Report

President Gutierrez reviewed the fund condition as provided in the board meeting materials. She explained 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. During the November 2015 board meeting, the board was provided with information about the analysis, methodology, etc. and subsequently was provided with a copy of the final audit on December 1, 2015, as part of the Sunset Report.

President Gutierrez stated that additional information on this issue is provided later in this report.

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

3. Governor's Proposed Budget for FY 2016/2017

President Gutierrez reported that on January 7, 2016, the governor released his proposed budget for FY 2016/17. She explained that included in this proposal was funding to make several limited term positions permanent. Provided below is a list of the positions.

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**

The board discussed how adding these positions would affect the board's fund. Ms. Sodergren explained that these positions are already included in the board's fund condition.

b. Possible Statutory Changes to Board Fees

President Gutierrez reported that as discussed during the November 2015 board meeting, the Department of Consumer Affairs completed an analysis of the board's fund condition and fee structure. This analysis was done to address the board's current structural imbalance and to determine if a statutory realignment of board fees was necessary.

President Gutierrez explained that the DCA evaluated the cost to deliver services for both application and renewal fees. The final analysis report was provided to board members as part of the board's Sunset Report. She noted that this analysis was conducted to provide the board with information necessary to make an informed decision in regards to addressing the board's fund condition and assessing the board's fee structure in the future.

President Gutierrez reported that as part of this analysis, the DCA determined the true cost of each fee based on the Board's resources dedicated to each application type. The goal of the analysis was to zero base the board's budget down to the services required for processing each of the board's initial and renewal applications. She noted that this included analysis of both direct and indirect costs for each of the license types.

President Gutierrez reported that during the November 2015 Board Meeting, the board suggested that public board member and CPA Greg Lippe review the analysis by the department, as well as delegated authority to the executive officer to work with the board's president and vice-president to establish a legislative proposal to recast the board's fees consistent with the findings of the department.

President Gutierrez reported that as requested, Mr. Lippe completed his review of the analysis and found the methodology used appropriate and consistent with this type of analysis.

President Gutierrez explained that as reflected in the proposal, only 18 fees will be immediately increased upon implementation of the legislation and three fees will be immediately reduced. In all other fees where a proposed change is being sought, the

current statutory maximum is becoming the new statutory minimum and a new maximum is established.

Ms. Sodergren provided the board with a summary of the proposal and explained that the proposed fees are designed to gradually re-build the board's reserves.

Mr. Law asked if staff looked at how much a pharmacy technician makes compared to other license types when they considered increasing their fees. Ms. Sodergren explained that recently there has been some legislation enacted that encourages programs to ensure that the fees assess are commensurate with the cost to deliver the services. Thus the methodology used focused on determining the cost to deliver the service for each license type.

Ms. Herold explained the various new programs implemented by the board that contributed to the need to increase the board's fees.

Motion: Approve the proposed fee bill (as provided in attachment 3 of the meeting materials).

M/S: Weisser/Lippe

Support: 9 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			

c. 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. This annual meeting is attended typically by the California's Board of Pharmacy's counterparts in the USA. California is thus designated as the host state for this meeting where more than 500 typically attend.

Ms. Herold encouraged board members to attend the meeting and stated that she would be seeking approval all interested board members to attend.

Members of the public spoke in support of board members attending the meeting in order to network with other states and discuss pharmacy issues that cross state lines.

d. Report on the Little Hoover Commission Public Hearing on Occupational Licensing

President Gutierrez explained that the Little Hoover Commission is an independent state oversight agency that was created in 1962. The Commission's mission is to investigate state government operations and – through reports, recommendations and legislative proposals – promote efficiency, economy and improved service.

President Gutierrez reported that the commission convened a meeting on February 4, 2016, to discuss occupational licensing and its impact California and Californians. There will be at least one additional hearing. Legislation may be an outcome of the commission's work in this area.

Ms. Herold reported that the commission was created to determine if board's actions are anti-competitive or are creating barriers to entry into a profession. Ms. Herold recommended that the board continue put protection of consumers first when they are considering taking action.

Mr. Weisser asked if new members receive training on who the board is mandated to protect. Ms. Herold stated that board members should know when they accept an appointment that they are charged with protecting the public; she added that during board member orientation this is also discussed.

e. Executive Officer Evaluation Process

President Gutierrez reported that the board's annual performance review of the Executive Officer will be conducted during the closed session portion of the April 2015 Board Meeting. She stated that each member would be provided with an evaluation form that they will fill out and provide to her prior to the April meeting.

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

f. Board Member Reimbursement and Mail Vote Information

President Gutierrez briefly reviewed the board member reimbursement and mail vote information.

g. Personnel Update

President Gutierrez reported that Rosalyn Hackworth resigned her position on the board on December 14, 2015. Rosalyn was appointed to the board by the Speaker of the Assembly on July 15, 2009. During her tenure on the board she served as a public member on several of the board's strategic committees, including serving as the chairperson for the Board's Communication and Public Education Committee. This position is currently is currently vacant. The board thanked Ms. Hackworth for her service on the board.

Ms. Herold briefly reviewed that staff recruitments and departures as provided in the meeting materials. Ms. Herold also thanked licensing staff for working to improve application processing times.

There were no comments from the public.

h. Future Board Meeting Dates

President Gutierrez announced the future board meeting dates as follows.

- April 27-28, 2016: Los Angeles
- July 27-28, 2016: Sacramento
- October 26-27, 2016: Location to be determined.

Board members asked staff to consider meeting locations in the bay area.

X. Communication and Public Education Committee

Chairperson Veale presented a summary of the committee's efforts at the January 20, 2016, meeting as follows.

a. Report on the Presentation by Department of Health Care Services Pharmacist James Gasper Promoting Naloxone and Buprenorphine Access

Chairperson Veale reported that Dr. James Gasper, BCPP, Psychiatric and Substance Use Disorder Pharmacist of the Pharmacy Benefits Division at the California Department of Health Care Services, presented to the committee on the current state of opioid addiction and opioid overdose deaths in California and nationally. Dr. Gasper discussed potential interventions that pharmacists can make today to improve access to treatment with the opioid overdose antidote naloxone and other forms such as buprenorphine.

Chairperson Veale reported that Dr. Gasper provided the committee with information indicating an increase in the number of opioid and heroin overdose deaths in the US. Specifically in California, the number of opioid deaths in northern rural California counties from 2008-2012 ranges from 11.2-23.9 deaths per 100,000 deaths where the statewide average is 4.9 deaths per 100,000 deaths. Dr. Gasper attributed this in part to a lack of

methadone maintenance in rural/northern counties in California. Solutions presented by Dr. Gasper to help solve this problem included safe prescribing practices, naloxone distribution, and access to treatment for opioid addiction.

Chairperson Veale noted that the committee found Dr. Gasper's presentation very informative and would be looking for ways to encourage pharmacists to talk with patients about opioid addiction and increase the number of pharmacies that provide naloxone.

Mr. Murphy stated that in his duty as law enforcement officer he had responded to opioid overdoses and he encouraged the board to continue to promote the use of naloxone.

Dr. Gray, pharmacist, suggested that the board work with the Medical Board to educate doctors on the availability of naloxone in pharmacies.

The board discussed issues with reimbursement for naloxone through insurance providers. President Gutierrez noted that naloxone is covered by Medi Cal.

b. Discussion on Development of Regulations to Allow for the Waiver of Patient-Centered Label Requirements (Business and Professions Code Section 4076.5(d))

Chairperson Veale reviewed the requirements for the waiver of patient-centered labels pursuant to Business and Professions Code section 4073.5(d). Currently, the process for a licensee requesting the waiver is to come before the committee for approval of the waiver which is then ratified by the full board. The development of the proposed regulations would allow for this decision to be made at the board staff level, provided the licensee has demonstrated meeting the required elements of section 4073.5(d).

Chairperson Veale reported that during the committee meeting Dr. Gray discussed issues with the accrediting requirement and the word "parenteral" included in (g)(2). He stated that "parenteral" is defined as "other than by enteral route by mouth or rectum."

Chairperson Veale reported that the committee made a motion to add the proposed language to the appropriate subsection of section 1707.5; incorporate the definition provided by Dr. Gray; add "include other accrediting agencies"; and delegate to the Executive Officer and board staff the authority to sign off on waivers.

Chairperson Veale explained that upon further evaluation, board staff recommends amending California Code of Regulation section 1703 to more efficiently achieve the committee's intent to delegating the authority to approve label waivers to the Executive Officer. Based on this additional review, the revised draft language is provided below.

Draft Proposal to Amend Section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1703. Delegation of Certain Functions.

The power and discretion conferred by law upon the board to receive and file accusations; issue notices of hearing, statements to respondent and statements of issues; receive and file notices of defense; determine the time and place of hearings under Section 11508 of the Government Code; set and calendar cases for hearing and perform other functions necessary to the business-like dispatch of the business of the board in connection with proceedings under the provisions of Sections 11500 through 11528 of the Government Code, prior to the hearing of such proceedings; the certification and delivery or mailing of copies of decisions under Section 11518 of said code; issue summary suspension orders or notices of suspension under Section 4311 of the Business and Professions Code; make changes to its regulations without regulatory effect pursuant to Title, California Code of Regulations section 100; and approve waivers pursuant to Section 4076.5 (e) are hereby delegated to and conferred upon the executive officer, or, in his or her absence from the office of the board, the acting executive officer.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4311, Business and Professions Code.

Ms. Freedman noted that if the executive officer determines that a waiver request needs additional information or clarification it will be brought to the committee for discussion and review.

Motion: Approve the language recommended by staff as provided above.

M/S: Butler/Law

Support: 9 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			

c. Consideration of Request for Waiver of Requirements for Patient-Centered Labels as Provided in California Business and Professions Code Section 4076.5(d) from Access IV

Chairperson Veale reported that the board received a waiver request from Access IV. At the January 2016 Communication and Public Education Committee, Ms. Ramona Moenter, General Manager presented Access IV's request for waiver grant an exemption to Business and Professions Code section 4076.5 (e) (2) and California Code of Regulation section 1707.5.

Chairperson Veale stated that the committee determined that Access IV does meet requirements outlined in section 4076.5 and recommended granting their waiver with the requirement that they report any complaints to the board.

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

Committee Recommendation (Motion): Recommend to the board that Access IV be granted a two year conditional waiver. Require Access IV to self-report complaints to the board.

Support: 9 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			

d. Consideration of Issuing a Revised Patient Consultation Survey Questionnaire

Chairperson Veale reported that at the October 2015 board meeting, President Gutierrez asked the committee to develop a broader patient consultation survey, as the initial survey conducted in early 2015 was intended only to start the conversation regarding patient consultation.

Chairperson Veale stated that the committee discussed entities that could assist the committee in the development of a survey including the Department of Consumer Affairs, schools of pharmacy, and associations for the survey to pharmacists. Steve Gray of Kaiser offered many contacts with survey expertise such as UCSB, Kaiser Family Foundation, and USC School of Business.

Chairperson Veale explained that the committee directed staff work with Dr. Castellblanch and research survey options. Board staff will continue to research and report at the March 2016 committee meeting.

Ms. Butler and Chairperson Veale noted that the committee is not sure if new information will be gained through the subsequent survey, however the committee wants to ensure that the survey is developed using appropriate methodology.

e. Update on Information on the Board's Website Regarding the State's Emergency Contraception Protocol

Chairperson Veale stated that at the October 2015 committee meeting, Dr. Sally Rafie, BCPS, from UCSD's School of Pharmacy requested that the committee reevaluate the emergency contraception information provided on the board's website. The committee requested Dr. Rafie provide letters of endorsements from reproductive organizations supporting her position that posting such information on the board's website would assist in public education. Chairperson Veale noted that, the committee also asked Dr. Rafie to provide the educational materials without reference to brand names, so as not to confuse the posting on the board's website with an endorsement for a particular brand of contraception.

Chairperson Veale reported that Dr. Rafie participated via telephone conference at the January committee meeting. Dr. Rafie presented a letter of support from Executive Director Kelly Cleland, MPA MPH of the American Society for Emergency Contraception (ASEC); President and CEO Jessica Arons of the Reproductive Health Technologies Project (RHTP); and Chair Brooke Griffin, PharmD, BCACP of the American College of Clinical Pharmacy Women's Health Practice & Research Network. Dr. Rafie also presented updated educational material for the board's website without brand name identification or pricing information.

Chairperson Veale stated that the committee motioned to post the Emergency Contraception: A Guide for Pharmacies and Retailers to the board's website. Mr. Weisser asked if the board needed to vote on every item that is placed on the board's website. Ms. Veale explained that the committee made the motion out of an abundance of caution. Ms. Freedman added that the executive officer has the authority to add or remove items on the board's website.

Committee Recommendation (Motion): Post the Emergency Contraception: Guide for Pharmacies and Retailers on the board's website.

Note: Mr. Schaad and Dr. Wong were not present for the vote.

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

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

Chairperson Veale reported that she and Dr. Castellblanch met with Webmaster Victor Perez and board management to discuss the progress of the website redesign. The new website design is scheduled for release in late spring 2016. Chairperson Veale stated that she and Dr. Castellblanch will continue to meet with board staff to oversee the progress of the redesign project.

Chairperson Veale noted that a new feature on the board's website will be the ability to translate the website into various languages.

There were no comments from the public.

g. Discussion on .Pharmacy Domain

1. Options for the Board to Distribute Public Information Via the Board's Website
   Chairperson Veale reported that this item was deferred by the committee until the board's website has been redesigned. After the completion of the website redesign the committee will discuss additional information to provide on the board's website.

2. Option of Sending a Letter of Support for .Pharmacy Domain

Chairperson Veale reported that board staff worked with NABP staff to draft a letter of support for the .Pharmacy program. She explained that during the meeting, the committee reviewed the requirements of the program and discussed if it would be appropriate for the board to support the program.

Chairperson Veale reported that after discussion the committee determined that it would be appropriate to send a letter of support to the NABP for their .Pharmacy domain initiative.

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

Committee Recommendation (Motion): Send a letter of support to the NABP for their .Pharmacy domain initiative.

Support: 9 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			

h. Discussion Regarding Prescription Label Translations of Directions for Use

Chairperson Veale reported that Assembly Bill 1073 was approved by the Governor on October 11, 2015. The bill requires a pharmacist to use professional judgment to provide a patient with directions for use of a prescription, consistent with the prescriber's instructions.

Chairperson Veale also explained that AB 1073 also requires a prescriber to provide translated directions for use, if requested, and authorizes the dispenser to use the translations made available on the board's website to comply with the requirement. Chairperson Veale noted that dispensers are not required to provide translated directions for use beyond what the board has made available. However, the bill does authorize a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated

directions for use. The provisions of the bill went into effect on January 1, 2016.

Chairperson Veale reported that the committee directed board staff to release a public service announcement immediately. The public service announcement was released on February 10, 2016. The release was translated into Chinese, Korean, Vietnamese, Russian and Spanish. Overall the release was sent to over 800 media outlets as indicated below:

- 499 media outlets received the English and translated press releases
- 272 media outlets received the Spanish translated press release
- 33 media outlets received the Chinese translated press release
- 17 media outlets received the Vietnamese translated press release
- 12 media outlets received the Korean translated press release
- 3 media outlets received the Russian translated press release

Chairperson Veale stated that the information was added to the board's website as a new topic on the homepage. Board staff contacted the Department of Consumer Affairs' (DCA) Public Affairs Office for assistance in disseminating the message through DCA's website, Facebook and Twitter account.

Chairperson Veale reported that the committee directed staff to develop a communication plan for information dissemination regarding the availability of written translations. The committee also discussed developing draft language for regulations requiring pharmacies to post information for consumers regarding the availability of written translations. Board staff will report their progress to the committee at the March meeting.

Dr. Wong asked if the board could provide information in additional languages. Chairperson Veale responded that this could be discussed at future committee meeting.

Dr. Gray, representing Kaiser, reminded the board that the translations can be provided either on the label or on a separate sheet of paper. Ms. Herold confirmed, and added that a news article would be provided in the next issue of The Script explained that the board prefers translations on the label, however a separate sheet of paper is acceptable.

i. Report on Development of FAQs Received From ask.inspector@dca.ca.gov

Chairperson Veale reported the board has implemented a program which gives licensees the opportunity to call and ask general questions to one of the board's pharmacist inspectors. This call-in service is available Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email request to a pharmacist inspector at ask.inspector@dca.ca.gov.

The board noted that licensees find this service valuable and asked staff to include the

FAQ's on the board's website. Ms. Herold noted that staff is working on compiling the FAQ's and they would need to be reviewed by the legal office prior to posting on the board's website.

j. CURES 2.0 Communication to Licensees

Chairperson Veale reported that the Department of Justice (DOJ) recently announced another milestone in its conversion to CURES 2.0. Specifically, the DOJ announced that beginning January 8, 2016, the upgraded prescription drug monitoring program is available. As part of this transition, on or after January 8, 2016, all current registrants are required to update their registration in the new 2.0 environment to ensure access to the system. This can be done electronically.

Ms. Veale stated that according to the DOJ, CURES 2.0 will be available to all registrants that use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system. Registrants that do not currently have access to one of those specified internet browsers will be able to continue to access the prior version of CURES until the legacy system's retirement, at that time the updated browser must be used.

Chairperson Veale reported the board is working with the DOJ to develop "Frequently Asked Questions" to assist registrants with understanding CURES 2.0. The board will send out updates via its subscriber alert system as it learns additional information from the DOJ. Questions regarding these changes should be directed to cures@doj.ca.gov .

Chairperson Veale noted that at the meeting a representative of CPhA reported to the committee that at least 10 pharmacists are having issues logging in and added that CPhA has limited contact with DOJ. The representative explained that the pharmacists are prompted to enter a new password; however, when they attempt to enter a new password there is an error screen. Board staff offered to help CPhA and any other licensees that experience this problem.

The board discussed issues that pharmacists are still having while trying to register in the system. Ms. Herold noted that many pharmacists have difficulty reaching representatives at the DOJ because they are not adequately staffing their phone lines.

Mr. Schaad asked if the board receives notice if a pharmacy or pharmacist is dispensing too many controlled substances. Ms. Herold responded that the board does not received such noticed, whoever they have staff that pulls statistics and analyses them for outliers.

Chairperson Veale stated that the committee will continue to receive updates on CURES 2.0 at their meetings.

k. Update on The Script Newsletter

Chairperson Veale reported Board staff has written the Winter issue of *The Script* newsletter. She noted that the Winter issue is currently under legal review, and will be issued soon.

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

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

Chairperson Veale reviewed the media activity and public outreach activities conducted by the board as provided in the meeting materials.

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

m. Future Committee Meeting Dates

Chairperson Veale provided the future committee meeting dates as provided below.

- March 23, 2016
- May 25, 2016
- July 6, 2016

XI. Closed Session

President Gutierrez adjourned the meeting to closed session at 4:12 p.m. to deliberate on disciplinary matters and to discuss the following pending litigation.

- Berjikian v. Board of Pharmacy
- IV Solutions, Inc. and Alex Vara v. Board of Pharmacy
- Sav On Corporation, et al. v. Board of Pharmacy

Thursday, February 25, 2016 8:31 a.m.

XII. Call to Order and Establishment of Quorum

President Gutierrez called the meeting to order at 8:31 a.m.

Board members present: Gregory Lippe, Allen Schaad, Amy Gutierrez, Deborah Veale, Stanley Weisser, Victor Law, Lavanza Butler and Ryan Brooks.

Note: Albert Wong arrived at 8:39 a.m., Ricardo Sanchez arrived at 9:17 a.m. and Ramon Castellblanch arrived at 9:40 a.m.

XIII. Petitions for Reinstatement of Licensure or Other Reduction of Penalty

Administrative Law Judge Marcie Larson presided over the petitions for reinstatement of licensure by Brandon Locke (TCH 77299) and Joseph Sheppard (TCH 61325).

XIV. Closed Session

The board recessed into closed session at 9:58 a.m. to deliberate on disciplinary matters, including the above petitions.

Note: Ricardo Sanchez left the meeting during closed session at 10:12 a.m.

At 10:50 a.m. President Gutierrez briefly returned the meeting to open session to announce that the board would deliberate on the following pending litigation during closed session.

- Berjikian v. Board of Pharmacy
- IV Solutions, Inc. and Alex Vara v. Board of Pharmacy
- Sav On Corporation, et al. v. Board of Pharmacy

President Gutierrez returned the meeting to closed session at 10:53 a.m.

The board resumed open session at 1:04 p.m.

Board members present: Gregory Lippe, Allen Schaad, Albert Wong, Deborah Veale, Amy Gutierrez, Ramon Castellblanch, Stanley Weisser, Victor Law and Lavanza Butler.

XV. Enforcement Committee Related Items

Part 1: New Items

a. Center for Disease Control and Prevention's Draft Guidelines for Prescribing Opioids for Chronic Pain, Including Staff's Letter of Support

President Gutierrez stated that on December 14, 2015, the Centers for Disease Control and Prevention published its Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain. President Gutierrez reported that Ms. Herold drafted and submitted a letter of support of the guidelines. She noted that a copy of the draft guidelines as well as the board's letter of support is provided in the board meeting materials.

Dr. Castellblanch thanked Ms. Herold for drafting and submitting the letter of support to the CDC.

There were no comments from the public.

Part 2: Enforcement Matters
President Gutierrez provided a report of the committee's efforts at the December 9, 2015 meeting as follows.

a. Report on the Presentation by the California Department of Health Care Services on California's Drug Utilization Review Program and the Medi-Cal DUR Educational Bulletin on "Morphine Equivalent Daily Dose to Prevent Opioid Overdose"

President Gutierrez explained that recent studies demonstrate that a patient's cumulative Morphine Equivalent Daily Dose (MEDD) is an indicator of potential dose-related risk for adverse drug reactions to opioids, including overdose. As a result, many state Medicaid Drug Utilization Review (DUR) programs have established recommendations for MEDD or opioid dose limitation.

President Gutierrez reported that the committee heard a presentation the Medi-Cal DUR program, and discussed the Medi-Cal DUR educational bulletin "Morphine Equivalent Daily Dose to Prevent Opioid Overdose." She noted that the committee also heard information from regarding the evaluation of MEDD in patient care.

President Gutierrez stated that the committee would like to post a link to the Medi-Cal DUR educational bulletin "Morphine Equivalent Daily Dose to Prevent Opioid Overdose" on the board's website.

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

Committee Recommendation (Motion): Post a link to the Medi-Cal DUR educational bulletin "Morphine Equivalent Daily Dose to Prevent Opioid Overdose" on the board's website.

Support: 9 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. Legislative Proposal for the Board of Pharmacy to Establish a List of Synthetic Cannabinoids that Would Be Illegal for Use in California

President Gutierrez explained that *Spice* (synthetic cannabinoids) and *bath salts* (synthetic cathinones) refer to two groups of designer drugs that have increased in popularity in recent years. These substances are created with *analogs* of commonly used illicit drugs. An analog is one of a group of chemical compounds that are similar in structure and pharmacology.

President Gutierrez explained that a form of synthetic cannabinoids, commonly referred to as "Spice" or "K2," is designed to affect the body in a manner similar to marijuana, but is not derived from the marijuana plant. These substances began appearing across the U.S. in 2008, and their popularity grew over the following years mainly because they could be sold legally and not detected in urinalysis drug tests.

President Gutierrez reported that synthetic cannabinoids are not currently identified using routine screening tests, and the creation of new products of this type makes it difficult to detect these chemicals or regulate products that contain these substances.

President Gutierrez noted that although these substances were made illegal nationally in 2012, synthetic cannabinoids and cathinones remain available, generally through black market internet sites, indicating a need for continued education, prevention, and enforcement.

President Gutierrez reported that the committee reviewed and discussed a legislative concept that would be authored as 2016 legislation by Senator Hernandez to have the Board of Pharmacy establish a list of synthetic cannabinoids and stimulants that would be illegal for use in California until incorporated formally as statutory modifications into Health and Safety Code sections 11375.5 and 11357.5.

Ms. Herold explained that Senator Hernandez is still working on a legislative concept; however, they are looking at options that will not require action by the board. Ms. Herold concluded that board staff will be available to Senator Hernandez if necessary.

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

c. 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 explained that at the Board of Pharmacy's April 2015 Board Meeting,

the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy. The study involves the use of an automated storage device from which staff and the families of a Sharp Hospital in San Diego, who opt in, may pick up their outpatient prescription medications. This device is located in a hospital and should be more convenient for employees than having to go to the community pharmacy. Consultation will be provided via telephone before medication can be dispensed to a patient.

President Gutierrez reported that this study was planned to start in June or July, 2015; however, at the September 9, 2015 Enforcement Committee meeting, Dr. Jan Hirsch, BS Pharm, PhD, spoke via telephone and anticipated the pilot study would not begin until December.

President Gutierrez reported that at the committee meeting Dr. Hirsch provided an update via telephone and stated that the study would go live on December 15, 2015. She provided a timetable which indicated that UCSD began a pre-kiosk 6-month data collection during the last quarter of 2015. She stated they would launch the device, enroll patients and refine data collection tools and processes during the first quarter of 2016, collect and review the data during the third quarter of 2016, and report back to the board with their results during the last quarter of 2016.

President Gutierrez explained that during the meeting the committee asked whether the drug class would be included in the data. Dr. Hirsch stated she thought they should have thought about collecting data at the drug class level and would be open to adding that data. The committee asked Dr. Hirsch to add the collection of drug class level to their study.

Dr. Castellblanch asked if the board would be closely monitoring the study. Ms. Herold responded that the committee would be receiving updates on the study at each of their meetings.

Ms. Veale asked how long the study would be. Ms. Herold stated that the board had approved an 18-month program.

There were no comments from the public.

Committee Recommendation (Motion): Request the collection of drug classifications as part of the study.

Support: 9 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			

d. Sunset Review Items Resulting in Possible Legislation

1. Regulation of Outsourcing Facilities by the Board

President Gutierrez reported that in 2012, medication contaminated by fungal material that was compounded by a Massachusetts pharmacy killed 65 and injured approximately 700 individuals in various states. In response, the California Board of Pharmacy initiated a review of its then sterile injectable compounding requirements that had been enacted in 2001. President Gutierrez stated that among other actions, the board sponsored legislation in 2013 to increase licensure requirements for sterile compounding pharmacies (SB 294, Chapter 565, Emmerson). The legislation expanded the definition of sterile compounding to include injectable medications, inhalation products and medication applied in the eyes. She explained that the law also eliminated accreditation by outside agencies as an alternative to licensure with annual board inspections, and the board began a massive upgrading of its sterile compounding regulations, a process that is nearing completion in late 2015.

President Gutierrez explained that the November 2013 enactment of the federal Drug Quality and Security Act (DQSA) responded to the 2012 compounding tragedy in a new way: this legislation created a new type of entity authorized to compound medications – the outsourcing facility. These generally large-scale production facilities are authorized to compound large quantities of medications for use by other entities, whereas a pharmacy generally compounds pursuant to a patient-specific prescription. Medications prepared by outsourcing facilities must be done under current good manufacturing practices (or cGMPs), which are more stringent than compounding requirements for sterile compounding pharmacies, since many patients in multiple locations can receive these medications that are not usually linked to patient-specific prescriptions.

President Gutierrez stated that currently California is licensing as sterile compounding pharmacies federally licensed outsourcing facilities located within or shipping medication into California. She explained that this is increasingly losing its viability as a regulatory solution. First, it does not recognize the federal outsourcing requirements

that permit large scale compounding. Second multiple states are moving to establish regulatory frameworks to license outsourcing facilities as separate entities, and some bar licensure of these facilities in their home states as sterile compounding pharmacies. This is currently an issue in Mississippi, will and be an issue in July in New Jersey. Several other states have pending legislation in this area as well.

President Gutierrez noted that in 2015, the board sponsored legislation (SB 619, Morrell) to license outsourcing facilities as separate entities both within and outside California to ship into the state. This bill was held in suspense by the Senate Appropriations Committee. President Gutierrez reported that in 2016, the board seeks to resume pursuing regulation of outsourcing facilities as separate entities. The Senate Business and Professions Committee will evaluate outsourcing facilities as part of its evaluation of the impact of the DQSA during the board's sunset review.

President Gutierrez explained that the sunset review committee staff indicated that establishing a licensing program for outsourcing facilities located within and outside California will be a sunset issue for the board to address. She added that board staff will be working with the committee staff to find a solution.

President Gutierrez reported that at the Enforcement Committee meeting public comment was received suggesting that any proposed legislation be specific when defining the provisions for a pharmacy and an outsourcing facility to do business at the same location.

President Gutierrez also clarified that the board does not allow two licenses to share the same premises. Some rare exceptions include a 3PL and a wholesaler as well as a wholesaler and a veterinary retailer. President Gutierrez explained that two different licensees need to have a hard wall between them, must have separate ingress and egress, and must maintain separate records.

Ms. Herold explained that outsourcing facilities operate differently than regular pharmacies and need to be regulated using different standards. She added that many states are adopting the outsourcing licensure model.

There were no comments from the public.

2. Registration of Automated Delivery Devices in Use

President Gutierrez explained that pharmacies are able to operate automated dispensing machines or devices in various settings away from the licensed pharmacy. This includes in:

- Skilled nursing homes and other health care facilities licensed under Health and Safety Code section 1250 (c), (d) or (k) (the devices are authorized under section

1261.6 of the Health and Safety Code, authority for pharmacies to do this in specific locations is specified in Business and Professions Code section 4119.1)

- Clinics licensed under section 4180 of the Business and Professions Code (the devices are authorized under section 4186) – these include licensed, nonprofit community or free clinics defined under Health and Safety Code 1204(a)(1), a clinic operated by a federally recognized Indian tribe or tribal organization referred to in Health and Safety Code section 1206(b), a clinic operated by a primary care community or free clinic operated on a separate premises from a licensed clinic and that is open no more than 20 hours per week as referred to in Health and Safety Code section 1206(h), a student health center clinic operated by a public institution of higher education such as college health center as referred to in Health and Safety Code section 1206(j).
- Hospitals may use Pyxis or Pyxis-type machines throughout a hospital to store medication under application of provisions in Title 22 that allow drugs to be stored in nursing stations. The Pyxis and like devices are considered secured storage units for drugs.

President Gutierrez explained that the board has no idea how many of these machines are in use, where they are in use, or which pharmacy is responsible for any machine.

President Gutierrez reported that the demand for additional use of devices is growing. As scheduled earlier at this meeting, a pilot study is underway that if proven valuable, would allow patients to pick up medication from machines not specifically located in a pharmacy.

President Gutierrez stated that at the September 9, 2015, committee meeting, staff suggested that a simple registration be established for pharmacies that operate each of these machines that identifies their locations, as a beneficial step in board oversight and enforcement. The list could be updated as needed via form submission to the board by a pharmacy adding, moving or removing a machine. This registration could operate much like the off-site storage waivers for records waivers. Then at annual renewal of the pharmacy, the pharmacy would update or confirm the list of machines it operates and where each is located. President Gutierrez noted that a regulation or statutory amendment is likely needed to establish this requirement.

The board reviewed the draft language provided by board staff.

Note: the draft language is provided immediately following these minutes.

President Gutierrez asked board staff to clearly define the term “devices” as there are many different types of devices that store medication. Ms. Sodergren explained that the language references the health and safety code that defines devices. President Gutierrez agreed that the definition of device in the health and safety code was

appropriate and did not need augmentation.

Ms. Veale asked the board to consider requiring inventory of the automated dispensing machines be taken a specific number of times per year.

Dr. Steve Gray, representing Kaiser, asked the board to consider creating separate requirements for automated dispensing devices that are being used in hospitals as they are more likely to be moved to different areas in within the hospital. President Gutierrez stated that the board may consider exempting the reporting of location changes for devices that are being used under a consolidated hospital license.

Dr. Gray stated that small hospitals that do not have a pharmacy (hospitals with less than 100 beds) may need different requirements than larger hospitals.

Dr. Gray noted that any machine that contains controlled substances would require DEA registration; he recommended that board address this requirement in the language.

Dr. Gray asked if unused medication in the machines could be transferred back to the hospital pharmacy. Ms. Herold confirmed that the drugs in the machine are part of the pharmacy inventory and could be transferred from the machine back to the pharmacy.

Stan Goldenberg, pharmacist, stated that most machines have an automated inventory program that sends inventory reports to the pharmacy. He recommended that the board consider this automated inventory feature when drafting the language.

Dr. Robert Stein, representing KGI School of Pharmacy, recommended that the board require hospitals to report the location dispensing devices that are being used in sites outside of the physical address of the main hospital.

The board asked staff to modify the draft language based on the discussion and bring it to the Enforcement Committee for further review and discussion.

e. <u>Proposal for Routine Inspections of Pharmacies Every Four Years</u>

Note: Mr. Brooks returned to the meeting at 2:07 p.m.

President Gutierrez explained that the board's charge is to regulate the pharmacy profession necessitates routine inspections of licensed facilities to confirm adherence to or identify failures in adherence to the requirements of pharmacy law. Failure to perform such inspections means that the board's enforcement program is reactive rather than proactive and relies solely on being advised of a potential violation of pharmacy law via a complaint or other information that would trigger an investigation.

President Gutierrez reported that for a number of years the board has wanted to inspect all facilities every three or four years. The board has been unable to complete these routine inspections of all facilities with any regularity, and in recent years has had to substantially reduce such inspections. She noted that while inspections are completed, inspections occur generally as part of the investigative process, prior to issuance or renewal of a sterile compounding license or as part of probation monitoring.

President Gutierrez stated that mandatory inspections on a routine but random basis would enable the board to perform compliance inspections to educate licensees about pharmacy law as well as identify problems early to prevent more serious consumer issues from developing. Like all inspections, such inspections would be unannounced.

President Gutierrez explained that compliance inspections provide an opportunity for board staff to answer questions about pharmacy law and to complete follow up inspections of facilities previously issued either citations or letters of admonishment to confirm compliance.

President Gutierrez reported that mandatory inspections once every four years would be an alternative to our current practice of conducting inspections principally to investigate problems (or inspect sterile compounders).

President Gutierrez explained that the board currently has 6,572 community pharmacies licensed in California. Some of these pharmacies have never been inspected by the board. The creation of a statutory mandate directing the board to perform inspections of all pharmacies every four years would require approximately 1,650 routine inspections annually. She added that over the last two years, the board completed an average of 1,215 inspections annually (routine plus investigation inspections).

President Gutierrez reported that after discussion, the Enforcement Committee made a motion to create a statutory mandate to complete random, unannounced routine inspections of resident pharmacies once every four years.
Ms. Herold explained that currently most pharmacies (with the exception of sterile compounding pharmacies) are only inspected if they are under investigation for a complaint.

Dr. Castellblanch expressed concern with the ability of the board to complete routine inspections with existing funding and staffing levels. The board discussed how many inspections each inspector would have to complete each year to meet the goal of visiting each pharmacy every four years.

The board asked staff to provide statistics on the types of violations and citations that inspectors find in pharmacies.

Dr. Dang, Supervising Inspector, explained the process that inspectors use to schedule inspections. She also noted that when inspectors are in locations the pharmacy staff uses it as an opportunity to ask law questions. The board encouraged the inspectors to look for ways to improve time their time management so that they can complete more routine inspections.

Brian Warren with CPhA supported the board using routine inspections to educate licensees and promote compliance.

Mr. Law stated that he agreed with the need for routine inspections; however he was unsure of the need to create a statutory mandate. Ms. Herold explained that she recommended creating the mandate to ensure that the board staff redirects resources as needed to meet the requirement.

Note: Mr. Weisser left the meeting at 2:16 p.m.

Dr. Castellblanch stated that he would support creating a statutory mandate.
Mr. Brooks asked if the board would need to increase funding. Ms. Herold responded that board staff believes that the inspections can be completed using existing funding and staffing levels.

The board discussed the need to consider ways to use technology and other recourses to increase productivity.

Board members expressed their support of conducting routine inspections, but questioned the need to make it a statutory mandate.

Megan Harwood, pharmacist, stated her support of increasing routine inspections.

President Gutierrez called for a vote on the committee's recommendation mandate routine inspections every four years.

Committee Recommendation (motion): create a statutory mandate to complete random, unannounced routine inspections of resident pharmacies once every four years.

Support: 5 Oppose: 4 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 2:45 p.m. and resumed at 3:00 p.m.

When the board returned from the break the members asked to conduct a vote to reconsider the prior motion.

Ms. Freedman recommended that the board members discuss the reason that they would like the vote to be reconsidered to avoid any issues with the Open Meetings Act and to ensure that the board's actions are transparent. Mr. Brooks and President Gutierrez explained that they had discussed their desire to have the board complete the routine inspections without creating a statutory mandate and therefor would like the board to reconsider the issue.

Motion: Reconsider the prior motion.

M/S: Brooks/Veale

Support: 8 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			

Ms. Freedman explained that the board could now revote on the motion to create a statutory mandate to complete random, unannounced routine inspections of resident pharmacies once every four years.

Dr. Castellblanch stated that he supports the board creating a statutory mandate to complete routine inspections every four years as it increases public protection.

President Gutierrez and Mr. Law stated that they support routine inspections; however they would like it to be completed via board policy rather than a statutory mandate. Mr. Brooks recommended that when creating the policy the board consider consequences for not completing the inspections.

Ms. Veale stated that this item should be sent back to the Enforcement Committee for further discussion.

Committee Recommendation (motion): create a statutory mandate to complete random, unannounced routine inspections of resident pharmacies once every four years.

Support: 1 Oppose: 8 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: Instruct the Enforcement Committee discuss the issue further and provide recommendations on how routine inspections could be completed every four years with existing funding and inspector staff.

M/S: Veale/Lippe

Support: 9 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			

f. Discussion of Items in the News

1. "Preventing Diversion in the ED" from www.pppmag.com, November 2015

Note: A copy of the article was provided in the meeting materials.

President Gutierrez explained that she added this item to the agenda for informational purposes. She explained that In the article, the author asserts that drug diversion by health care workers is quite common. The article reviews the techniques health care workers use to divert drugs and suggests multifaceted approaches for preventing and identifying diversion.

2. Settlement Agreement between the Drug Enforcement Administration and Massachusetts General Hospital for Drug Diversion

Note: A copy of the settlement was provided in the meeting materials.

President Gutierrez explained that earlier this fall, the U.S. Drug Enforcement Administration alleged that Massachusetts General Hospital failed to make and keep records required by the Controlled Substances Act, and failed to provide effective controls and procedures to guard against theft and loss of controlled substances from October 4, 2011 through April 1, 2015. She added that on September 28, 2015, Massachusetts General Hospital agreed to pay a settlement amount of $2,300,000.

g. Review of Controlled Substances Losses Reported to the Board

President Gutierrez reported that board discussions in recent meetings have included drug thefts from automated drug dispensing machines. Board staff was recently asked to tabulate how many controlled substances losses have been reported to the board from automated dispensing machines.

President Gutierrez explained that while there is no category listed on the DEA 106 report to capture this specific type of data, board staff reviewed all loss reports since January 1, 2015 and identified the following losses that had been identified in automated dispensing machines. She noted that when reviewing the data it is important to keep in mind:

1. The amount of controlled substances reported lost is usually lower than the actual amount of loss determined at the end of an investigation, and
2. Without a reporting category for this type of loss, some losses from automated dispensing machines could be reported under other categories.

Reports of Losses Related to Automatic Dispensing Machines (ADMs: Pyxis, Omnicell, Acudose, etc.) January 1, 2015 - November 30, 2015	Total # Reports	ADM Losses - Percent of Total Reports	Total Dosage Units Lost
180	2,267	8%	6,714

*total dosages (mLs converted into 5mL dosage units and added to solids)

Board of Pharmacy License Type for ADM Losses	# of Reports
Hospitals	177
Pharmacies	3
Total	**180**

Type of loss	# of Reports
Pilferage/Possible Pilferage or Not following proper procedures by nurse(s)	97
Unknown cause	78
Lost in transit to/from Automatic Dispensing Machine	2
Automatic Dispensing Machine error	1
Possible Pilferage by Pharmacy Technician	1
Possible Theft by patient	1
Total	**180**

President Gutierrez stated that staff will begin reporting all controlled substances losses reported to the board at each committee meeting.
President Gutierrez reported that after discussion the committee wanted more information about the controls in place in the pyxis machines. The committee invited vendors to present at the next committee meeting on the ways that the machines are designed to help prevent diversion.

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

h. Enforcement Options for Patient Consultation Violations

President Gutierrez explained that the Communication and Public Education Committee would be handling all items related to patient consultation.

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

i. Discussion and Update to the Board's Emergency Response Policy

Note: A copy of the board's current emergency response policy, an excerpt of the board meeting minutes where the policy was adopted and a copy of Business and Professions Code section 4062 was provided in the meeting materials.

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 board for evaluation and assessment to determine if changes to the policy are necessary.

President Gutierrez stated that at the October 28-29, 2015 board meeting, this item was referred to the enforcement committee for discussion.

President Gutierrez reported that at the committee meeting staff counsel, Laura Freedman, provided some background and discussed some of the challenges of the current policy. The current policy suggests that a meeting wouldn't need to be held pursuant to the open meeting act. Ms. Freedman advised amending the opening statement to specify that if the board is not able to establish a quorum, three members would be able to exercise the board's authority pursuant to Business and Professions Code section 4062. Ms. Freedman also stated that the board has other options including delegating the authority to a specific board member, perhaps the board president. She recommended that if the board chose that option, that it limit the authority to 14-30 days.

President Gutierrez explained that after discussion the committee made the recommendation to delegate authority pursuant to Business and Professions Code section 4062 to the board president for a period of 30 days.

Committee Recommendation (motion): Modify board policy to delegate its authority pursuant to Business and Professions Code section 4062 to the board president for a period of 30 days.

Support: 8 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks	x			

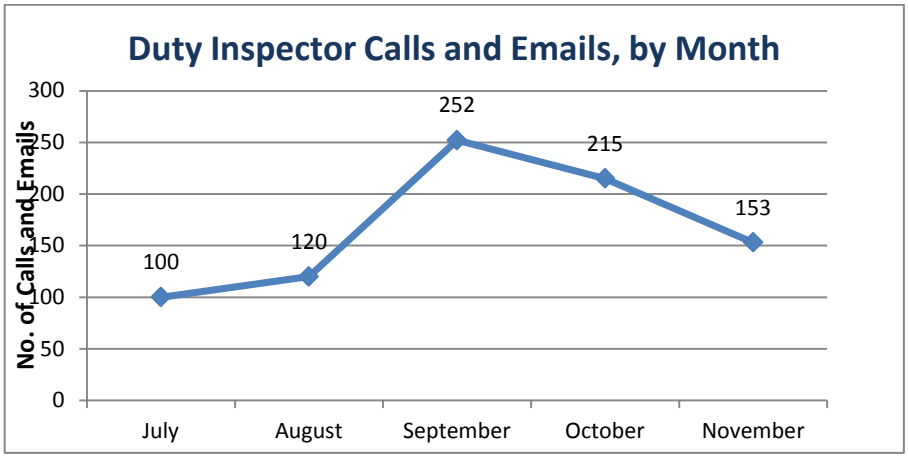
Butler	x			
Castellblanch	x			
Gutierrez			x	
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser				x
Wong	x			

j. Review of Duty Inspector Activities

President Gutierrez reviewed the following statistics:

Between July 1, 2015 and November 2015, board inspectors responded to 840 calls, an average of 168 calls each month. The highest month was September, with 252 calls. July was the lowest month, with 100 calls.

Chart: All Inspector Calls, Trends by Month



President Gutierrez reported that in September, the board expanded its inspector answer program in two ways. First, the board tripled the hours inspectors take phone calls from six hours each week to 16 hours. Second, the board added the "Ask.Inspector" email box. Board inspectors respond to emails five days a week. Additionally, in September, licensees were sent a Subscriber Alert to let them know of the expanded inspector hours.

Ms. Butler noted that she has received positive feedback on the "Ask Inspector" program.

There were no comments from the public.

k. Enforcement Statistics

President Gutierrez reported that the second quarter report of the Enforcement Statistics and SB 1441 Program Statistics were provided in the meeting materials for review.

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

l. Future Committee Meeting Dates

The committee has established the following enforcement committee meeting dates:

- March 2, 2016
- June 1, 2016
- August 31, 2016

Note: Mr. Law and Ms. Butler left the meeting at 3:30 p.m.

Part 3: Compounding Matters

a. 2015 FDA Intergovernmental Meeting on Drug Compounding and Drug Supply Chain Security Held in November 2015

President Gutierrez reported that on November 16 and 17, the Food and Drug Administration (FDA) convened the 2015 Intergovernmental Working Meeting on Drug Compounding and Supply Chain Security. This meeting had representatives from about 45 states and was intended to exchange information with states as the 2013 Drug Quality Security Act is being implemented.

Ms. Herold reported that the purpose of the meeting was to update states on emerging FDA policy regarding sterile compounding, outsourcing facilities and supply chain security requirements (the latter are the provisions that preempted California's e-pedigree requirements). She added that most of the meeting focused on compounding/outsourcing requirements, with the last quarter of the meeting focusing on the licensing requirements for wholesalers and third-party logistics providers.

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

b. Development of a Waiver Process from Building Standards Requirements Contained in Proposed Title 16 California Code of Regulations Sections 1751 et seq.

President Gutierrez reported that during the October 2015 board meeting, the board discussed and took action on proposed changes to compounding requirements. As part of this discussion, the board discussed the need to establish a waiver requirement for some of the structural requirements.

President Gutierrez stated that the waiver process would be discussed at a future Enforcement Committee meeting. There were no comments from the board or from the public.

c. Review of "USP <800>: Key Considerations and Changes for Health Systems," Hospital Pharmacy 2015; 501(1):941-949

President Gutierrez explained that on March 28, 2014, the United States Pharmacopeia and the National Formulary (USP-NF) published USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings, as open for public comment in the USP Pharmacopeial Forum (PF) 40(3).

President Gutierrez directed the board and the public to the meeting materials for information on some of the more important aspects of the regulations in USP <800>.

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

XVI. Legislation and Regulation Committee

Part 1: Legislation Report

Chairperson Lippe briefly reviewed the following legislation. It was noted that the Legislation and Regulation Committee would meet to discuss these bills in detail and provide recommended positions to the full board.

Note: full details on each bill were provided in the board meeting materials.

- AB 45 (Mullin) Household Hazardous Waste
- AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
- AB 1389 (Low) Epinephrine Auto-Injectors
- AB 12 (Cooley) State Government: Administrative Regulations
- Implementation of Assembly Bill 15 (Chapter 1, Statutes of 2015-16 Second

No action was taken by the board on any of the above bills and there were no comments from the public.

The board discussed SB 952 (Anderson) which was sponsored by the National Healthcareer Association and would amend section 4202 to modify the PTCB requirement. Specifically the new language would state that the individual is certified by *"a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National*

Commission for Certifying Agencies that is approved by the board."

The board decided to have the Legislation and Regulation Committee review this bill in detail and report back to the board with a recommended position.

Dr. Gray, representing Kaiser, noted the board would need to hold its next Legislation and Regulation Committee meeting in early March in order to meet legislative deadlines. The board agreed that the committee would need to meet prior to the April Board Meeting and it was suggested that the board look to schedule the committee meetings in conjunction with the legislative calendar.

Pat Whalen, representing the sponsor of the bill, offered to work with the board on any concerns the board may have with SB 952.

Motion: Direct the Legislation and Regulation Committee to review SB 952 and report back to the board with a recommended position.

M/S: Veale/Brooks

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			x
Weisser				x
Wong	x			

Part 2: Regulation Report
As no action was required by the board on any of the following regulations, Chairperson Lippe provided brief updates on the status of each regulation.

Note: full details on each regulation were provided in the meeting materials.

- Regulations to Add Title 16 CCR section 1746.2 related to Nicotine Replacement Products

- Regulations to Add Title 16 CCR section 1746.3 related to Naloxone Hydrochloride (Non-Emergency Adoption)
- Board Approved – Submitted for Administrative Review by the Department of Consumer Affairs or the Office of Administrative Law Proposed Regulations to Add 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.
- Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists.
- Proposed Regulations to Amend Title 16 CCR section 1703 (Title 1, CCR, Section 100 changes)
- 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 and/or Add Title 16 CCR section 1780 – 1786, et seq, related to Third Party Logistics Providers.

No action was taken by the board on any of the above regulations and there were no comments from the public.

Ms. Sodergren asked the board to return to CCR 1730, 1730.1 and 1749 (Advanced Practice Pharmacist) for additional discussion and action.

Ms. Sodergren reported that In July 2015, staff initiated a formal rulemaking to add Section 1730 to Title 16 of the California Code of Regulations to set out specific requirements for the type of training, documentation, and fees needed to be paid to obtain an Advanced Practice Pharmacist (APP) license. The provisions allow a pharmacist with an APP license to perform physical assessments, order and interpret drug therapy-related tests, refer patients to other health care providers, and initiate, adjust, and discontinue drug therapies and evaluate and manage diseases and health conditions in collaboration with other health care providers.

Ms. Sodergren stated that on January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board approved the final regulation text.

Ms. Sodergren explained that while compiling the rulemaking package to submit for review by the Department of Consumer Affairs and the Office of Administrative Law staff found comments that had been submitted during prior comment periods. Ms. Sodergren stated that staff was unable to confirm if the comments had been provided to the board for

review, so out of abundance of caution the comments are being brought to the board to review.

Note: The comments were provided to the board and the public to review.

The board reviewed the comments and determined that the substance of the comments had been addressed at previous meetings. Because the subjects of the comments were previously addressed, the board did not modify the language in response to the comments.

Motion: Process with the rulemaking without changing the language in response to the comments.

M/S: Veale/Brooks

Support: 6 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			x
Weisser				x
Wong	x			

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Veale/Brooks

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			x
Weisser				x
Wong	x			

XVII. Proposed Regulations to Add Title 16 CCR section 1730.2 related to Advanced Practice Pharmacists – Certification Programs

President Gutierrez explained that at the November 2015 Board Meeting, the board approved proposed text to add Section 1730.2 of Title 16 CCR, related to Advanced Practice Pharmacist – Certification Programs. The 45 day comment period began on December 25, 2015 and ended February 8, 2016.

President Gutierrez noted that the board received several comments during the comment period.

President Gutierrez stated that at this meeting the board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. She explained that the board's options were to:

1. Adopt the regulation as approved at the November 2015 Board meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

Note: The proposed regulation text as noticed on December 25, 2015 and a compilation document of the comments received during the 45 day comment period were provided in the board meeting materials.

Staff manager Lori Martinez summarized the comments received during the comment period.

Ms. Veale noted that the comments received were all on topics that had previously been discussed at both the board and committee level. She added that she does not feel that that language should be modified in response to the comments.

Brian Wilson with the Board of Pharmacy Specialties expressed his concern with the use of the term "certification."

President Gutierrez stated that the board has discussed the use of the terms "certificate" and "certification" extensively at prior meetings.

Jon Roth, from CPhA, stated that CPhA would support the board moving forward with the regulation without modifying the language.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Veale/Allen

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			x
Weisser				x
Wong	x			

XVIII. Proposed Regulations to Amend Title 16 CCR sections 1732.05, 1732.2, and 1732.5, related to Board Accredited Continuing Education

President Gutierrez reported that at the October 2015 Board Meeting, the board approved proposed text to amend Sections 1732.02, 1732.2, and 1732.5 of Title 16 CCR, related to Board Accredited Continuing Education. The 45 day comment period began on November 13, 2015 and ended December 28, 2015. Additionally, a regulation hearing was held on February 2, 2016.

President Gutierrez stated that the Board received several comments during the comment period and at the regulation hearing.

President Gutierrez explained that at this meeting the board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the October 2015 Board meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

Ms. Martinez reviewed the comments received and noted that many of the comments received expressed concern with the board dictating what areas of continuing education

licensees must complete.

Note: copies of each comment received were provided in the meeting materials.

Dr. Castellblanch stated that he would need to recuse himself from this agenda item due to a conflict. However, as the board would lose quorum without Dr. Castellblanch, Ms. Freedman recommended that using the "rule of necessity" Dr. Castellblanch could abstain from the vote rather than recusing himself entirely.

President Gutierrez expressed concern that the board may be over regulating continuing education and added that pharmacists should be allowed to use their professional judgement to determine what continuing education they need.

Mr. Lippe and Ms. Veale noted that pharmacists are only required to take six hours of continuing education in one of the listed subject areas; they still have the flexibility to choose other areas of continuing education.

Ms. Veale motioned to reject the comments and move forward with the regulation process.

Brian Warren, representing CPhA, agreed with the statement made by President Gutierrez.

Dr. Gray, representing Kaiser, stated that the board should simplify the list of required continuing education subjects. He recommended requiring a law and ethics course which would cover immerging issues and changes to pharmacy law.

President Gutierrez recommended sending the item back to the Licensing Committee so that they could review the content areas and determine if they are still appropriate or if they should be simplified. Ms. Veale agreed and withdrew her previous motion.

Motion: Direct the Licensing Committee to review the continuing education content areas and report back to the board with a recommendation.

M/S: Veale/Gutierrez

Support: 6 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			x
Weisser				x
Wong	x			

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

President Gutierrez reported that at the January 19, 2016 Board meeting the board approved a modified text and initiated a 15 day comment period. The 15 day comment period began January 27, 2016 and ended February 11, 2016.

Ms. Martinez explained that one comment was received during the 15 day comment period. The comment was from Dr. Goad and it recommended that the board modify the text to use the term "certificate" instead of "certification." Ms. Martinez added that Dr. Goad also stated in his comment that programs that only train on medications are not adequate. Note: Dr. Goad's comment was provided in the board meeting materials.

Motion: Accept the comments submitted by Dr. Goad and modify the language. Initiate a 15-day comment period.

M/S: Lippe/Schaad

President Gutierrez asked for public comment prior to the board voting on the motion made by Mr. Lippe.

Ms. Freedman explained that if the board changed the term "certification to "certificate" it would require a 15-day comment period.

Brian Warren, from CPhA, agreed with the board's motion to use the term certificate in place of certification. However he recommended that the board not modify the language in response to the second part of Dr. Goad's comment regarding the components of the training program. He explained that some training programs cover items that an APP pharmacist would not need to know in order to provide travel medicine to patients. Thus the board had previously modified that language to specify that the training program only needed to cover medication related components of the International Society of Travel Medicine's Body of Knowledge.

Steve Gray, representing Kaiser, stated that the board should not change the term "certification." He recommended leaving language as noticed because the word certification implies that a knowledge assessment was completed as part of the training. He added that by using the term certification it will encourage programs to add knowledge assessments to their training programs.

Mr. Warren noted that the program offered by CPhA does include an examination.

Ms. Freedman explained that for this section of the regulation, the board could use the term certification without ruling out current certificate programs, as long as they complied with Business and Professions Code section 4052.8.

After hearing the comments from the public and legal counsel Mr. Lippe and Mr. Schaad withdrew their motion.

Motion: Adopt the language as noticed without modifying it based on the comment received. Delegate authority to the executive officer to make any technical or non-substantive changes required to complete the rulemaking file.

M/S: Lippe/Wong

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			

Due to time constraints President Gutierrez explained that the following items would be agendized for the April Board Meeting.

- Proposed Regulations to Amend Title 16 CCR section 1744 related to Drug Warnings
- Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient-Centered Labels
- Proposed Regulations to Add Title 16 CCR section 1715.65 related to Reconciliation and Inventory of Controlled Substances
- Presentation on the North Carolina State Board of Dental Examiners v. Federal Trade Commission United States Supreme Court Ruling

President Gutierrez adjourned the meeting at 4:50 p.m.