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

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

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

DATE:	April 24-25, 2013
LOCATION:	DoubleTree - San Diego 1515 Hotel Circle South San Diego, CA 92108
BOARD MEMBERS PRESENT:	Stanley C. Weisser, RPh, President Randy Kajioka, PharmD, Vice President Ramón Castellblanch, Public Member Rosalyn Hackworth, Public Member Deborah Veale, RPh Greg Lippe, Public Member, Treasurer Amy Gutierrez, PharmD Victor Law, PharmD Ryan Brooks, Public Member Albert C.M. Wong, PharmD Lavanza Butler, PharmD
BOARD MEMBERS NOT PRESENT:	Shirley Wheat, Public Member Tappan Zee, Public Member
STAFF PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Robert Ratcliff, Supervising Inspector Kristy Shellans, DCA Staff Counsel Carolyn Klein, Legislation and Regulation Manager Laura Hendricks, Staff Analyst

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Note: The webcast for this meeting is available at:
http://www.pharmacy.ca.gov/about/meetings.shtml

Call to Order

President Weisser called the meeting to order at 9:38 a.m.

DRAFT

I. GENERAL ANNOUNCEMENTS

President Weisser announced 6 hours of continuing education credit would be available for attending the entire first day of the meeting.

President Weisser announced the presence of prior board members in the audience.

President Weisser introduced the newest board member Dr. Lavanza Butler.

President Weisser conducted a roll call. Board members present: Stanley C. Weisser, Randy Kajioka, Ramón Castellblanch, Rosalyn Hackworth, Greg Lippe, Amy Gutierrez, Victor Law, Ryan Brooks, Albert C.M. Wong and Lavanza Butler. Board members not present: Shirley Wheat and Tappan Zee.

Note: Deborah Veale arrived at the meeting at 10:25 a.m.

II. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

Mr. Subash Mediratta commented that pharmacists-in-charge at of out of state wholesalers should be licensed in California and noted it is common practice in other states.

III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF FEBRUARY 5 & 6, 2013

Discussion:
No comments provided by the board or public.

Motion: Approve the minutes of the February 5-6, 2013 meeting.

M/S: Lippe /Hackworth
Note: Ms. Veale was not present for the vote

Support: 9 Oppose: 0 Abstain: 1 (Butler)

IV. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

President Weisser recognized Mr. Martin Krishel for 50 years of service as a pharmacist.

V. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE REPORT

Chairperson Ryan Brooks provided the Communication and Public Education Committee Report from the April 19, 2013 meeting as follows.

a. Joint Forum to Promote Appropriate Prescribing and Dispensing Held February 21 and 22, 2013

Chairperson Ryan Brooks discussed the success of the Joint Forum to Promote Appropriate Prescribing and Dispensing which was held February 21- 22, 2013. Mr. Brooks noted that the committee discussed the increasing problem of prescription drug abuse by children/teenagers. The committee recommended that the board consider creating a subcommittee and producing a curriculum directed at schools to ensure that the message is getting out to school-aged children.

Discussion:

President Weisser commented that prescription drug abuse and the need for outreach is an area that the board needs to be involved in and agreed that a subcommittee should be formed.

Dr. Gutierrez commented that action items were created at the end of the joint forum, and asked if the board could be provided with them.

Ms. Herold answered that there is an action item list, and added that the Medical Board and Board of Pharmacy staff had reviewed the action items and would be collaborating on future outreach opportunities.

Ms. Herold added that there is a lot of public interest in prescription drug abuse and the DEA has an existing program that does outreach with schools and noted that the board could leverage the use of this program.

Mr. Castellblanch noted that research shows that the age group most likely to die of a prescription drug overdose is 25-45 years old. He also added that prescription drug abuse is also a major issue in the workplace and with veterans.

Dr. Kajioka commented that a study indicated that prescription drug overdoses have killed more people than car accidents.

Dr. Darlene Fujimoto provided public comment and shared that that 50% of those in attendance at the joint forum were enrolled in CURES, which is well above the norm. She also noted that there were a lot of pain specialists in attendance, which shows that many of those who work in the industry are looking for answers. Dr. Fujimoto also recommended that the board partner with existing programs that work with schools on drug abuse awareness and stated that the board should continue to encouraged the use of CURES.

Dr. Gutierrez agreed with Dr. Fujimoto on the continued promotion of the CURES program and noted that only 6% of practitioners currently have access to CURES.

Dr. Law commented that he pleased that the board is partnering with the Medical Board and looking for ways to address the prescription drug abuse problem.

b. Update on the New Notice to Consumers Posters, Video Display Option for the Notice for Consumers, and Notice of Interpreter Availability

Chairperson Brooks reported that the new Notice to Consumer Posters will be mailed out to pharmacies in the coming days.

Discussion:

Ms. Herold noted that there was a delay in the mailing, but the posters should be received in the very near future.

There was no public comment.

c. Discussion on Patient-Centered Prescription Drug Container Labels

Chairperson Brooks reported that prescription labels have been a key issue for the board and added that the committee is pleased to see that the Pharmacopeia Guidelines for Prescription Drug Labels closely mirror the board's requirements. Mr. Brooks noted that at the committee meeting Mr. Castellblanch expressed concern that the minimum font size is 10 point and he feels it should be increased to 12 point font.

Discussion:

Mr. Weisser noted that font size will be discussed in the Legislation and Regulation section of the meeting.

Mr. Castellblanch added that a survey of California consumers was conducted and font size was mentioned as the number one item that should be changed to make prescription labels easier to understand.

Ms. Herold also noted that a vendor presented a product to the committee that can provide prescription information in audio format.

d. Research Advisory Panel's Annual Report for 2011

Ms. Herold reported that pursuant to Health & Safety Code Sections 11480 & 11481, California Law requires proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office. The Research Advisory Panel primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled

substances used in the study. The panel members evaluate the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research. The board has one appointee to this committee, Sheri VanOsdol, PharmD. Dr. VanOsdol is a faculty member at UCSF. The board will be replacing her on the panel in the near future.

e. Continuing Education Credits for Joint Board of Pharmacy/DEA Presentations to Pharmacists on Preventing Drug Diversion and Abuse

Ms. Herold reported that there are three proposals for board sponsored continuing education courses which the committee discussed and reviewed. These proposals are aimed at providing important educational information to board licensees and other interested parties, and to provide licensees with CE credit for attending.

Proposal 1:
Over the last two years, the board has hosted several one-day seminars for pharmacists and other interested parties on drug diversion, prescription drug abuse and corresponding responsibility for pharmacists. The board's partner in this has been the Los Angeles Office of the Drug Enforcement Administration.

On dates to be determined later in 2013, board staff hopes to again host two or three of these seminars with the Los Angeles DEA office. Board licensees in the regional area will be invited to attend.

The last regional presentation of this kind was held on April 12, 2012, on Drug Security for Pharmacists, for which the board awarded attending pharmacists and pharmacy technicians five hours of continuing education credit.

Board staff recommended to the committee and board to again award five hours of CE credit for pharmacists and pharmacy technicians who attend this meeting.

Proposal 2:
The board's executive officer was advised that in mid-August 2013, the Washington, DC headquarters office of the DEA has invited the board to co-host with them four, one-day seminars for pharmacists in California on controlled substances issues, prescription drug abuse, corresponding responsibility and other matters related to curtail drug diversion. This is a return of the original concept for the seminars outlined in Proposal 1, but using national DEA staff. Initially started in San Diego in 2010, the DEA has provided these seminars across the country in conjunction with the state boards of pharmacy, and upwards of 300 pharmacists have attended each of these presentations.

The dates are August 16 and 17 in San Diego, and August 18 and 19 in San Jose. Additional material will be provided to the board in the near future.

Board staff recommended to the committee and board that the board agree to cohost these events (the July meeting is too late to provide adequate advance publicity to encourage attendance) and that five or six hours of CE credit (as determined by the content hours) be provided for these meetings.

Proposal 3:
Periodically, board staff (principally board inspectors, supervising inspectors and the executive officers) provide 1-2 hour presentations to licensees on key Board of Pharmacy issue areas. For example:

- Duties of a pharmacist in charge
- The operations, functions and key priorities of the board's enforcement program
- New pharmacy laws
- E-Pedigree parameters
- Medication errors

Discussion:

There was no public comments, and no additional comments by the board.

MOTION: Approve CE Units as described for each of the three proposals.

M/S: Brooks/Kajioka
Note: Ms. Veale was not present for the vote

Support: 10 Oppose: 0 Abstain: 0

f. Creation of the Required Consumer Fact Sheet on Emergency Contraception in Accordance with Title 16 California Code of Regulations Section 1746

Chairperson Brooks reported that very recently, the Office of Administrative Law approved the board's rulemaking to update section 1746 regarding a joint protocol with the California Medical Board to authorize pharmacist to provide emergency contraception without a prescription to patients of any age. This regulation will take effect July 1, 2013.

Part of the regulation requires that a fact sheet for patients be developed by the board and made available so that pharmacists can provide it at the time of consultation. Specifically:

> *1746 (6)(4) The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record by Section 1707.1 of Title 16 of the California Code of Regulations. Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code section 4052.3.(e)*

(The full text of the regulation was provided in the meeting materials)

University of Southern California School of Pharmacy Professor Katherine Besinque, who was the board's subject matter expert in developing the modified regulation, very recently provided the board with an updated version of a draft fact sheet that can be used by the board for the final version.

The current version of the fact sheet (pre-regulation change) and draft developed by Dr. Besinque were provided in the meeting materials. During the meeting, the committee approved the draft fact sheet.

Discussion:

Ms. Shellans expressed concern that the wording on the fact sheet provided medical advice and the language used makes it seem like emergency contraception is safe for *everyone*, when in fact a person's medical history may make it dangerous to use. Additionally she noted the "after vomiting" section should be changed because someone may need to consult a physician if they vomit after taking the medication. Ms. Shellans also added that it might be overstepping to talk about family planning on the fact sheet and she does not feel that it is necessary to mention that the emergency contraception may be covered by the Affordable Care Act.

Chairperson Brooks expressed that many people will not get a prescription because they cannot afford it, and that cost could be a concern when considering emergency contraception.

Ms. Herold noted that the board needs to work with the Medical Board and the two consultants to further refine the fact sheet.

Mr. Castellblanch agreed that the board needs to verify if emergency contraception is covered by insurance. He also noted that there might be too much wording on the fact sheet and it might cause people to miss some of the information.

Ms. Hackworth asked if putting the fact sheet out now is too early because the Affordable Care Act will not go into effect until 2014.

Chairperson Brooks approved Ms. Herold working directly with the Medical Board on revisions to the fact sheet and then providing reports to both himself and President Weisser.

Mr. Castellblanch noted that what the Affordable Care Act will cover is still very uncertain.

President Weisser noted that the instructions to "not wait" provided on the fact sheet is included to attempt to give frantic patients clear and detailed instructions.

Dr. Gutierrez asked if the language could be changed to say “may be safe and effective” rather than “is safe and effective.” Ms. Shellans responded that this language change may work.

Chairperson Brooks asked when the fact sheet would be given to the patient.

Ms. Herold confirmed that it would be given out at the time emergency contraception is dispensed.

Chairperson Brooks responded that he is not as concerned about some of the specific language because the patient will just have had a consult in person with a pharmacist.

Mr. Castellblanch added that he does not think the board should just say it is safe and effective with no further qualifications.

Dr. Kajioka commented that perhaps this fact sheet should also be provided at family planning locations in addition to at the time the emergency contraception is dispensed.

Mr. Lippe asked if the fact sheet should say “safe and effective when used as directed” and also expressed his concern about possible drug interaction.

Ms. Herold commented that maybe the fact sheet should just say “is effective” and remove the word safe completely. Chairperson Brooks agreed with Ms. Herold’s suggestion.

Ms. Shellans again raised her concern that family planning goes beyond the board’s authority.

Dr. Law noted that emergency contraception is free for certain patients.

Chairperson Brooks asked the professional members to clarify if a patient can wait 8 hours to take the next dose so that they can contact a doctor or pharmacist if they vomit immediately after taking the medication.

Ms. Hackworth answered that she feels the board should remove the instruction to take another pill immediately after vomiting because they could be vomiting due to an allergic reaction to the medication.

Dr. Kajioka agrees a patient should contact a healthcare provider prior to taking another dose.

Dr. Fujimoto commented that there are already educational resources available on emergency contraception. She feels there should be consistency in the information provided to patients and the board should use material that is already approved by the FDA.

Chairperson Brooks commented that perhaps the board can improve the material that is already being used.

Ms. Castellblanch noted that the board should be alert to what organization created the education material that is already in circulation.

Dr. Ken Schell, pharmacist, commented that a possible language change could be "it has been shown to be safe and effective".

Chairperson Brooks agreed with Dr. Schell's "has been shown to be safe and effective" language suggestion.

Dr. Kajioka noted the board should add "when taken as directed."

Mr. Castellblanch expressed his concern in making a blanket statement about a product's safety.

Ms. Herold added that it is important to keep in mind that the patient will have had a face-to-face consultation with their pharmacist.

Motion: Adopt the changes to the fact sheet language as noted below and forward the changes to the medical board for review. Upon return from the Medical Board, have the fact sheet signed off by the board president and chairperson.

- "When taken as directed emergency contraception has been shown to be safe and effective."
- "If you vomit after taking emergency contraception you may need to take another dose, before you do, contact a pharmacist or health care provider immediately."

M/S: Brooks/Gutierrez

Support: 10 Oppose: 0 Abstain: 1 (Castellblanch)

g. <u>Update on *The Script*</u>

Chairperson Brooks reported the most recent issue of *The Script* was released in March 2013. This issue includes an article on the FDA Guidelines for Medication Guide Distribution and detailed the compliance guidelines for electronically transmitted prescriptions. Also included in this issue were answers to frequently asked questions, best practices and a summary of disciplinary actions taken. The next issue of the newsletter is currently under development.

There was no public comment or additional board discussion.

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

Chairperson Brooks reported that as time permits, staff is continuing work on the new design for the board's website. The new site will provide a more contemporary design and color palette and be consistent with the look and feel of the Governor's office website and those of other DCA boards and bureaus.

There was no public comment or additional board discussion.

i. Update on the Board's Consumer Education Materials

Chairperson Brooks reported that staff is continuing to evaluate the board's existing consumer education materials and fact sheets to identify those that should be updated or removed from the board's library. Priority has been given to the production of new consumer brochures that address urgent and relevant public pharmaceutical issues. The following new consumer brochures have been written and are in the design and print stage of production:

1. *Prescription Drug Abuse*
2. *Prescription Drug Abuse Among Teens*
3. *Counterfeit Drugs*
4. *Purchasing Pet Meds Safely from Online Pharmacies*

Several more topics have been identified and brochures will be developed on an ongoing basis.

There was no public comment or additional board discussion.

j. Public Outreach Activities Conducted by the Board November 2012 – March 2013

Chairperson Brooks reported that board staff provided the public outreach listed below.

- November 8: Inspector Bob Kazebee provided a presentation to pharmacists on the duties and responsibilities of being a pharmacist-in-charge to 70 pharmacists at a CE event in
- November 16: Inspector De' Bora White provided a presentation to pharmacists on the duties and responsibilities of being a pharmacist-in-change at a CE event hosted by the UFCW.
- February 21 and 22: Board cohosts with the Medical Board a forum on Appropriate Prescribing and Dispensing of Controlled Substances in San Francisco. Nearly 400 people attend each day.

- February 25: Supervising Inspector Dang provided a presentation on the duties and responsibilities of being a pharmacist-in-charge to students at Western University School of Pharmacy
- Supervising Inspector Judi Nurse provided a presentation to Loma Linda University School of Pharmacy Students on the Board of Pharmacy
- March 12: Executive Officer Herold provided information on the board's enforcement program and new pharmacy laws to over 50 pharmacy students at Touro School of Pharmacy
- March 18: Executive Officer Herold provided information on the board's enforcement program and new pharmacy laws to 100 attendees at the annual meeting of the California Pharmacist Association.
- March 20: Executive Officer Herold provided a webinar to a large number of manufacturers, wholesalers and pharmacies regarding implementation issues for e-pedigree
- March 26: Executive Officer Herold provided information about California regulation of those who dispense, store, ship and sell prescription drugs and devices in California to a group of travelers from China at the request of the Department of Consumer Affairs
- March 26: Executive Officer Herold provided information on the board's enforcement program and new pharmacy laws to 60 attendees at California Northstate School of Pharmacy

k. <u>Committee Goals for 2012/17 to Fulfill the Board's Strategic Plan</u>

Chairperson Brooks reported that the committee has not yet completed work to update the committee's strategic plan. Board staff will prepare materials that will be brought to the next committee meeting, and then referred to the board for incorporation into the board's plan.

There was no public comment or additional board discussion.

l. <u>Meeting Summary</u>

Chairperson Brooks reported that the meeting summary for the April 12, 2013 Committee Meeting were provided in the meeting materials

VI. <u>BOARD MEETING DATES FOR 2014</u>

The remaining Board Meeting dates for 2013 are listed below.

- July 30-31, 2013 - Sacramento
- October 23-30, 2013

The proposed 2014 Board Meeting Dates are listed below.

- January 22-23, 2014
- April 23-24, 2014
- July 30-31, 2014
- October 22-23, 2014

Discussion:

Ms. Herold noted that the October dates were listed incorrectly and the correct dates should be October 29-30, 2013.

Ms. Shellans noted that she has a conflict for the January board meeting, she will work with staff to determine a new date or send another member of her office in her place.

Ms. Hackwoth noted that she will be unable to attend the July board meeting.

VII. BOARD MEMBER OFFICER ELECTIONS

Position of Board President

Motion: Reappoint Stanley Weisser as the Board's President.

M/S: Brooks /Gutierrez

Support: 11 Oppose: 0 Abstain: 0

Position of Board Vice President

Motion: Nominate Randy Kajioka as the Board's Vice President.

M/S: Veale/Hackworth

Motion: Nominate Amy Gutierrez as the Board's Vice President.

M/S: Law/Castellblanch

Randy Kajioka: 4 votes (Hackworth, Veale, Brooks, Kajioka)
Amy Gutierrez: 5 votes (Law, Lippe, Gutierrez, Wong, Castellblanch)
Abstain: Butler and Weisser

Position of Board Treasurer

Motion: Nominate Deborah Veale as the Board's treasurer.

M/S: Gutierrez/Kajioka

Support: 11 Oppose: 0 Abstain: 0

The board recessed for a break at 10:55 a.m. and resumed at 11:14 a.m.

VIII. LICENSING COMMITTEE REPORT

Chairperson Deborah Veale provided the Licensing Committee Report from the April 12, 2013 meeting as follows.

a. Licensing Committee Dates

The committee dates for the remainder of the year. The location for these meetings will be Sacramento.

- May 28, 2013
- September 24, 2013
- December 11, 2013

There was no public comment or additional board discussion.

b. Recommendations for Regulation Changes to Require or Standardize the Reporting of Convictions and Discipline at the Time of Renewal for Pharmacists, Pharmacy Technicians and Designated Representatives

Background

As part of the Consumer Protection Enforcement Initiate in 2008/2009, the board undertook review and evaluation of several areas of its enforcement and licensing functions to identify areas where the board could improve its ability to ensure it received or had access to information necessary to make appropriate licensing decisions as well as ensure it received relevant information to initiate investigations and take appropriate action to better protect consumers.

As part of this effort the board sought new regulatory authority to require fingerprinting of pharmacists that had not previously submitted fingerprints to the Department of Justice in an electronic format. To augment this effort, the board also sought to require as a condition of renewal, that a pharmacist also self-report any convictions. These changes took effect in December 2010. At the time the board adopted the changes, they requested

that similar provisions be implemented for pharmacy technicians and designated representatives at a future date.

During the meeting, the committee discussed a staff recommendation that would make changes to the existing pharmacist renewal as well as place similar renewal requirements on pharmacy technician and designative representatives. The proposed changes to specific the pharmacist renewal include:

- Disclosure of disciplinary action
- Removing reference to the implementation date
- Clarifying that disclosure of criminal conviction information and disciplinary action is for action taken since the last renewal of the license.

Based on comments received by the committee and counsel, the board was advised that language will be revised and considered during the next committee meeting for possible action.

The committee expressed support for the concept of the proposal and will review the proposed regulation language during its next meeting for possible action.

There was no public comment or additional board discussion.

c. <u>Recommendation for Regulation Changes to Require Site Licensees to Report Disciplinary Actions by Other Entities at Time of Renewal</u>

<u>Background</u>

As part of the requirements for initial licensure as either a nonresident pharmacy or nonresident wholesaler an applicant must hold a current license in the resident state. Prior to issuance of a CA license, such applicants provide the board with license verification from the resident state that provides our board with confirmation of the current standing with the other state board as well as notification if the license has been disciplined.

This information is very valuable when making a licensing decision; however it only provides information at the time of licensure.

During this meeting, the committee discussed the proposal to require as a condition of renewal, disclosure of any disciplinary action taken against the entity it its home state.

The committee discussed the policy behind the recommendation and expressed support for the concept. The committee heard concerns about the draft language in its current form and the need to better clarify some of the language in the provision.

The draft language that was provided to the committee was provided in the meeting materials. Based on comments received by the committee and counsel, the board was

advised that the language will be revised and considered during the next committee meeting for possible action.

Discussion

No comments were provided by the board or by members of the public.

d. Proposed Amendments to California Business and Professions Code Section 4053 Regarding the Qualifying Experience of Designated Representatives

Current pharmacy law establishes the requirements for licensure as follows:

a. High school graduation or equivalent
b. One year paid work experience within the past three years OR

Meet all of the prerequisites to take the pharmacist licensure examination

c. Completion of a training program

The board is currently seeking changes to this section of law through an omnibus proposal to clarify that the experienced required above is earned in a licensed facility.

The board was advised that during the meeting, the committee discussed one additional proposed change to B&PC 4053 to waive the training program for an individual that meets the requirements to take pharmacist licensure examination. By law, such an individual would have either a Bachelors of Science in Pharmacy or PharmD as well as at least 1500 hours of intern experience.

Further, based on public comment received during the meeting, the committee considered a recommendation to also seek an additional change to this section that would specify that an applicant must also be at least 18 years old.

Committee Recommendation

Accept the staff recommendation to amend B&PC 4053 as provided and also include an additional amendment to require the applicant to be at least 18 years of age.

The language was provided in the meeting materials for board consideration.

Motion: Accept the staff recommendation to amend B&PC 4053 as provided and also include an additional amendment to require the applicant to be at least 18 years of age.

Support: 11 Oppose: 0 Abstain: 0

e. Review of Request from Det Norske Veritas (DNV) to Renew Board of Pharmacy Approval as an Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacist

Background

For the past several years the board has been discussing several elements of pharmacies that compound sterile injectable products, including the requirements for private accreditation agencies. As part of the current approval process, such agencies apply to the board for consideration and approval by the board.

Det Norske Veritas (DNV) was previously approved by the board for a three year period. This approval will expire later this year. As such DNV has submitted a new request to the board. Regrettably because the Licensing Committee meeting was rescheduled, a representative from DNV was unable to attend the committee meeting.

The committee briefly discussed the current approval of DNV and was advised that their approval expires in July 2013, unless the board extends it. The committee expressed its interest in having the opportunity to appropriately review and evaluate DNV as part of its next committee meeting and discussed how this could be accomplished.

Committee Recommendation

Recommend a three month extension to the approval of DNV to allow the company to present at the next committee meeting scheduled in May.

Discussion

Mr. Castellblanch asked if the board has had any negative experiences at all with DNV.

Chairperson Veale answered that the board has not had a chance to do any research, thus the committee's request for an extension.

Ms. Herold noted that about a year ago the board inspected a facility that was accredited by DNV and there were no issues at the time.

Ms. Gutierrez asked if the board is tracking if they find any problems with facilities that are accredited and noting who accredited them. Ms. Herold answered yes.

Motion: Recommend a three month extension to the approval of DNV to allow the company to present at the next committee meeting scheduled in May.

Support: 11 Oppose: 0 Abstain: 0

f. Update on Implementation of BreEZe and Potential Impact on License Applications and Renewals

Background

Over the past several years, the board has been apprised of the status of implementation of the new computer system, BreEZe, through the board's Organizational Development Committee. This will continue to be the case; however board staff would like to also advise the committee about the upcoming transition to the new system by some of the boards within DCA.

As part of the implementation strategy used by the DCA to deploy this new system, boards and bureaus within the department are transitioning to this new system in three releases. While our board is scheduled for the second release, its operations will be impacted during the actual cut over time period for those programs in release one. Specifically, it is anticipated that several of the board's licensing functions will be on hold for about four to six days. During this time applications cannot be processed and licenses cannot be renewed. The board has been advised that the cut over is scheduled for mid-May.

The committee discussed the potential impact to the cutover will have to licenses that renew the end of April and May as well as the impact to applicants. Board staff indicated some ways to mitigate some of the potential impact. In response to concerns about communication with other regulators about license status, Ms. Herold offered to serve as the point of contact and in her absence, Ms. Sodergren could be contacted.

Discussion

Ms. Sodergren noted that the release has been moved, with no new date announced. However the message is still the same, renew early.

Ms. Herold added that as soon as licensees get their renewal notice they should renew.

Dr. Gutierrez asked if it is ever too early to renew.

Ms. Herold answered that licensees should renew as soon as they get the notice in the mail.

g. Accreditation Reviews Planned During 2013 of California Schools by the Accreditation Council on Pharmacy Education

Background

All schools of pharmacy in the United States are accredited by one body, the Accreditation Council for Pharmacy Education (ACPE).

Schools of pharmacy are visited according to a schedule developed by ACPE. Typically a California board member is invited to participate as an observer during accreditation visits of California schools of pharmacy by the ACPE. As the board learns the schedule of which school is undergoing review, typically Board President Weisser asks several board members if one of them would be interested in participating in this review as an observer.

Two California schools are currently under review. California Northstate was reviewed in April, and UCSF will be evaluated in the fall. Board Member Kajioka participated as an observer at California Northstate and President Weisser will participate as an observer at UCSF.

Six additional pharmacy schools in California that are in various stages of development and accreditation. If all are successful, California will have 14 accredited programs.

Discussion

Mr. Castellblanch asked what it means if a student goes to an unaccredited school.

Ms. Herold answered that there is one acceding body for pharmacy education in the United States. If a student goes to a non-accredited school they will be unable to be licensed in California.

Mr. Castellblanch noted that he is concerned that many students wouldn't know if they were going to a non-accredited school.

Dr. Wong asked if more than one person could attend the accreditation review.

Mr. Dennis McAllister, from the board of directors for ACPE, commented that information on the accreditation process could be found on ACPE's website www.acpe-accredit.org. He provided a brief overview of the accreditation process and noted that students are required to sign a document disclosing that the school is in the accreditation process. Mr. McAllister also noted that if a school does not pass accreditation they must have a teach-out program with other schools so that students can receive their degree and become licensed.
Mr. Lippe asked why a student would go to a school if it was in the accreditation process.

Mr. McAllister answered that often admittance to these schools is easier.

Mr. Castellblanch noted that students are on a timeline to get their degree and start working he asked what happens to this timeline if the school does not become accredited.

Mr. McAllister answered that there has never been a school that applied for accreditation and did not receive it.

Dr. Kajioka commented just because there have been no schools that have not become accredited it does not mean the process is easy. He commented that the school where he attended the review did not receive accreditation the first time and was given one year to come into compliance and ACPE did a very detailed review of the school.

Dr. Law asked what happened to the students who should have graduated in the year the school was given to come into compliance.

Mr. McAllister answered that it did not affect the student's progression and noted that the students who graduated actually beat the national average on the NAPLEX exam.

Mr. Ray Vrabel, pharmacist, commented that there are two parts to pharmacy education: the education component that students get in the classroom and the hands-on clerkship component. He feels there are not currently enough clerkship sites to properly educate students.

h. <u>Results from Continuing Education Audits</u>

<u>Background</u>

Business and Professions Code Section 4231 establishes the continuing education requirements for pharmacists. Specifically, this section requires pharmacists to complete 30 hours of continuing education every two years (except for the first renewal). Further, this section establishes the board's authority to conduct audits to confirm compliance with this requirement and sets forth the parameters for noncompliance with this requirement.

To facilitate the provisions of B&PC 4231, all pharmacists are required to complete a renewal application that provides an attestation to the completion of continuing education. The language is provided below.

> I successfully completed the hours of continuing education for renewal. I completed ___ hours of CE during my last renewal period.
>
> I declare under penalty of perjury under the laws of the state of California that the foregoing is true and correct.
>
> Signature_____
>
> Date_____

Every year, the board audits a number of pharmacists who certify they have completed the required CE. During these audits, not all pharmacists are able to provide proof that they have completed the CE they reported.

A review of the audit results for the past two years reveals that almost 20% of all pharmacists are unable to provide proof of completion of the required continuing education. In such cases, the pharmacist in issue a citation and fine.

The board was advised that the committee reviewed the statistics provided. During the past two years the board conducted 422 random audits. Of those completed, 82 pharmacists failed the audit. 55 of the pharmacists later became compliant, however 27 failed to do so and as such licenses were placed on an inactive status.

The committee also discussed the NABP's CE monitoring program that provides states with a centralized database to confirm compliance with CE coursework completed. The committee discussed the limitation on that monitoring program that currently only collects information on CE courses and that are ACPE approved. Because CA law allows for courses recognized by the Medical Board, Dental Board and others, this reporting system is not an option to confirm compliance.

Discussion

Ms. Hackworth asked how long a licensee has to submit proof of their CE. Ms. Herold answered they have 30 days.

(Public comment returned to the previous agenda item)
Mr. Stan Goldenberg commented, in response to the education of pharmacists as discussed earlier, that doctors get trained by working in hospitals which gets paid to have the program. He asked if the board could consider looking into this model.

Mr. Ray Vrabel clarified that his earlier comment was refereeing to clerkship programs being needed prior to graduation.

Dr. Gutierrez noted that some pharmacy schools do have clerkship programs.

Mr. Subash Mediratta commented that as a pharmacy owner he cannot find qualified compounding pharmacists.

i. Review of Statistics Regarding Discipline and License Denial of Pharmacy Technicians

Background

At the request of President Weisser, the committee began a review of statistics regarding the number of pharmacy technicians who are formally disciplined following licensure, are denied licensure at time of application, or who are issued a probationary license.

The committee reviewed the statistics provided. It noted that the board denies about 1% of all of the application received. In about 50% of those cases, the applicant requests an

appeal of the board's decision. Although a number of the denials are still pending, of those that are completed no denials have been dismissed. Slightly over 50% of the denials have been upheld and the remained have been issued a restricted license.

The committee did not take action on this item, but suggested that the committee should evaluate the underlying violations or convictions that warrant the action and if the board should evaluate the impact on medical marijuana. The statistics reviewed by the committee were provided in the meeting materials.

Discussion

Mr. Brooks noted that he feels the board should deny a license for anyone who has an arrest involving medical marijuana.

Mr. Castellblanch asked what the current process is in regards to the use of medical marijuana.

Ms. Herold answered that an applicant may be denied based on how recent the violation is and the board takes drug trafficking much more seriously.

Ms. Veale noted that medical marijuana will be added to the agenda for Licensing Committee meetings.

Dr. Schell commented that in addition to medical marijuana the board should look at any type of therapy that could impair the ability to perform the duties of a pharmacist.

j. Competency Committee Report

The board was advised that effective April 1, 2013, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means that there will be a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. The board will release scores as soon as possible. Based on historical patterns, the board anticipates results being released approximately May or June 2013. The board encourages all qualified applicants to continue to schedule and take the CPJE exam. The greater the number of applicants who take the exam during this review period, the sooner results can be released.

Discussion

Ms. Herold commented that examination data is available in the board materials. The data includes the performance of graduates from the various schools of pharmacy.

b. Licensing Statistics

The board reviewed licensing statistics provided in the meeting materials. To date the board has received over 11,800 applications and issued over 10,700 licenses. The number of applications received decreased over 11% and the number of licenses issued decreased over 1% when compared to the same time periods last fiscal year. It was noted that March 2013 revenue received information was not available until after the development of this report. The board will include the information in subsequent reports once the information is available.

Discussion

Mr. Castellblanch asked how it is possible for the number of applications to go down while the number of pharmacy schools is increasing.

Ms. Herold answered that the drop is actually due to the number of technician applications decreasing.

c. Third Quarterly Report on the Committee's Goals for 2012/13

The third quarterly report on the Licensing Committee's goals was provided in the meeting materials. As demonstrated in the quarterly report, the board is meeting the acceptance parameters for Success Indicators.

Discussion

No comments were provided by the board or by the public.

IX. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

President Weisser provided the Organizational Development Committee Report as follows.

a. Budget Update/Report

The budget year began July 1, 2012 and will end June 30, 2013. The board's spending authorization for the year is $15,289,000.

Budget charts detailing the board's expenditures and revenue for the current fiscal year were provided in the meeting materials. The board has collected almost $10.5M in revenue thus far. About 80% or $8.3M has come primarily from license fees.

The board has expended $9.2M (over 60%) during the first eight months of the fiscal year, primarily in personnel services. Further, based on projections, it is estimated that the board will exceed its line item authorization for Attorney General Expenses by about $400,000. Board staff is working closely with the DCA and the Attorney General's Office to ensure funding through the end of the fiscal year. Curtailing the board's enforcement efforts is not an option without significantly undermining the board's consumer protection mandate

Over the years the board's authorized expenditures have exceeded revenue resulting in an imbalance. This imbalance has become more pronounced in recent years as the board has established new personnel. It will continue to decrease if the fees stay the same.

2011/12	$13,577,000	10.9 months in reserve (actual)
2012/13	$10,605,000	8.0 months in reserve
2013/14	$6,641,000	4.9 months in reserve
2014/15	$3,413,000	2.5 months in reserve

The board was advised that during the committee meeting, it was noted that the board needs to consider a fee increase in the very near future to ensure the financial solvency of the board. The board's fees are established in statute and in most cases, the fees in statute include a range (minimum and maximum) the board can charge. All of the board's fees are currently set at the statutory minimums. Therefore, to facilitate a fee increase if it so chooses, the board could do this through a regulation change. Such a change would result in an increase of about $3M in revenue each year, which would be sufficient to address the imbalance, but not any future growth in resources.

In addition to the board's fund condition report, the meeting materials included the following:

- Draft regulation language
- Fee comparison detailing the board's current fee structure vs. proposed fees
- Copy of the Fee Audit performed in 2008

<u>Discussion</u>

Ms. Sodergren provided the board with a brief overview of the fee audit that was conducted in 2008.

Mr. Brooks asked if the fees could be indexed and if the board could look at ways to work more efficiently.

Ms. Sodergren answered that currently it is not known how the new BreEZe system will improve efficiencies and added that staff is always looking for ways to work smarter.

Ms. Herold commented that current staffing levels do not allow the board to inspect pharmacies enough and small violations are turning into major violations before the board can inspect a location.

Mr. Lippe asked why the board is projecting revenues to stay the same with the number of pharmacy schools increasing.

Ms. Herold answered that there is a slight increase built in.

Ms. Sodergren added that the decrease in technician applicants will offset any increase seen in pharmacists' applications.

Ms. Shellans commented that the Office of Administrative Law (OAL) currently requires a cost per unit breakdown of *each* fee that illustrates how the fee was determined. She advised the board that going forward they will need to have a spreadsheet for each fee with the cost per unit breakdown. Ms. Shellans also added that for the last two years every single regulation package that did not include cost per unit breakdowns for each fee was rejected.

Mr. Brooks commented that he agreed such and analysis should be conducted but asked how a surplus could be created using that system.

Ms. Shellans answered that renewal fees allowed for more flexibility and could allow for a surplus.

Ms. Sodergren commented that the fee audit conducted in 2008 included a cost per unit breakdown.

Ms. Herold added that the board is unusual in regards to the fact that they actually conducted an independent fee audit to determine its statutory minimums and maximums.

Ms. Shellans commented that OAL may want to see 2013 data.

Dr. Raffi Simonian commented that improving efficiency is always important to consider and added that the board will have to step up its enforcement activities and needs to have the funding in order to do so.

Motion: Direct staff to take all steps necessary to initiate formal rule making process including noticing the proposed language in 45 day public comment, setting the proposed language for a public hearing, and authorizing the executive officer to make any non-substantive changes to the rulemaking packet.

M/S: Weisser/Lippe

Support: 10 Oppose: 1 (Brooks) Abstain: 0

b. Update on BreEZe and DCA's Plans for a New Computer System

Ms. Sodergren reported that for a number of years, the department has worked to replace and/or enhance its legacy licensing and enforcement tracking systems used by most DCA agencies that were developed in the 1980s. A few years ago, the department initiated an "i-Licensing" project which would have offered online application and renewal of licenses (a much needed relief from mail-in renewals). This new system is vital to the board's operations as the current system limitations significantly impede our ability to perform efficiently. Based on the current timeline for implementation, the board is in the second phase of programs transitioning to the new system. The board was initially going to release the new system in September but this date has been delayed.

The board continues to commit a significant amount of resources to this project to ensure the board's operational needs are met. The executive officer continues to serve as an executive sponsor of this project and serves on the change control board, part of the established governance plan for this project. Throughout this process, the board has dedicated board staff, some of which have been working part-time for this project, assisting the department in documenting system requirements that meet the needs of our board as well as others throughout the project.

Discussion

Mr. Brooks expressed his concerns with using a "customizable" off the shelf product and asked it the board had the option to find other solutions.

Ms. Herold answered that the only way to not be a part of BreEZe would be to separate from the Department of Consumer Affairs. She also noted that board staff are part of key committees in order to have input into the decision making process in regards to the project.

c. Personnel Update

The board was updated on changes to the board as well as board staff. Since the last board meeting, Lavanza Butler has been appointed to the board by Governor Brown.

Lavanza "Kercheryl" Butler, 61, of Los Angeles, has been appointed to the California Board of Pharmacy. Butler has been a pharmacist, vice president and union representative at United Food and Commercial Workers International Union Local 770 since 2002. She was a head pharmacist at Rite Aid Pharmacy from 1980 to 2002. Butler is a member of the California Pharmacists Association and United Food and Commercial Workers Professional Division. This position does not require Senate confirmation and the compensation is $100 per diem. Butler is a Democrat.

For the first time in several years there are no vacancies on the board.

Staff Changes

- Taydene Dalrymple accepted a position with the board as an Associate Governmental Program Analyst in the complaint unit on February 25, 2013.
- Jamie Lazarus accepted a position with the board as an Associate Governmental Program Analyst performing budget and contracting duties on March 18, 2013.

Departures

- Jade Franklin left state service.
- Valerie Knight left state service.

Recruitment

The board continues its efforts to fill several vacant positions:

- Three Inspector
- One Staff Services Manager II

d. Initiation of Evaluation of the Executive Officer

The Department of Consumer Affairs encourages all boards within the department to conduct annual performance appraisals of all staff, including the executive leadership within the program. President Weisser provided the board with the evaluation packets and asked the board members to complete and return them to him in one month.

e. FOR DISCUSSION: Committee Assignments and Restructuring of Board Committees

President Weisser discussed some changes to committee assignments and offered recommendations to changes and restructuring of some of the board's committees.

Mr. Brooks will continue as the chair of the Communication and Public Education Committee. Mr. Castellblanch will be the chair of the newly formed Communication and Public Education subcommittee on prescription drug abuse.

To address the expanding demands of e-pedigree and sterile compounding the Enforcement Committee will be split into two Committees. Once committee will handle only matters pertaining to e-Pedigree and will be chaired by Dr. Kajioka. The second committee will handle all matters pertaining to compounding in addition to other board enforcement activities and will be chaired by Dr. Gutierrez.

Discussion:

Ms. Shellans asked what dates would be picked for the two committees.

Ms. Herold answered that Dr. Gutierrez's committee will meet on the dates already scheduled and the e-pedigree meeting dates will be determined.

(Public comment returned to the previous agenda item)
Dr. Raffi Simonian commented that the problems with the BreEZe system need to be highly publicized and asked if the system is working in testing mode.

Ms. Sodergren answered that there are reasons the release has been delayed and the vendor and staff are working hard to address the problems with the system.

X. LUNCH

The board recessed for lunch at 12:45 p.m. and resumed 1:54 p.m.

XI. LEGISLATION AND REGULATION COMMITTEE REPORT

Chairperson Greg Lippe provided a report from the April 11, 2013 Legislation and Regulation Committee as follows.

Part I: Regulations

The board was advised of the status of several regulation changes.

a. Regulations Approved by the Office of Administrative Law

The board's rulemaking to amend Section 1746 related to the Emergency Contraception Protocol was approved by the Office of Administrative Law on March 13, 2013. The regulation goes into effect on July 1, 2013. The Fact Sheet utilized by pharmacists when dispensing emergency contraceptives pursuant to this protocol is being updated and should be available when the regulation goes into effect.

b. Board-Approved Regulations – Recently Noticed

At the February Board Meeting, the board voted to modify the text of its proposal at Section 1762. This is the board's combined rulemaking to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 of the California Code of Regulations. Staff is preparing a notice of modified text that will be issued for a 15-day public comment period. The modified language approved by the board was provided in the meeting materials.

c. Board Approved Regulations Undergoing Administrative Review

The board noticed its proposal to add a new Article 5.5 to Title 16 of the California Code of Regulations related to Pedigree Requirement. The board's proposal to add a new Section 1747 would establish requirements for the "unique identification number" required by Section 4034 of the Business and Professions Code, and the board's proposal to add a

new Section 1747.1 would establish requirements for declarations that must be filed with the board, as required by Sections 4163.2 and 4163.5 of the Business and Professions Code.

The board's proposal was initially noticed on September 21, 2012. The board conducted a regulation hearing in conjunction with the December 2012 Board Meeting and subsequently issued two Notices of modified text. Thereafter, the board adopted the final regulation language at the Board Meeting held February 5, 2013, and staff completed the rulemaking file. The rulemaking file was submitted to the department for administrative review in March.

A copy of the Adopted Text was provided in the meeting materials. The board will be updating its website with its Final Statement of Reasons and other rulemaking documents.

d. Board Approved – Awaiting Notice

Below are four board-approved regulatory proposals that have not yet been noticed for public comment. A copy of the language approved for public notice was provided in the meeting materials, a summary of each is provided below.

Committee Recommendation: Hold the Notice for 1751.9 until a later date, and issue for public comment the board's proposals for 1732.2, 1732.5, and 1732.05.

The board has approved for a 45-day public comment period four proposals: three related to continuing education, and one related to standards for agencies that accredit sterile injectable compounding pharmacies.

The committee recommends that the board hold off on noticing the board-approved text to amend Section 1751.9 – Standards for Agencies that Accredit Sterile Injectable Compounding Pharmacies. This regulation may no longer needed given the board's legislation (SB 294) to strengthen board's ability to regulate and monitor pharmacies that compound sterile drug products, which would eliminate existing requirements that authorize accreditation in lieu of licensure for sterile compounding pharmacies that do business in California.

A summary of the four board-approved proposals is provided below.

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education
In January 2012, the board withdrew a pending regulation to Section 1732.2 which, at that time, was pending final review at the Office of Administrative Law. Thereafter, the Licensing Committee vetted revised language which, in May 2012, was approved by the board for public notice.

Proposal to Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas
In May 2012, the board approved a draft regulatory proposal for public comment to require continuing education in specific content areas. The proposed text would require six of the 30 units required of continuing education for a pharmacist renewal to be in specified content areas.

Proposal to Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education
In May 2012, the board approved a draft regulatory proposal to modify Section 1732.05(a)(2) and to initiate a rulemaking. This proposal was at the request of the California Pharmacists Association, to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association.

Proposal to Add Section 1751.9 – Standards for Agencies that Accredit Sterile Injectable Compounding Pharmacies
In May 2012, the board approved for public notice a draft regulatory proposal from the Licensing Committee to add Section 1751.9 to Title 16 of the CCR for the purpose of specifying standards for agencies that accredit licensed sterile injectable compounding pharmacies.

Motion: Hold the Notice for 1751.9 until a later date, and issue for public comment the board's proposals for 1732.2, 1732.5, and 1732.05.

Support: 11 Oppose: 0 Abstain: 0

Part II: Legislation

The board discussed several pieces of pending legislation, the current status of the legislation, monitoring efforts by staff as well as committee discussion and recommended positions.

a. <u>SB 294 (Emmerson) Compounding Sterile Drug Products</u>

SB 294 is the board-sponsored legislation that would strengthen the board's ability to regulate and monitor pharmacies that compound sterile drug products.

In March, the Board President, along with the board's Executive Officer, established a position of support on this bill. A copy of that letter was provided with the board materials. The Legislation and Regulation Committee recommends that the full board ratify the position established in March.

Discussion

In response to the issues involving sterile compounding a subcommittee was formed. Dr. Gutierrez provided an overview of the subcommittee meeting that was held on March 19, 2013. The meeting minutes were provided in the meeting materials. The committee will meet on June 4, 2013, in Sacramento.

Jonathan Nelson commented that CSHP is officially supporting the bill.

Motion: Ratify the position of support for SB 294 taken 3/25/13.

Support: 11 Oppose: 0 Abstain: 0

b. Board –Approved Proposals for 2013-2014

Copies of the approved proposals were provided in the meeting materials.

Amendment to Business and Professions Code 4107 – One Site License per Premises; Exception

Business and Professions Code Section 4107 provides that the board may not issue more than one site license to a single premises, unless there is a specific exemption to do so. Following the passage of AB 377 (Hospital Central Packaging Pharmacy), the board approved language that would provide for a specific exemption to issue the central packaging pharmacy permit to a premise that also holds a hospital permit. The board's proposal has been provided to the Senate Committee on Business, Professions and Economic Development and staff has been advised that the language will be amended into the committee's Omnibus bill, SB 821.

Addition of Business and Professions Code Section 4008.5 – Requirement to Provide Arrest and Court Documents as Requested by the Board

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; these agencies cite the board's lack of authority to receive these documents. At the October 2012 Board Meeting, draft language was approved to add Section 4008.5 to provide the board with the express authority to receive certified records for this purpose. In lieu of adding this provision to the Senate Committee on Business, Professions and Economic Development's omnibus measure, the committee has developed draft amendments to add a general BPC code that would be applicable to all DCA boards. Staff will continue to monitor legislation and advise the committee when this language has been amended into a bill.

Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative

Existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. At the October 2012 Board Meeting, the board approved a draft amendment that would clearly specify that the one year of paid work experience shall be earned in a licensed facility, as specified. The board's proposal has been provided to the Senate Committee on Business, Professions and Economic Development and staff has been advised that the language will be amended into the committee's Omnibus bill, SB 821.

The board's proposals to Amend Sections 4107 and 4053 will soon be amended into a Senate omnibus bill – SB 821.

The board's proposal to add Section 4008.5 is expected to be added as a general Business and Professions Code (144.5) that would apply to all boards. The board had not yet seen the provision in print as of the board meeting.

The board has a proposal to add Section 4310.5, which would authorize the board to issue a Public Letter of Reprimand at the time an applicant is licensed. A copy of the board-approved language was provided with the board materials, and staff is working to secure an author for this provision.

c. Board Proposal to Define "Correctional Pharmacy"

The board is proposing to add Section 4046 to the Business and Professions Code to define the term "Correctional Pharmacy" – which would be included within a Senate omnibus measure.

> *4046. "Correctional Pharmacy" means a pharmacy, licensed by the board, located within any state correctional facility for the purpose of providing pharmaceutical care to inmates of the state correctional facility.*

The Legislation and Regulation Committee is recommending that the board approve this language, with one amendment: that the word "state" be stricken from "state correctional facility."

Discussion

Ms. Herold noted that the Corrections Department and the Governor's office have not approved of the changes the committee made.

Dr. Steve Gray, representing CSHP, asked if there is an official definition of what a correctional facility is.

Motion: Ratify the language provided to Senate Committee on Business, Professions and Economic Development for inclusion in a committee Omnibus measure.

Support: 9 Oppose: 0 Abstain: 2 (Brooks and Kajioka)

AB 396 (Fox) Prescription Label – Condition or Purpose

The board was advised that this proposal was not moving.

AB 670 (Atkins) Pharmacy: Incentive Payments

The author's office is addressing the issue where pharmacists or pharmacy employers receive incentives to substitute a patient's medication therapy. AB 670 is intended to eliminate specific financial inducements that encourage pharmacists to change one drug product for another that does not have the same active ingredient. At the committee meeting, members questioned the necessity of the bill; expressed concern over the broad wording of the bill; and noted that it does not address various practice settings for pharmacists. Additionally, the board does not see consumer complaints in this area – and if it did, has existing authority under which it would investigate and charge violations.

The bill was amended on April 16th, a copy of the bill was provided in the meeting materials. As amended the bill would not apply to payments that are received as part of a comprehensive medication review (which includes a consultation with the patient).

Discussion

Mr. Brooks did not see why the board would oppose this bill.

Ms. Klein read the bill in its entirety for the board.

Dr. Castellblanch noted that the committee was concerned that the bill as written is overly broad.

Ms. Mary Staples commented that the National Association of Chain Drug Stores is strongly opposed to this bill.

Ms. Herold commented that the board has not received a complaint on this issue.

Mr. Jonathan Nelson commented that CSHP strongly opposes this bill as there are unattended negative consequences.

Dr. Steve Gray from Kaiser clarified that even making the recommendation to substitute a medication would be a violation under the proposal and stated that Kaiser strongly opposes this bill.

Ms. Mariel Farsi commented that OptumRx also opposes this bill.

Mr. Ray Vrabel commented that in his experience it is a common practice to substitute a medication for a cheaper option in order to benefit the patient.

Motion: Oppose AB 670.

Support: 10 Oppose: 0 abstain: 1 (Brooks)

AB 1136 (Levine) Pharmacists: Drug Disclosures (Drug Warning Labels)

AB 1136 is intended to address drug warning labels related to dispensed prescriptions where the drug may impair a person's ability to operate a vehicle or vessel. Existing pharmacy law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a dangerous drug if the drug poses substantial risk to the person when the drug is taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle. The board's regulation at 16 CCR 1744 requires a pharmacist to inform a patient of the harmful effects of certain drugs dispensed by prescription. A pharmacist utilizes professional judgment when adhering drug warning labels to a dispensed prescription. AB 1136 would remove such discretion when it involves a drug that may impair a person's ability to operate a vehicle or vessel.

Staff attended the Assembly Health Committee hearing and answered the committee's questions regarding current requirements. As noted in the staff analysis provided in the meeting materials the board's regulation specifies substances for which a pharmacist shall orally or in writing provide such warnings. AB 1136 seeks to mandate a drug warning label for these types of substances.

<u>Discussion</u>

Ms. Shellans noted that the current amendments did not completely address the board's concerns with the bill.

Dr. Kajioka commented that this bill takes away the professional judgment of the practitioner.

Dr. Law commented that the intention of the bill was good but a competent pharmacist would already warn a patient of possible side effects of the drugs they are taking.

Motion: oppose AB 1136.

Support: 11 Oppose: 0 Abstain: 0

a. AB 1139 (Lowenthal) Prescriptions: Biosimilar Products

AB 1139 seeks to amend Section 4073 to specify that a pharmacist filling a prescription order for a biological product, as specified, may select a biosimilar product, provided that the substituted biosimilar product is deemed by the FDA to be interchangeable with the prescribed product. The amendments would prohibit a pharmacist from making such a substitution if the prescriber indicates "Do not substitute" or words of similar meaning. As with current law, the pharmacist would be required to communicate to the patient the name of the drug dispensed, and ensure the drug container is appropriately labeled.

Additional legislation (SB 598, Hill) also seeks to amend Pharmacy Law as it relates to the substitution and dispensing of a biosimilar product, where a biological product is prescribed. Randy commented that he would recommend the board support AB 1139.

Discussion

Dr. Kajioka commented that after further researching the bill he changes his position to support the bill.

Ms. Shellans commented that as the FDA has not gone through the process of approving the product it may be too soon to take a position.

Ms. Veale agrees with the committee's recommendation to remain neutral on the bill.

Ms. Mariel Farsi, from OptumRX, commented that to date the FDA has not received a single application for a biosimilar drug.

Motion: Remain neutral on AB 1139 and send a letter to the author expressing the board's concerns.

Support: 10 Oppose: 0 Abstain: 1 (Kajioka)

SB 204 (Corbett) Prescription Drugs: Labeling (Translations) and SB 205 (Corbett) Prescription Drugs: Labeling (12-point Font)

Discussion

President Weisser recommended that due to amendments these two bills (204 and 205) be considered by the Public Education Committee at their next meeting and a recommendation be brought back to the board.

Sarah de Guia from the California Pan-Ethnic Health Network, the sponsor of SB 204, stated CPEHN's willingness to work with the board on SB 204.

Motion: Table SB 204 and SB 205.

M/S: Gregg/Castellblanch

Support: 11 Oppose: 0 Abstain: 0

SB 493 (Hernandez) Pharmacy Practice

SB 493 would create a board designation of "Advanced Practice Pharmacist" to be recognized by the Board of Pharmacy; would declare that pharmacists are health care providers who have the authority to provide health care services. Additionally, SB 493 would specify expand the types of services that may be provided by a pharmacist to include immunizations and other functions, as specified; and make conforming changes to Sections 4052 and 4060 to effect the provisions of the bill.

Discussion

Dr. Gutierrez commented that she supports this bill.

Dr. Steve Gray, representing CSHP, commented that the wording in the bill does not require the board to create another license type.

Ms. Shellans disagreed with Dr. Gray, and commented that the bill will require a new license type.

Dr. Gray clarified that he meant that there would not need to be a new exam created.

Dr. Schell says that this is not really an expansion of the scope of practice for pharmacists.

Motion: Support SB 493.

Support: 11 Oppose: 0 Abstain: 0

SB 506 (Hill) Ephedrine: Retail Sale

Until January 1, 2019, SB 506 would restrict the furnishing of ephedrine products without a valid prescription. SB 506 would eliminate the current reporting of specified ephedrine products to the California Department of Justice (DOJ) and, instead, provide for the collection and reporting into a single web-based database operated by the National Precursor Log Exchange (NPLEx) specified proposed transactions of those products. The

web-based single database would be available to a retailer at no charge, but would require a retailer to access this web-based system via the internet. Retailers would be required to submit specified information prior to completing a transaction, and the retailer would be prohibited from completing the transaction if an alert is generated by the system.

While the measure addresses the recordkeeping of these transactions during a mechanical or electronic failure of the system, the measure does not specify whether a retailer would be authorized to complete a transaction under those circumstances.

Discussion

No comments were provided by the board or by the public.

SB 598 (Hill) Biosimilars

SB 598 would add Section 4052.55 to the Business and Professions Code to specify conditions under which a pharmacist may exercise professional discretion to substitute a *biosimilar* for a prescribed *biological* product, if certain requirements are met. Additional legislation (AB 1139, Lowenthal) also addresses the substitution of a biosimilar, where a prescription for a biologic was prescribed.

Discussion

Ms. Veale commented that the board should oppose the bill.

Mary Staples commented that the National Assassination of Chain Drug Stores is strongly opposed to this bill.

Motion: Remain neutral on SB 598 and send a letter of concern to the author.

Support: 1 (Gutierrez) Oppose: 10 Abstain: 0

Motion: Change the board's position to oppose SB 598.

M/S: Veale/Castellblanch

Support: 10 Oppose: 0 Abstain: 1 (Brooks)

SB 669 (Huff) Emergency Medical Care: Epinephrine Auto-Injectors

SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors (EpiPens), make them available to trained individuals (as specified) and allow those individuals to administer an EpiPen, without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic

reaction. Staff has sought clarification from the author's office on various components of the measure, as specified in the analysis provided in the meeting materials. The committee recommends that the bill should be changed to also specify that a pharmacist be authorized to approve the requisite training certificates and issue the prescriptions, as intended in this legislation. The committee believes that pharmacists are skilled health care professionals and that they also should be able to authorize the dispensing of the epinephrine auto-injectors as specified in the bill.

Discussion

Dr. Steve Gray, from Kaiser, commented that this bill is intended to be very simple, it creates a training course for the proper use of epinephrine auto-injectors and then requires a doctor to verify the completion of the course and then writes a prescription for an injector. However in his opinion a pharmacist could also verify completion of the course and write the prescription.

Dr. Kajioka commented that the board should clarify what a certificate would look like.

Motion: Support SB 669 if amended, to include the ability for a pharmacist to issue the requisite prescription for dispensing of the epinephrine auto-injectors, as specified in the bill.

Note: Mr. Brooks was not present for the vote.

Support: 10 Oppose: 0 Abstain: 0

SB 809 (DeSaulnier) CURES

Health and Safety Code Sections 11165 – 11165.3 establishes and defines the parameters and use of the CURES Program within the California Department of Justice. Under current law, prescribers and pharmacies are required to report each week to DOJ every Schedule II, III and IV prescription dispensed.

Following substantial funding reductions that were part of the 2011-2012 Governor's Budget, the Department of Justice has been maintaining the program with limited resources. In 2009 DOJ launched an automated Prescription Drug Monitoring Program (PDMP) within CURES. This program allows authorized users, including pharmacists, prescribers, and others, to access at the point of care patient controlled substance prescription information. This information allows prescribers and pharmacists to make informed decisions about patient care and to detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners. SB 809 would establish permanent funding for CURES by increasing fees for specified health care

practitioners and also to wholesalers, nonresident wholesalers and veterinary food-animal drug retailers.

Discussion

Dr. Kajioka commented that the current CURES system does not have immediate search capability.

Ms. Herold stated that Schedule 5 drugs should be added into the system.

Dr. Kajioka again expressed his concern with requiring pharmacists search the system prior to dispensing drugs, when the system is not currently capable.

Ms. Sodergren commented that the bill addressed this and the mandatory look-up does not take effect until the DOJ has determined that the system is robust enough to do so.

Mr. Castellblanch expressed concern over not supporting a bill that provides funding for a program that the board needs for enforcement matters.

Ms. Mary Staples from the National Association of Chain Drug Stores commented that they support the use of CURES however mandatory searches will create an increase in workload.

Mr. Jonathan Nelson commented that CSHP supports CURES but mandatory searches create an additional impediment to providing care.

Mr. Dennis McAllister commented that Express Scripts supports the program but mandatory look up will significantly increase the patient wait time. He also gave a brief description of a new system being used in Ohio.

Dr. Raffi Simonian of the UC San Diego Health System commented that funding for CURES is critical.

Dr. Fujimoto commented that the board should just fund the CURES system and not make reporting/searching mandatory.

Mr. Castellblanch again expressed his concern that the board should not oppose this bill or require it to be amended, when the board has someone in the legislature who is interested in getting funding for the program.

Ms. Herold commented that the board's job is to protect the consumer and the CURES system was designed to differentiate between someone who is doctor shopping and someone who has a legitimate need. She also agreed with Mr. Castellblanch concerns and recommended that the board support the bill and offer suggestions to the author for amendments.

Dr. Law commented that the board should support if amended.

Ms. LuGina Mendez-Harper, from the New Mexico Board of Pharmacy, and representing Prime Therapeutics, commented that in New Mexico they suggest that the pharmacist refer to the prescription drug monitoring program, but they ultimately left it up to the pharmacist's professional judgment.

Dr. Simonian commented that the board should support the bill.

Dr. Schell commented that while this bill would create more work for pharmacists, however, there is so much diversion it needs to be done.

Motion: Support SB 809

Support: 11 Oppose: 0 Abstain: 0

The board recessed for a break at 3:4 p.m. and resumed at 4:10 p.m.

SB 62 (Price) Coroners: Reporting Requirements: Prescription Drug Use

As introduced, this bill would have required coroners to also file with the Board of Pharmacy reports where a death was determined to be the result of prescription drug use, but the board was amended out of the bill on April 9, 2013.

The bill was also amended earlier this week. The most recent amendment specifies that where a licensed pathologist indicates that a contributing factor in a cause of death is related to toxicity from a Schedule II, III or IV drug, the report shall be filed with the Medical Board.

Discussion

Ms. Herold noted that the Medical Board has promised to share the reports it receives.

Ms. Shellans commented that the board may want to write a letter to the author to ensure that the Medical Board can share the information.

AB 186 (Maienschein) Professions and Vocations: Military Spouses: Temporary Licenses

Under current law, a DCA board is required to expedite the licensure process for applicants who meet certain requirements.

The committee expressed concerns regarding a requirement to issue someone a provisional license where the board has not verified the minimum requirements for licensure had been

met; where an underlying permit may have been disciplined or not in good standing; and that the measure lacked the authority for a board to revoke a provisional license. The committee also noted technical challenges to implement such a measure given DCA's migration to a new applicant tracking system, and where a 'provisional' license type is not currently programmed.

The most recent version strikes the "provisional" license and – instead – requires a temporary license to be issued to an applicant who meets certain criteria. The new amendments appear to address the committee's concerns regarding the authority to revoke the license, and where the underlying permit is to be in good standing.

However, the new amendments do not address the committee's concerns that an individual would receive a temporary license while the board confirms that they meet the minimum requirements for licensure. This means an individual would be able to work in a pharmacy setting while the board processes the application.

Discussion

Ms. Klein commented that the amendments did not address all of the board's concerns.

Ms. Sodergren commented that the amendment states that the board must issue the license after an appropriate investigation.

Motion: Remain neutral on AB 186 and write letter of concern to the author.

Support: 11 Oppose: 0 Abstain: 0

AB 213 (Logue) Healing Arts: Licensure and Certification Requirements: Military Experience

The committee did not make a recommendation on this bill. The intent of the bill was to allow for applicable military experience and training as a part of the path to licensure.

The bill was recently amended twice, and a copy of the April 18th amendment was provided to those in attendance.

The latest version of the bill requires that where a board accredits or approves schools or educational courses for licensing, that the board should also ensure that the school or course has procedures in place to evaluate an applicant's military education and practical experience.

For pharmacy technician's, the board currently recognizes training programs offered by the federal armed services (for which an individual has a certificate of completion) as meeting

the minimum educational requirements for licensure as a board-licensed Pharmacy Technician.

Discussion

No comments were provided by the board or by the public.

AB 258 (Chavez) State Agencies: Veterans

SB 258 would standardize the way any state government organization would ask an individual as to their veteran status. Committee comments reflect that if such a question is asked, perhaps the questions as to how the individual was discharged should also be asked.

The bill was amended on April 22, 2013 but the amendments were not available as of the board meeting. According to the author's office, the amendments will delay implementation of the requirement to July 2014.

The committee did not recommend a position on this bill, and staff will continue to watch this measure.

Discussion:

No comments were provided by the board or by the public.

AB 512 (Rendon) Healing Arts: Licensure Exemption

The committee recommended that the board support AB 512.

Currently, until January 1, 2014, an individual can be exempt from licensure and regulation requirements to provide health care services through sponsored events. AB 512 extends these provisions to 2018.

The committee spoke in support of these health care events, and noted it was in the board's best interest to ensure that matters related to the practice of pharmacy at these events were adequately enforced and monitored.

Discussion

No comment was provided by the board or by the public.

Motion: Support AB 512

Support: 11 Oppose: 0 Abstain: 0

AB 555 (Salas) Professions and Vocations: Military and Veterans

The current amendment took the board out of AB 555.

AB 1057 (Medina) Professions and Vocations: License: Military Experience

AB 1057 would require every board to inquire on every application for licensure if the applicant is serving in, or has previously served in the military. It is one of many bills that the Department is watching related to licensing requirements for all boards. The committee did not recommend a position on this measure.

Discussion

No comment was provided by the board or by the public.

AB 299 (Holden) Health Care Service Plans / Insurer: Mail Order

AB 299 was amended prior to the board meeting, a copy of the new version was provided in the meeting materials. The committee recommended that the board establish a position of Support if amended, suggesting that the provisions related to third-party agreements would be better placed in the Health and Safety or Insurance Codes.

The bill would prohibit a resident or nonresident pharmacy that delivers prescriptions via mail from entering into, or being a party to, an agreement with a health care service plan or disability insurer that requires a plan enrollee to utilize mail order services, or that requires a plan enrollee or insured to opt out of a mail order process. At the committee meeting, counsel noted the board is not in the business of regulating private party agreements. Still, committee members spoke in support of patients being able to get their prescription medications without having to go through mail order.

Discussion

Dr. Gutierrez commented that this bill was in response to an insurance provider who started requiring HIV patients to get their medications through the mail.

Ms. Shellans expressed concern in regulating private party agreements.

Dr. Steve Gray, from Kaiser, commented that there are certain drugs that are only administered though a specialty pharmacy.

Mr. Tony Park, from CPHA, commented that forcing people to get medications through the mail is not in the best interest of the public.

Mr. Robert Moore, a pharmacist, commented that in his experience patients are often underserved by mail order pharmacies.

Motion: Support if AB 299 if amended.

Support: 8 Oppose: 2 (Gutierrez and Brooks) Abstain: 1 (Butler)

SB 445 (Price) Pharmacies: Advertising: Controlled Substances

Existing Pharmacy Law requires that an advertisement of the retail price of a drug shall be limited to quantities of the drug that are consistent with good medical practice, and specifies information required for such an advertisement. There is no section that restricts the advertising of controlled substances. Additionally, existing law requires every pharmacy to post a notice concerning the availability of prescription price information; the notice may be provided to consumers via a written receipt with the required information, and allows an individual to receive price information, as specified.

SB 445 would specify that under no circumstances may an advertisement from a pharmacy specifically promote the sale or dispensing of controlled substances.

Discussion

Ms. Hackworth asked if any pharmacy currently advertises for controlled substances.
Ms. Herold answered that she did not believe so.

Dr. Gray, for Kaiser, commented that others who dispense controlled substances should not be allowed to advertise. He also asked if posting drug prices on a company website as required by Medicare Part D would violate this bill.

Ms. Shellans commented that constitutional free speech is protected and she does not recommend that board tries to regulate this area.

SB 727 (Jackson) Medical Waste: Pharmaceutical Product Stewardship Program

The committee did not recommend a position on this bill.

Currently, the Medical Waste Management Act (MWMA) prescribes the methods for treating pharmacy waste (i.e., bio hazardous waste) because of the potential harm to public health and safety and the environment if not managed properly. The MWMA establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements. Regulation of the MWMA is performed by the California Department of Public Health.

SB 727 would add the "Drug Abuse Prevention and Safe Disposal Program to the Public Resources Code. This article would set forth definitions, requirements for stewardship plans, to include the minimum number of collection sites for each plan submitted. SB 727 would require that a stewardship plan include the number of collection services, and that there shall be on and after January 1, 2016 one collection service within 10 miles per person in the state, with a 20 percent increase in the number of collection services one year thereafter, and other information. The plan shall also include a description of the methods to be used to collect, transport and process home-generated pharmaceuticals in this state.

At the Legislation and Regulation Committee meeting held April 11, 2013, co-sponsors of the bill encouraged the board's participation to finding a statewide solution to handle the disposal of prescription drugs.

This is an opportunity for the board to work on a system by which these drugs can be taken back, and the committee encouraged staff to work with the author's office to ensure the board's concerns related to the safety of the drugs are addressed.

Discussion

Ms. Herold noted that the author's office has reached out to the board to work on the bill.

Dr. Steve Gray added that if the board is working with the author's office the board should be sure to clarify the 10 mile radius requirement.

A member of the public commented that currently Alameda County has a drug take-back program. He added that the hospital he works in will often have patients bring in bags of unused medications to return, but the DEA will not allow them to take them back. The large amount of unused drugs in patients' homes creates potential for drug abuse and is a huge problem.

Ms. Herold noted that the board's position is that all drugs must remain unsorted/uncounted and must be pulverized to keep them from re-entering the supply chain and they are working with the author of the bill on this point. Ms. Herold added that Alameda County is being sued by drug manufactures for product stewardship.

AB 1045 (Quirk-Silva)

AB 1045 by Assembly Member Quirk-Silva, has amended a bill to now address Sterile Compounding Pharmacies. A copy of AB 1045 was provided in the meeting materials. The bill was amended to no address sterile compounding pharmacies. The bill provides that if the home state license of a non-resident pharmacy is revoked or suspended for any reason the California license will be immediate suspended by operation of law. It also requires that any resident or non-resident pharmacy that issues a recall notice for a sterile compounded drug to contract the Pharmacy Board, recipient pharmacy, prescriber or patient about the recalled drug within 24 hours of the recall if the use of or exposure to the recalled drug my

cause serious, adverse health consequences or death and if the recalled drug was dispensed or was intended for use in California. Because the violation of these requirements would be a crime the bill would impose a state mandated local program. The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state, this bill would establish that no reimbursement is required.

Discussion

Ms. Herold noted that this bill is the assembly's attempt to do something about the compounding issue.

Ms. Sodergren added that staff supports this bill because this provision allows the board to automatically take an entities license away if the license in their home state is revoked or suspended.

Mr. Brooks asked if there would ever be a circumstance where another state takes away a license and California would allow them to stay licensed in our state.

Ms. Herold answered no, because a condition of licensure in California is having a valid license in the home state.

Ms. Shellans and Mr. Brooks asked for clarification on the due process for someone whose license is suspended.

Ms. Herold answered that if a license in an entity's home state is suspended or revoked then they would have to resolve the issue with the home state before California would remove the suspension on their license to do business in California.

Motion: Support AB 1045.

M/S: Lippe/Law

Support: 10 Oppose: 0 Abstain: 1 (Brooks)

XII. CLOSED SESSION

Meeting adjourned to closed session at 4:53 p.m.

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters.

ADJOURNMENT FOR THE DAY

Thursday, April 25, 2013

Resumption of Open Session **9:59 a.m.**

XIV. EXECUTIVE OFFICER REPORT

Ms. Herold announced that the Notice to Consumer Posters have been mailed out and should be received by pharmacies soon.

Ms. Herold announced the next DEA Drug Take Back Day will be held on Saturday April 27, 2013.

Ms. Herold reported that for the first time the subscriber alert was used to send out a notice of suspected counterfeit drugs.

Ms. Herold noted that BreEZe continues to take considerable staff time for both our subject matter experts and executive staff.

Ms. Herold reported that the board is still under travel restrictions from the governor's office, however the board is still allowed to travel to conduct board meetings, to investigate complaints, to conduct inspections and to conduct other licensing functions. Additionally the one day furlough per month is still in effect until June 2013.

Ms. Herold announced that there is a governor's directive to turn in a Leave Reduction Plan to reduce the amount of banked vacation days held by executive staff.

Ms. Herold reported that the Appropriate Prescribing and Dispensing Forum held in San Francisco was successful, and the board hopes to work with the Medical Board to hold another.

Ms. Herold noted that the board is using video conferencing equipment to hold staff meeting with the inspectors without them having to travel to Sacramento.

Ms. Herold announced that State and Consumer Services Agency and the California Health and Human Services Agency will be working with an outside consultant to see if there are areas of duplication between the two agencies.

Ms. Herold also reported that the House and the Senate at the Federal level have released new versions of solutions for supply chain security. The board will be submitting comments.

Discussion

Mr. Brooks asked if the board was working with California representatives on e-pedigree.

Ms. Herold answered that the board has a very interested representative who we are working with.

President Weisser conducted a roll call. Board members present: Stanley C. Weisser, Randy Kajioka, Rosalyn Hackworth, Greg Lippe, Amy Gutierrez, Victor Law, Ryan Brooks, Albert C.M. Wong and Lavanza Butler. Board members not present: Shirley Wheat and Tappan Zee

Note: Ramon Castellblanch arrived at the meeting at 12:30 p.m.

XV. ENFORCEMENT COMMITTEE REPORT

Chairperson Randy Kajioka provided a report from the March 14, 2013 Enforcement Committee as follows.

a. Request from Walgreens to Store Prescription Records Older than Five Years Outside of a Licensed Pharmacy

California has requirements that all pharmacy records be readily retrievable in the licensed premises, and open to inspection by the board. These records are generally required to be retained for at least three years.

California law also permits the offsite storage of records if an offsite waiver has been approved by the board.

Walgreens requested that because CMS requires storage of records for 10 years, they would like the ability to store records older than five years offsite at a firm that specializes in records storage.

Al Carter, representing Walgreens provided the committee with an overview of the requirements for records retention to comply with the requirements of CMS. Walgreens had requested authorization to store records off site after five years. The records storage is an issue because law specifies which persons have access to records, including pharmacy staff. The offsite storage vendor is not included in those authorized persons, although five years is two years longer than the three-year record retention period required by CA Pharmacy Law.

Mr. Carter provided an overview of the proposed vendor, Iron Mountain, which has multiple locations statewide. He commented that records will be stored on a store by store basis and will only be accessed by Iron Mountain staff. Mr. Carter indicated that any access to the records will be recorded.

Discussion included mention that Iron Mountain has to respond to a request for records, per the contract, and provide the records within 48 hours. Iron Mountain is already used by some pharmacies with approved offsite-waivers to store records to comply with California's three-year retention requirements.

One concern of the committee was how records would be destroyed after the time period had elapsed or if the pharmacy closes before the three years are elapsed. In response, Mr. Carter stated that the contract specifies that the only authorized storage sites may be used and that if Walgreens fails to pay the vendor, the records would be returned to Walgreens.

Mr. Carter indicated that Walgreens could provide a spreadsheet that includes each pharmacy and the location of the Iron Mountain facility where the records will be stored.

Discussion

Mr. Law asked if currently each location had to come before the board to get approval to store records off site.

Chairperson Kajioka answered that currently when a store opens they apply for an offsite records storage waiver.

Motion: Approve Walgreens request for offsite storage of records older than five years.

Support: 10 Oppose: 0 Abstain: 0

Walgreens Request to Install an Automated Drug Delivery Device (or Kiosk) in Workplace Centers

Several years ago, the board promulgated a regulation (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances. These circumstances include, that the patient must opt in to use the machine, the medication to be refilled through the machine is appropriate. The conditions are listed below in the highlighted segment of section 1713.

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must Be to or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence

designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

In 2009-10, Philip Burgess, on behalf of Asteres, a manufacturer of automated delivery devices, sought an exemption to permit the use of these machines in areas away from adjacent to the licensed pharmacy premises. The board did not approve the request, and requested more information about how and where the kiosks would be used. One concern was that the board considered that it lacked the ability to provide the exemption sought (which would have required a regulation change). There was no further interest pursued by Asteres after the January 2010 meeting.

Walgreens recently requested an opportunity to address the board to seek a waiver of Section 1713 to permit the use of an automated delivery device in a workplace setting, away from a pharmacy. A copy of this request was provided in the meeting materials.

Mr. Carter, representing Walgreens, discussed the request that would allow Walgreens to place kiosks in workplace settings. Mr. Carter advised the committee that the workplace has a clinic on an employee campus that serves a large number of employees.

Mr. Carter provided an overview of the types of services that are provided at the clinic and how Walgreens would provide medication. Mr. Carter highlighted that the kiosk would not be located in the clinic, but would be housed across the street in a separate building. The kiosk would be in a secured building and advised the committee that a patient would have access to a pharmacist via a video link 24 hours a day.

Mr. Carter discussed who will put the medications in the machine and the safety features of the machine including barcoding. Safety features include a log-in and pin or a fingerprint scan and pin number. A camera is also used to take pictures for auditing purposes. Mr. Carter discussed the specifics of the enrollment process. Mr. Carter indicated that no refrigerated items or bulk items would be provided via this kiosk. [A copy of Mr. Carter's PowerPoint presentation is provided at the conclusion as part of the meeting minutes.]

In response to questions Mr. Carter stated that an authorized agent could pick up the prescription since there was a consent process in place, but the authorized agent is limited to just family members. If consultation was determined by the pharmacist to be necessary, the patient would be required to go to the pharmacy to obtain the medicine.

Mr. Room discussed some possible options the board could consider depending on the full nature of the request. Ms. Shellans indicated that her legal opinion is more limited and that current law only allows for refill prescriptions. Ms. Shellans indicated that expansion to allow for new prescriptions would require a regulatory change.

Ms. Hackworth asked what others services or items are in the room that will house the kiosk and was advised that Walgreens believes the kiosk will be the only item in the room.

Mr. Carter commented that Schedule II controlled substances would be dispensed via the kiosk if allowed by the board.

The kiosk would be filled by only by pharmacists. The prescriptions will be filled at a local Walgreens and delivered to the Kiosk, not filled by a central fill pharmacy.

Mr. Room clarified that under the current regulation, the board lacks the authority to waive the requirement that the kiosk be adjacent to a pharmacy. Further, Mr. Room noted, in that access to a machine not housed in a pharmacy by board staff for investigative purposes could be problematic.

Committee Member Zee suggested that perhaps Walgreens could work with counsel to develop language that could address the boards concerns as an interim solution to allow for a temporary waiver to be considered at a future committee meeting. Mr. Carter expressed a willingness to work with the board.

Mr. Carter indicated that a few other states allow for the use of a Kiosk as being proposed and offered to survey and provide information to the board.

Discussion:

Dr. Gutierrez asked if there is a way to the board to review automation and new technology in regards to the practice of pharmacy.

Mr. Ray Vrabel, pharmacist, asked why the board denied the request.

Dr. Kajioka answered that the current regulation required them to deny the request.

Ms. Hackworth added that another issue with was it was not known what else would be housed in the building with the kiosk.

Mr. Darrel Martin, pharmacist, commented that Kern County is looking at distributing medications to its employees and asked if medications can be delivered downstairs at an office building for the employee to pick up later.

Ms. Herold answered that if they are leaving the medications downstairs for pick-up then they would need to come before the board for approval.

Dr. Gray, from Kaiser, commented that currently medication can be left at another pharmacy, another place of care, *and* place of employment. This was verified by Chairperson Kajioka and Ms. Herold.

Supervising Inspector, Bob Ratcliff, stated that each individual patient would have to provide instructions for where to drop off each of their prescriptions.

Mr. Dennis McAllister with Express Scripts agreed with Dr. Gutierrez on the need to address immerging technologies.

Dr. Wong noted that audits require patient signatures for the receipt of each prescription.

Mr. Brooks asked if the board could address this issue by going to the legislature.

Ms. Herold answered that it would be possible for a member of the public to advocate the issue to the legislature.

Motion: Enforcement Committee: Deny the request but have the board re-evaluate the regulation and determine if changes are necessary to address emerging technologies.

Support: 10 Oppose: 0 Abstain: 0

Request for a Waiver of Security Prescription Blank Prescribing Requirements for Controlled Substances in a Closed Health Care System

Existing law requires the use of security prescription forms for written prescriptions for controlled substances. Security prescription forms must be printed by state-registered printers and conform to specific requirements to make forgery of these forms difficult. There are few exceptions to the use of these specialized forms when a prescriber writes a prescription.

Schedule III-V drugs may be prescribed orally; only in very limited cases, may Schedule II drugs be orally prescribed.

In 2010, the DEA released Interim Final Rules to permit the e-prescribing of controlled substances, and all e-prescriptions for controlled substances must the DEA's regulatory requirements, including a third-party audit of the computer application certifying that the system meets the requirements of the DEA regulations.

E-prescribing is not faxing (where a prescription is actually written and signed by the prescriber, and a facsimile is transmitted to the pharmacy). Faxing is not allowed for controlled substances, although faxed prescriptions for Schedule III- V prescriptions are sometimes treated as oral prescriptions by pharmacies which if received, must verify the fax with the prescriber's office. (Note: a security prescription form, if faxed, is required to

display a “VOID” impression on the faxed document, showing that the fax is not a legitimate written prescription.)

Kaiser Permanente requested an opportunity to address the committee to seek an exemption within Kaiser’s closed system of patient care to use plain paper to prescribe controlled substances.

Dr. Steve Gray, representing Kaiser Permanente, provided a brief overview of Kaiser Permanente including its closed integrated system. Dr. Gray provided a brief overview of the concerns with their current process and handling of schedule III and IV controlled substance prescriptions. Dr. Gray indicated that the result of their current process is delays in delivering pharmacy services. Instead, Kaiser proposes to print all controlled substances prescriptions for Schedule III and IV drugs on plain white paper, hand this document to the patient, and then have the Kaiser pharmacy access patient electronic records to confirm the controlled drug and quantity are as written on the plain paper “prescription.” Dr. Gray indicated that the proposal would reduce drug diversion as well as diversion of security of prescription forms.

Kaiser provided a PowerPoint to discuss the overview of the current system as well as the proposal alternative process. (Copies of the Powerpoint are attached to the committee’s meeting minutes.)

Kaiser had previously presented this proposal to the CA Department of Justice, who stated that the proposal appeared to comply with the intent of the law, but this is not an official position of the agency. Dr. Gray also spoke about the security features of the Kaiser system. Dr. Gray indicated that it this system would address the issue of someone calling in a fake oral prescription and well as the diversion of security prescription blanks.

Kaiser was directed by the DOJ to discuss their proposal with the board to ascertain the guidance of the board to determine if the board has concerns with the proposal. This information would then be brought back to the DOJ who establishes the requirement for the security prescription requirement.

Ms. Herold indicated that she firmly believes that the board lacks the authority to act on this provision to grant Kaiser the ability to use non-security forms to prescribed controlled drugs. Ms. Herold indicated that DOJ also lacks the authority to accept this waiver of state law as well. Ms. Herold indicated that she would strongly advise the board to not consider this waiver until the statute is changed.

Dr. Gray advised the committee that the DOJ has indicated that they do not believe that the Health and Safety Code does not prohibit this type of prescribing.

Mr. Room indicated that he would need to discuss this proposal with the DOJ to determine if the law is in fact flexible enough to allow the proposal without a statutory change.

Mr. Room has reached out to the Department of Justice, and he has requested that Kaiser provide a legal analysis justifying such an action. A report will be provided to the committee at the next meeting.

Discussion

Mr. Law asked if Kaiser uses an electronic prescription program.

Dr. Steve Gray, from Kaiser, answered yes but the program does not currently meet the DEA requirements for electronic prescribing of controlled substances. The paper prescription still has to be used and faxed over. This has to be done until the electronic version comes into compliance with the DEA. Dr. Gray added that currently Kaiser is having problems getting someone from DOJ to meet with them.

d. Board of Pharmacy's Comments on the Drug Enforcement Administration's Proposed Regulations Related to the Disposal of Controlled Substances

In 2009, California adopted guidelines for the take back and destruction of unwanted pharmaceuticals from the public so they could be appropriately destroyed and not misused by others or flushed down the drain. However, the guidelines were only guidelines until the DEA promulgated regulations to deal with the collection and destruction of controlled substances.

The DEA developed proposed regulations to deal with the take back and destruction of controlled substances and released them for comment in December 2012, with a final comment date of February 19, 2013. At the February Board Meeting, the board directed that comments be submitted to conform to board policy and California's guidelines in this area.

During the meeting, the committee briefly discussed the board's comments and the proposed regulations. In the coming months, the board may wish to develop provisions to specify how pharmacies and reverse distributors handle unwanted drugs returned for destruction from the public. This is already being requested pursuant to pending legislation

e. Proposal for Statutory Provisions to Prevent a Wholesaler from Purchasing Prescription Medication from a Pharmacy When the Pharmacy Did Not Initially Purchase the Medication from the Wholesaler

California law has provisions to prohibit pharmacies from acting as wholesalers, specifically prohibiting pharmacies from purchasing prescription medication and reselling these medications to other pharmacies or wholesalers, with specific exceptions. These provisions were enacted in 2004 as part of the first e-pedigree law as one method to stop drug diversion, and safeguard the supply chain.

The specific provisions are:

4126.5. Furnishing Dangerous Drugs by Pharmacy

(a) A pharmacy may furnish dangerous drugs only to the following:
  (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
  (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
  (3) A licensed wholesaler acting as a reverse distributor.
  (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
  (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
  (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
  (7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

Over the last few years, there has been notice of drug shortages at higher levels than in the past. Desperate providers and patients will pay high prices to obtain the medication they need. Also over the last few years, the board has identified multiple cases where smaller wholesalers have recruited pharmacies to purchase medication in short supply <u>specifically</u> for the wholesaler. These purchases exceed the allowances authorized in section 4126.5(a)(4) whereby a pharmacy can sell product to alleviate the shortage. By recruiting a number of pharmacies to do such purchasing, the wholesaler can obtain enough volume of a short supply drug to charge very high rates for the medication they are able to obtain. This has occurred in California and it has occurred nationally.

Board staff suggests that to prevent California wholesalers from purchasing drugs from pharmacies outside California, that a reciprocal provision be pursued to prevent a California

wholesaler from purchasing drugs from a pharmacy if the pharmacy did not initially purchase the drugs form the wholesaler.

Proposed language to do this is provided below.

§ 4126.5. Persons or organizations that pharmacies may furnish with dangerous drugs; violations; offset of amounts due; definitions

(a) A pharmacy may furnish dangerous drugs only to the following, and only the following may receive dangerous drugs furnished by a pharmacy:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section ~~by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities~~ may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code.

Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

Staff indicated that under investigation is a wholesaler that is purchasing drugs from nonresident pharmacies, drugs that are short supply, and this proposal would prohibit a CA located wholesaler from purchasing drugs from a nonresident pharmacy. In existing law is a prohibition that a CA pharmacy cannot sell drugs to a wholesaler that it did not initially buy the drugs from – with several exception. However the law does not appear to explicitly prohibit such a transaction when the pharmacy involved is not located within CA.

Mr. Room discussed the intent of the legislative proposal and outlined the current law relating to this area. He stated that under current law, a pharmacy is allowed to sell a drug that is currently in stock to a wholesaler to alleviate a shortage. He indicated that three conditions must be met to allow for a sale from a pharmacy to a wholesaler from other than that from which they originally purchased the drugs.

1. The pharmacy already has it in stock

2. The drug for which there is a shortage and

3. A person will be denied health care

Discussion during the meeting was that the committee needs to more fully discuss the topic.

Concern from one attendee was that the legislative proposal would limit the ability for pharmacies and wholesalers to conduct business relationships that ensure patients receive their medications when a shortage occurs. This commenter discussed the type of business he currently operates that allows him to fill a given order for a drug in short supply through a network of wholesalers and to ensure patients receive the medications they need.

Another commenter stated that several pharmacies are confused about what are the preconditions for the limited sales transactions to occur between pharmacies and wholesalers. He recommended that the board should provide clarity on these issues.

No action was taken on this item.

f. Implementation of California's Electronic Pedigree Requirements for Prescription Medication

This portion of the Enforcement Committee focused on e-pedigree implementation issues. There were no action items from the meeting, but the committee and public had an opportunity to view proposed new regulation language during the meeting on inference, certification (of sales and purchases into the e-pedigree) and inspection (provided in the meeting materials). The next committee meeting will provide the public with a chance to provide information specifically on these proposed regulations.

To promote communication, future meetings of the committee will be configured around a large hollow square. Whereas webcasting is a priority, due to staffing changes in the Department of Consumer Affairs, it may be difficult to continue to maintain such broadcasts. Board staff is currently looking at ways to provide these services ourselves.

1. Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015 Has been Determined (Proposals to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1)

The board has compiled the rulemaking file on these regulations, and it is currently undergoing the required review by Administration agencies.

Copies of the final version of the regulation approved by the board were provided in the meeting materials.

2. Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule

During this part of the meeting, members of the supply chain presented information or discussed issues involving their readiness to implement e-pedigree tracking and tracing. The board encourages such discussion as a way to foster better understanding, to speed and ease implementation, and to identify and resolve issues.

The committee heard a presentation from Bob Celeste representing GS1. Mr. Celeste provided information the very recently released Implementation Guideline from GS1 to support US pharmaceutical supply chain business practices on pedigree and track and trace. Mr. Celeste indicated that the document is a preliminary document at this point; it is being used by some companies to move forward with pilots, but may change as a result of pilot projects as well as further review of the overall process (this document is provide as an attachment to the Enforcement Committee Minutes).

Mr. Celeste spoke about the use of the EPCIS standard to comply with the board's law. He indicated that the EPCIS model would appear to be able to comply with the legal requirements for e-pedigree. However, Mr. Celeste indicated that there are some issues surrounding the use of the centralized model, data governance and who will have access to view and see information that still need to be worked out.

Ms. Liz Gallenagh and John Howells representing HDMA provided a presentation focused on the use of drop shipments by members of the supply chain.

During committee discussion, the HDMA representatives stated that members of the supply chain learn in various ways when a product is being drop shipped – there is no one model. The committee also discussed some of the parameters of wholesale brokering and its similarity to drug shipments and how this could compromise the pedigree process. Mr. Room pointed out that the manufacturer designee drop ship model using a third party logistics provider as described would not comply with section 4163.1.

3. Elements for Possible Regulation Requirements to Permit Inference

Mr. Room introduced and described possible regulatory language on inference, certification and expectations on how to access data for purposes of inspections. These regulation proposals where provided in the meeting materials.

As explained by Deputy Attorney General Room, California statute requires every trade partner who owns a drug product to be sold in California to verify the product at the unit level. In the absence of action by the board to allow for inference, verification is required at the unit level. The board needs to have data to support what types of inference industry wants.

Since July 2012, the board has three times released written requests seeking specific comments needed to develop possible regulations to authorize inference. The board has received only a few comments in response to these requests for information, and few of the comments received were appropriately responsive to the board's inquiries.

The committee heard various comments on inference. Walgreens spoke in need of inference in their distribution center. When asked what percentage of cases go through their distribution center without being broken down, Walgreens indicated that an unsealed case going through to their pharmacies would be an exception.

Mr. Room again asked for documentation and reemphasized the need for industry members to provide comments in response to board requests for detailed information on inference and drop shipments. This information and detail is necessary to develop appropriate regulation requirements.

Ms. Herold also underscored the need for the board to have comments on the draft language to ensure that the regulation is appropriate, ensures the necessary protections are in place but does not prevent the flow of drugs through the supply chain.

Discussion

Ms. Mary Staples from National Association of Chain Drug Stores, provided the board with written comments on the draft language. These comments have been provided after the meeting minutes.

Dr. Steve Gray, from CPHA, commented that they are concerned about the ability to use inference to receive products.

Discussion on the Use of Drop Shipments in the e-Pedigree System

In March staff released a solicitation request through the board's email notification system that the board was seeking information on drop shipments from members of the supply chain. In the short time since the release of this request, the board received one comment that was shared with the committee.

Institute of Medicine Report: Countering the Problem of Falsified and Substandard Drugs

The Institute of Medicine in February released a report on the compromises and problems of US and world drug supplies. This lengthy report describes this problem. It has been added to this agenda only to provide the board and public with knowledge about this problem. A San Francisco Chronicle article on this report and the problem in general was provided in the meeting materials.

h. Enforcement Statistics

The Enforcement Statistics where provided in the meeting materials

i. Presentation by Bob Celeste from GSI

The committee heard a presentation from Bob Celeste representing GS1. Mr. Celeste provided information the very recently released Implementation Guideline from GS1 to support US pharmaceutical supply chain business practices on pedigree and track and trace. The presentation as been provided after the meeting minutes.

XVI. LUNCH

The board recessed for lunch at 11:29 p.m. and resumed 12:31 p.m.

President Weisser conducted a roll call. Board members present: Stanley C. Weisser, Randy Kajioka, Ramón Castellblanch, Rosalyn Hackworth, Greg Lippe, Amy Gutierrez, Victor Law,

Ryan Brooks, Albert C.M. Wong, Deborah Veale and Lavanza Butler. Board members not present: Shirley Wheat and Tappan Zee.

XVII. PETITION FOR EARLY TERMINATION OF PROBATION

Michael Lenzner, RPH 33245
James Palm, RPH 41806

The board recessed for a break at 2:33 p.m. and resumed at 2:43 p.m.

XVIII. PETITION FOR MODIFICATION OF PENALTY

Reza Abolahrar, RPH 47355

XIX. CLOSED SESSION

The board recessed to closed session at 2:56 p.m.

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on the Petitions for Early Termination of Probation or Reduction of Penalty and to Deliberate on Disciplinary Matters

ADJOURNMENT **4:30 p.m.**