



**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 23-24, 2014

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

**BOARD MEMBERS**

**PRESENT:** Stanley C. Weisser, President  
Amy Gutierrez, PharmD, Vice President  
Greg Lippe, Public Member, Treasurer  
Victor Law, RPh  
Ryan Brooks, Public Member (4/23/14 only)  
Rosalyn Hackworth, Public Member  
Albert Wong, PharmD  
Deborah Veale, RPh  
Lavanza Butler, PharmD  
Allen Schaad, RPh  
Gregory Murphy, Public Member  
Shirley Wheat, Public Member  
Ramon Castellblanch, PhD, Public Member (4/24/14 only)

**BOARD MEMBERS**

**NOT PRESENT:** Ramon Castellblanch, PhD, Public Member (4/23/14 only)  
Gregory Murphy, Public Member (4/23/14 only)  
Ryan Brooks, Public Member (4/24/14 only)

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Michael Santiago, DCA Staff Counsel  
Carolyn Klein, SSM2  
Laura Hendricks, Staff Analyst

---

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

## **Wednesday, April 23, 2014**

*Note: The Legislation and Regulation Committee Meeting was held immediately before the board meeting from 8:00 a.m. – 11:00 a.m.*

### **CALL TO ORDER**

President Weisser called the board meeting to order at 12:13 p.m. President Weisser conducted a roll call. Board members present: Stanley Weisser, Amy Gutierrez, Greg Lippe, Deborah Veale, Victor Law, Ryan Brooks, Rosalyn Hackworth, Albert Wong, Lavanza Butler, Allen Schaad, Shirley Wheat. Note: Gregory Murphy arrived late at 12:20 p.m. Board members not present: Ramon Castellblanch.

### **I. GENERAL ANNOUNCEMENTS**

President Weisser announced that continuing education would be offered for attending the meeting on April 24, 2014. President Weisser recognized former Board President Holly Strom, and Dennis McAllister, a board member from Arizona, in the audience.

### **II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JANUARY 29-30, 2014**

Greg Lippe noted that on page 3 “presidential” should be changed to “precedential.”

**Motion:** Approve the January 29-30, 2014 minutes with the noted correction.

M/S: Lippe/Law

Support: 11    Oppose: 0    Abstain: 0

### **III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF MARCH 17 & 18, 2014**

**Motion:** Approve the March 17-18, 2014 minutes.

M/S: Lippe/Law

Support: 11    Oppose: 0    Abstain: 0

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

There were no 50 year pharmacists in attendance.

### **V. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS**

President Weisser noted that comments on items not on the agenda would be limited to four minutes.

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

Note: Gregory Murphy arrived at 12:20 p.m.

## VI. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

Summary of the Organizational Development Committee meeting held on April 14, 2014.

### a. **Board and Committee Meeting Dates for the Remainder of 2014**

President Weisser reviewed the board and committee meeting dates for the remainder of 2014. It was noted that the October meeting may be held in Southern California.

#### 2014 Board Meeting Dates

- July 30-31, 2014 - Sacramento
- October 22-23, 2014 - Possibly Southern California

Note: A complete list of board and committee dates can be found on the board's website: <http://www.pharmacy.ca.gov/about/meetings.shtml>

### b. **Board Meeting Dates for 2015**

The board reviewed the proposed board meeting dates for 2015. President Weisser noted that additional meeting dates may be required to deal with compounding regulations and other time sensitive matters.

- January 27 & 28, 2015
- April 21 & 22, 2015
- July 28 & 29, 2015
- October 20 & 21, 2015

### c. **Budget Update/Report**

#### 1. Budget Report for 2013/14

Anne Sodergren provided a report on the fee increase which was approved by the Office of Administrative Law and will go into effect on July 1, 2014. It was noted that due to necessary programing changes, the new renewal forms with the new fees are being delayed. Those businesses with licenses that expire on July 1 will be mailed a letter and a generic renewal form. Ms. Sodergren stated that the board will be reaching out to pharmacy organizations and schools of pharmacy to get the word out about the fee changes. The new fees will be sent out in a subscriber alert and also be posted on the board's website and published in *The Script*.

President Weisser provided that the board will again exceed its authorized budget, mainly due to enforcement expenses. President Weisser reported that in response to this, board staff prepared a deficiency notice seeking an additional \$1.7 million in spending authority for attorney general (AG) expenses, which has subsequently been approved. Virginia Herold added that the additional AG expenditures reflect the substantial increase in the number of enforcement cases that the board has opened. President Weisser stated that the board is very proactive in disciplining errant licensees and thanked board staff for their enforcement work. Ms. Herold thanked the department's budget office for their work in obtaining the AG funding augmentation.

## 2. Budget Report for 2014/15

President Weisser reported that the final budget for 2014/15 budget should be finalized in June and staff is currently testifying in budget hearings at the capitol.

## 3. Fund Condition Report

President Weisser reported that even with the July 1, 2014, fee increase by the end of 2015/16, the board will have less than a month in its reserve. Ms. Herold responded that staff is watching this very carefully and the fund condition illustrates that another fee increase will be needed due to board growth. Gregory Lippe asked about the process for the board to increase its current statutory maximum fees. Ms. Herold stated that another fee audit will be conducted and based on the results of the audit, the board would seek to increase the statutory maximums through the legislative process in 2015.

## 4. Update on BreEZe

Ms. Sodergren provided an update on the implementation of the new BreEZe system. Ms. Sodergren explained that the BreEZe system is designed to be an integrated computer system replacing the multiple systems currently in use. Ms. Sodergren added that many of the boards in release 1 were not as complex as this board and consequently there have been some challenges in modifying the system so it will meet the board's needs. Currently, the board has not been provided with a project schedule; however, it is likely that the October release date will be moved back into sometime in 2015. Ms. Sodergren concluded by stating that she, President Weisser, Amy Gutierrez and Ms. Herold continue to work together to advocate the board's needs to the contractor and the department.

## 5. Updates on Board Member Attendance, Reimbursement and Mail Votes

President Weisser stated that board member attendance, reimbursements and mail vote statistics have been provided in the meeting materials.

### **c. Personnel Update**

Mr. Herold reported that recently the board has had some significant personnel changes, particularly in site licensing. In part due to new staffing, site license applications are now well over the 45-day processing time. The board is redirecting staff and implementing mandatory overtime to decrease the processing times back to 45 days by July 1, 2014. Ms. Herold added that in addition to new staff and vacancies staff being redirected to the BreEZe project has also contributed to the increase in application processing times.

Holly Strom, former board member, noted that discipline of technicians takes up a significant amount of the enforcement costs and asked if there was a way for the board to garnish their wages or put a lean on their property to ensure the board recoups its enforcement costs. Ms. Herold responded that with citation and fines the board can go to the Franchise Tax Board and

garnish any of their tax returns. However, if the board revokes a technician's license, then the board will not receive any cost recovery until they re-apply for licensure - if they ever do. Ms. Strom recommended that the board consider warning technicians that they could be responsible for enforcement costs when they apply for licensure.

## VII. EXECUTIVE OFFICER REPORT

### a. **Update on Activities of the Medical Board of California –Kimberly Kirchmeyer, Executive Director**

Ms. Herold noted that due to scheduling conflicts Ms. Kirchmeyer was unable to attend the meeting.

### b. **Update on the Activities of the Executive Officer**

#### 1. Compounding Regulation

Ms. Herold reported that the compounding work group has reviewed the comments received and revised the initial regulation draft. Additionally, the board has begun inspecting hospital pharmacies - 229 inspections have been completed and 263 inspections remain. It has been a priority for the board to complete the inspections of California hospital pharmacies before July 1, 2014 to ensure that patient care is not impacted by the implementation of SB 294. To complete the inspections, each board inspector is required to inspect one hospital pharmacy a week. Additionally, the board has been inspecting California hospital pharmacies even if they have not submitted an application. Ms. Herold reported that the compounding regulation will likely not be in effect by July 1, 2014, through adoption via the emergency rulemaking process. The board wants to be sure that the necessary time is taken to create a good regulation. Ms. Herold stated that the board will begin conducting inspections of out-of-state sterile compounding facilities in June 2014 pending travel approval from the Governor's Office.

#### 2. Training

To ensure that board inspectors are prepared to regulate sterile compounding pharmacies, they have undergone extensive training through *Critical Point*. One component of the *Critical Point* training was a 53-hour online course which the inspectors completed during the second half of 2013. Recently, the inspectors received classroom training from two highly regarded experts in the field of sterile compounding. Ms. Herold added that Dr. Gutierrez and Allen Schaad attended the training to ensure that the compounding regulations will be in line with current compounding practices. The Department of Public Health's consultants will also be receiving access to the web component of the *Critical Point* training program so they will have similar training. Dr. Gutierrez and Mr. Schaad commented that both the online and classroom training were extremely valuable. Mr. Schaad noted that he appreciated the common sense approach that the training highlighted. Dr. Gutierrez reported that USP 800 has been released for public comment and it contains significant changes to USP 797, including the definition of a batch.

Ms. Herold reported that board inspectors also received training on the aseptic technique and smoke testing from a compounding expert from the FDA. Deborah Veale asked what smoke

testing was. Ms. Herold and Dr. Gutierrez responded that smoke testing is done to test the airflow in a compounding pharmacy. Ms. Veale asked if the board inspectors would be receiving smoke testing kits, Ms. Herold confirmed that they would.

### 3. FDA Compounding Meeting

Ms. Herold reported that in mid-March she was allowed to attend a national meeting held by the FDA on compounding. The meeting was held to discuss the FDA's roll-out of its outsourcing facility licensure program. Outsourcing facility licensure is one way FDA's can regulate entities that make large quantities of non-patient specific compounded preparations and ship them sometimes across state borders. The board has already determined that even if a facility is registered with the FDA as an outsourcing facility, it will still have to become licensed with the board in order to compound in California or ship compounded drugs into California. The board and the FDA will each conduct inspections of facilities based on their separate standards.

Ms. Herold clarified that the FDA could inspect a pharmacy and determine that it was doing enough non-patient specific compounding that they should be classified as a manufacturer rather than an outsourcing facility. Ms Herold added that regardless of the FDA's determination, the board will still regulate the entity as a pharmacy unless the facility was so large that it was clearly a manufacturer. If so, the board will refer the facility to the FDA and/or California Department of Public Health.

Ms. Veale asked if a facility would have to meet both the FDA's standards and the board's standards. Ms. Herold confirmed that they would.

### 4. Implementation of CURES

Ms. Herold assured the board that dispensing boards are continuing to work with the Department of Justice on the implementation of the CURES system. The additional \$6 per year CURES fee went into effect April 1, 2014 and will fund the new computer system and ongoing maintenance and staffing. Ms. Herold noted that the DOJ will not actually receive the funds until July 2015.

Ms. Herold stated that currently 17 percent of pharmacists in California are registered in the CURES system. Ms. Herold reported that in response to the slow CURES registration process the board has been working with the DOJ to create a process to allow the board to certify registration documents in an attempt to speed up registration.

Ms. Herold provided that the DOJ has selected to use a custom-off-the-shelf computer system for the new system. Staff is concerned that the system may not meet all the board's enforcement needs and will continue to monitor the situation and update the board.

### 5. Prescription Drug Abuse

Ms. Herold reported that she, along with President Weisser, Ryan Brooks, and Ramon Castellblanch, would be attending a prescription drug abuse summit hosted by the US Department of Justice in San Francisco on May 7, 2014.

Ms. Herold stated that the California Department of Public Health has recently created a Prescription Drug Abuse Subcommittee.

Ms. Herold provided that she would be presenting information on corresponding responsibility at a Ralph's Pharmacy annual managers' meeting.

Ms. Herold reported that she and Dr. Castellblanch would be presenting information on prescription drug abuse at MediCal's Drug Utilization Review Board meeting.

6. Drug Take-Back

Ms. Herold reminded the board and the public that the next DEA drug take-back day would be held April 26, 2014.

7. IT Equipment

Ms. Herold reported that all of the board's computer equipment has been replaced and updated to a new operating system. Ms. Herold thanked Victor Perez, Sue Durst, Jeff Smith and Richard Hultgren for their work on updating the board's IT equipment.

President Weisser asked if the board inspectors would receive continuing education on sterile compounding. Ms. Herold confirmed that they would receive ongoing training.

Steve Gray, representing CSHP, asked if after July 1, 2014 hospitals would be able to purchase compounded products from out of state facilities if the board had not yet inspected them and issued them a non-resident sterile compounding license. Ms. Herold responded that facilities' current licensure will remain concurrent, so if a hospital is purchasing from a facility that has a sterile compounding pharmacy license that will expire in November, then the board will inspect the facility sometime before November and the hospital can continue to purchase from this pharmacy.

Dr. Gray noted that some states do not require a sterile compounding facility in their home state to be licensed as a pharmacy. Dr. Gray asked if as one of California's qualifications for licensure as a sterile compounding facility is licensure as a pharmacy in your home state, then would those facilities be able to ship into California. Ms. Herold responded that unless a facility is licensed as a pharmacy in their home state they will not be able to receive a sterile compounding license in California.

Rebecca Cupps, from Ralph's, thanked Ms. Herold for agreeing to speak at their upcoming meeting and reported that the DOJ will also be at the meeting to register pharmacists in the system. Ms. Herold asked if Ralph's pharmacy computers allow access to CURES. Ms. Cupps confirmed that they did.

**c. Update on Pharmacy/Medical Board Future Joint Forum on Appropriate Prescribing and Dispensing**

Ms. Herold reported that after the Medical Board finalizes its revised pain management guidelines there will be another Pharmacy/Medical Board Joint Forum on Appropriate Prescribing and Dispensing. The meeting will likely be held at the end of 2014.

## VIII. LEGISLATION AND REGULATION COMMITTEE REPORT

Chair Greg Lippe provided a report on the Legislation and Regulation Committee Meeting held on April 23, 2014.

### a. **Legislation Report**

#### 1. Legislation Recently Enacted

Chair Lippe reported that Assembly Bill 467 (Stone, Chapter 10, Statutes 2014) was signed by the Governor on April 9, 2014, and provides for the licensure of a "Surplus Medication Collection and Distribution Intermediary" to allow such an entity to perform specified duties related to the donation of drugs to a Surplus Medication Collection and Distribution program. AB 467 contained an "urgency clause" whereby upon filing with the Secretary of State, the provisions became operative.

No action was taken on this item.

#### 2. Status of Board-Sponsored Provisions

##### **A. AB 2131 (Morrell) / SB 960 (Morrell) Pharmacy Licenses: Letters of Reprimand**

Chair Lippe provided that Senate Bill 960 contains the board's sponsored provision to add section 4310.5 to the Business and Professions Code (BPC) to authorize the board to issue a letter of admonishment for violations that may not warrant license denial or issuance of a probationary license in addition to its existing authority to issue letters of admonishment to licensees. The board's proposal mirrors a tool utilized by the Medical Board of California.

Chair Lippe noted that the board's provisions were previously contained in AB 2131. Senator Morrell moved the content into SB 960 after winning a Special Election (3/25/14) to fill the Senate seat formerly held by Senator Bill Emmerson.

No comments from the board or from the public.

**Committee Recommendation (Motion):** Support SB 960.

Support: 11   Oppose: 0   Abstain: 1

##### **B. SB 1466 (Committee on Business, Professions, and Economic Development) Omnibus Provision Relating to Requirements for a Designated Representative**

Chair Lippe reported that Senate Bill 1466, as introduced, contains one board-sponsored provision, and one other amendment to pharmacy law. Section 8 of the bill contains the board's sponsored provisions to amend section 4053 BPC to specify that a designated representative shall be at least 18 years of age.

SB 1466 also contains an amendment to section 4021.5 of the Business and Professions Code (BPC) to modify the definition of a "correctional pharmacy." The current definition applies to "state" correctional facilities – and the bill removes "state" – an amendment the board

discussed and supported in concept in 2013. Chair Lippe added that to implement the provision, the board will need to seek funding to modify the board's licensing system, as correctional facilities currently licensed are fee exempt.

Dr. Gutierrez asked if there are any non-government correctional facilities in California. Greg Murphy responded that there are privately operated correctional facilities.

No comments from the public.

**Committee Recommendation (Motion):** Support SB 1466.

Support: 11      Oppose: 0      Abstain: 1

### **C. Repeal of Pedigree Requirements**

Chair Lippe stated that this bill has not yet been assigned a number. The Drug Quality and Security Act preempted California's pedigree requirements in 2013. In January 2014, the board voted to seek a legislative repeal California's e-pedigree provisions. The board also published a notice of preemption in the California Regulation Notice Registry on February 21, 2014.

Chair Lippe noted that the committee did not take any action on this item.

### **D. Licensure Requirements for Third Party Logistics Providers**

The federal legislation enacted to eliminate California's e-pedigree requirements also contained provisions to establish national standards for wholesalers and establish specialized regulation of third party logistics providers (3PLs). The new federal law requires the FDA to establish regulation provisions regarding national standards for wholesalers and 3PLs over the next one to two years. If a state does not regulate wholesalers and 3PLs, the national registration will be required. The law specifically prohibits the regulation of 3PLs as wholesalers (which is exactly what California law currently does). To ensure the continued oversight of these active participants in the drug supply chain, the board voted to secure legislation to implement a separate license category for third-party logistics providers.

Chair Lippe stated that a copy of the board's proposal was provided in the meeting materials, and staff is working to secure an author to carry the board's provisions.

No action was taken on this item.

## **3. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction**

### **A. AB 1535 (Bloom) Pharmacists: naloxone hydrochloride**

Chair Lippe reported that Assembly Bill 1535 will add section 4052.01 to the BPC to authorize a pharmacist to furnish naloxone hydrochloride (NH) pursuant to a standard procedure or protocol developed by the board and the Medical Board of California (MBC), in consultation with the California Pharmacists Association, the California Society of Addiction Medicine and other appropriate entities. Chair Lippe noted that the bill requires specific information to be included in the procedures or protocol, prohibits a pharmacist from allowing a person receiving NH to waive consultation, and other requirements.

No comments from the board or from the public.

**Committee Recommendation (Motion):** Support AB 1535.

Support: 12      Oppose: 0      Abstain: 0

**B. AB 1727 (Rodriguez) Prescription Drugs: collection and distribution program**

Chair Lippe provided that AB 1727 would prohibit a drug that can only be dispensed to a patient registered with a drug manufacturer in accordance with FDA requirements from being donated to a county repository and distribution program. It was noted that AB 1727 was scheduled to be heard in Assembly Health on May 6, 2014.

No comments from the board or from the public.

**Committee Recommendation (Motion):** Support AB 1727.

Support: 11      Oppose: 1      Abstain: 0

**C. AB 2165 (Patterson) Professions and vocations: licenses**

AB 2165 would require license applications to be reviewed, processed, and issued to applicants who have completed the necessary requirements within 45 days of the application filing date and also requires that each exam is offered a minimum of six times per year.

Chair Lippe stated that the board monitors its license processing activities through the Licensing Committee and through its strategic plan. Staff is concerned that with the transition of the board's licensing systems to BreEZe, it is unknown how the board's processing times will be impacted and additional staff resources may be required to meet the 45 (calendar) day requirement.

Chair Lippe commented that the committee did not feel this bill was necessary so it took no position. Rosalyn Hackworth asked what the board's average processing time is. Chair Lippe responded that the board's average processing time is 45 business days.

No action was taken on this item.

**D. AB 2605 (Bonilla) Pharmacy: sterile drug products**

The committee took no position on AB 2605. No discussion from the board or from the public.

**E. SB 981 (Huff) Regulations: review process**

Senate Bill 981 amends California Rulemaking Law to require each agency to review every regulation adopted prior to January 1, 2014, and to develop and submit to the Legislature on or before January 1, 2016, a report with specified information, and require a similar report every five years thereafter.

Chair Lippe reported that the committee took no position on SB 981 as the board already undergoes a program review every four years as part of its sunset review.

No action was taken on this item.

**F. SB 1014 (Jackson) Pharmaceutical waste: home generated**

Staff was advised on April 10, 2014 that amendments are expected which would codify California's (now inoperative) drug take-back model guidelines. The California Integrated Waste Management Board (now CalRecycle) developed the model guidelines through a working group with the Board of Pharmacy and others in 2008.

Chair Lippe reported that the committee was concerned that the bill would allow Cal Recycle to develop the model guidelines with no input from the board.

No comments from the board or from the public.

**Committee Recommendation (Motion):** Support SB 1014 if amended to include the Board of Pharmacy in the development of the model guidelines.

Support: 11      Oppose: 0      Abstain: 1

**G. SB 1039 (Hernandez) Pharmacies: furnishing drugs**

Chair Lippe reported that according to the author, Senate Bill 1039 will make more efficient use of pharmacy personnel in the acute care facility setting by expanding the type of tasks that pharmacy technicians and interns are permitted to perform, with the goal of freeing up pharmacists to focus on patient care.

This bill was discussed in depth at the committee meeting. The committee expressed concerns that the bill would allow technicians to complete tasks that may increase the potential for diversion. Chair Lippe stated that ultimately the committee chose to take no position on the bill.

Allen Schaad commented that in his 20 years of experience in hospital settings he found that for repetitious tasks, such as taking stock, technicians actually tend to be more accurate than pharmacists. He added that he feels this bill could actually improve patient healthcare. Mr. Schaad proposed that the board support SB 1039 rather than take no position.

**Motion:** Support SB 1039.

M/S: Schaad/Brooks

Dr. Gutierrez commented that currently the California Department of Public Health (CDPH) enforces Title 22 which states that a pharmacist must perform the duties that SB 1039 would authorize technicians to complete. The concern was raised that SB 1039 would create conflicting standards for licensees.

Ms. Veale asked for an example of how Title 22 would conflict with SB 1039. Dr. Ratcliff responded that Title 22 states that monthly inspections of medication storage areas be inspected by a *pharmacist* and emergency medical supply containers are to be sealed by a *pharmacist*. SB 1039 would allow technicians to perform these tasks.

Mr. Brooks commented that much of the board's concern seems to be centered on the conflicting guidelines between Title 22 and SB 1039. He asked if the board could make a policy statement that would clarify how the board interprets Title 22. Mr. Santiago responded that the board has no jurisdiction over how CDPH interprets or enforces Title 22.

Dr. Gray, representing CSHP, commented that Title 22 has not been updated in decades. Dr. Gray added that SB 1039 is intended to free pharmacists from tedious tasks so that they can better work the doctors and nurses to help patients. Dr. Gray reported that CPHA met with leadership at CDPH to ask them to update Title 22. In the past they have been reluctant to change, however at the most recent meeting they encouraged CSHP to take a legislative approach to update the statutes so that technicians can complete these tasks under the supervision of the pharmacist. Dr. Gray asked the board to support SB 1039 to improve hospital efficiency and safety.

Dr. Ratcliff commented that current statute 4115 (a) states that a pharmacy technician may preform packaging. Dr. Gray responded that the statute does not mention the sealing of packages and it also does not specifically state that it can take place in a hospital setting.

Dr. Gutierrez asked if SB 1039 would supersede Title 22. Mr. Santiago responded that SB 1039 would not supersede Title 22 so the conflicting standards would still exist. President Weisser noted that if the conflict would still exist it might be fruitless to support this legislation.

Dr. Gray noted that studies have shown that technicians are more accurate than pharmacists when performing repetitive, non-discretionary tasks. Dr. Ratcliff commented that the study looked at re-filling of unit dose floor stock, not conducting inspections of drug inventory. Dr. Gray agreed but added that the inspection of drug stock is also a repetitive, non-discretionary task that will be done under the complete supervision of a pharmacist.

Mr. Murphy asked how a pharmacist's time will be freed up if all the work still has to be done under their complete supervision. Dr. Gray responded that pharmacist supervision in a hospital requires that a pharmacist must be on the premises at the time the technician is completing the task and everything they do has to be documented as approved by the pharmacist. Mr. Santiago clarified that 4023.5 requires that a pharmacist be on the premises at all times and be fully aware of all activities performed by a pharmacy technician or intern pharmacist.

Ms. Herold asked for clarification on what an emergency medical supply system entails. Dr. Gray responded that an emergency medical supply system allow hospitals to replenish ambulances and other emergency vehicles of medical supplies they have used on a call. The system is overseen by a medical director. Ms. Herold asked how a technician would replenish an ambulance. Dr. Gray responded that the medications must be ready to go 24/7, so they are packaged, sealed, inspected and approved by a pharmacist and are stored in the emergency department. Ms. Herold asked if the medications are unit dose. Dr. Gray usually they are unit dose. Dr. Gray clarified that currently a pharmacist has to package and seal these supplies, SB 1039 will allow the technician to do the packaging and the sealing for subsequent pharmacist approval.

Dr. Ratcliff noted that “crash cart” medications are replenished by the pharmacy and are handled separately than the supplies to be used by ambulances.

Mr. Lippe asked if the ambulance has to turn-in the used medication packages and who handles the reconciliation of what was used on a call and what was replenished. Dr. Gray responded that this would vary by hospital.

Mr. Santiago commented that regardless of the conflict that will exist with Title 22, the board needs to decide if it supports the changes to technician duties in SB 1039. Dr. Gray responded that in his experience CDPH enforces *all* laws (Federal, DEA, Board of Pharmacy, etc.) when they conduct inspections, not just their own. That is why CSHP feels it is necessary to change the statute with SB 1039. Dr. Gray added that CSHP is willing to work with the author on finding ways to remove the conflict with Title 22.

Mr. Brooks expressed his concern with the board’s inspectors having to make judgment calls while in the field because of the conflicts that exist between the board’s statute and Title 22.

Mr. Schaad commented that he wants the board to express its support for the concepts in SB 1039 even though it will not change CDPH’s enforcement of Title 22. Dr. Gutierrez agreed.

Mr. Schaad and Mr. Brooks withdrew their previous motion to support SB 1039.

**Motion:** Support SB 1093 if amended to address the discrepancy with Title 22 specifically in California Code of Regulations section 70263.

M/S: Lippe/Gutierrez

Support: 11                      Oppose: 0                      Abstain: 1

The board recessed for a break at 2:20 p.m. and resumed at 2:35 p.m.

**H. SB 1258 (DeSaulnier) Controlled Substances: prescriptions: reporting**

Chairperson Lippe explained that the Uniform Controlled Substances Act (HSC 11000 et seq.) 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 Schedule II, III and IV prescriptions dispensed. SB 1258 would permit the oral and electronic transmission of controlled substances prescriptions; establish dispensing limits; require the reporting of Schedule V controlled substances furnished to CURES; and allow DCA investigators access to CURES data for specified investigations.

Chairperson Lippe reported that the committee took a support if amend position at their meeting. The reason the committee felt an amendment was necessary was the possible discrepancies with federal law with respect to the dispensing of controlled substances.

Ms. Herold asked the board to support the bill and noted that we can provide technical expertise to the author on areas where there may be discrepancies with federal law.

Steve Gray, speaking as an individual offered his support for the bill.

**Committee Recommendation (Motion):** Support SB 1258 if amended to address any discrepancies with the federal law.

Support: 10          Oppose: 1          Abstain: 1

**I. AB 2603 (V. Manuel Perez) Controlled Substances: permissive lawful possession**

Chairperson Lippe reported that AB 2603 would amend the Health and Safety Code to expressly authorize a person to possess another person's controlled substances if the prescription holder so authorizes the person to possess them. The author seeks to add clarity to the Health and Safety Code to ensure that ill people who must rely on others to get their medications for them can do so without fear. Chairperson Lippe added that the author also states that the bill will address a conflict between the Health and Safety Code (and Pharmacy Law), to provide protections when a patient's agent picks up their prescription medications for the patient.

Chairperson Lippe stated that the committee's position was for staff to provide technical assistance to the author and report back at the July board meeting.

Ms. Wheat asked if the bill defines what person can be in possession of the medication for the patient. Chairperson Lippe responded that currently family member or agent can pick up a prescription for a patient; however, there is nothing that would protect the family member in the event they are stopped and found to be in the possession of another family member's controlled drugs.

Ms. Veale noted that she feels the board should oppose this bill. Mr. Murphy agreed.

Ms. Hackworth asked if the bill defined authorization as written or verbal. Chairperson Lippe responded that the bill does not.

Ms. Brooks said that even if the board provided technical assistance he does not feel that it will make it a better bill and he will oppose it. Ms. Veale and Ms. Wheat agreed.

**Motion:** Oppose AB 2603.

M/S: Veale/Murphy

Support: 9          Oppose: 2          Abstain 1

4. Other Legislation Being Tracked by Board Staff

**A. AB 1437 (Mullin) Medically important antimicrobials: nontherapeutic use**

Chairperson Lippe reported that the committee took no position on this bill. No comments from the board or from the public.

**B. AB 1743 (Ting) Hypodermic needles and syringes**

Chairperson Lippe provided that AB 1743 would delete the limit on the number of syringes a pharmacist has the discretion to sell to an adult without a prescription and deletes the sunset date of January 1, 2015, that would end the statewide authorization to sell syringes without a

prescription. Existing law allows a pharmacist or physician to furnish up to 30 hypodermic needles and syringes for human use, without a prescription or local government authorization, to a person 18 years of age or older, until January 1, 2015.

Chairperson Lippe reported that the committee took a support position.

Ms. Wheat commented that she does not feel like the board needs to take a position on this bill. President Weisser noted that as the syringes are being supplied by a pharmacy the board needs to be involved.

Mr. Brooks explained that this provision was originally established in response to the spread of HIV due to sharing needles.

Ms. Hackworth asked since the limit of 30 would be removed by AB 1743 if there would be another limit created. Chairperson Lippe responded that there would no longer be any limit.

Ms. Veale noted that when a pharmacist supplies the syringes there is an opportunity for the pharmacist to speak with the customer and offer some medical counseling.

Mr. Law noted that this bill will also help diabetic patients and other patients in need of syringes.

Mr. Brooks stated that while he understands the intention of the bill, he will not support it. Mr. Brooks added that by removing the 30-syringe limit they are going to increase the number of needles that will be improperly disposed of by drug users thereby placing others at risk.

Mr. Murphy also expressed his opposition to this bill due to the elimination of the 30-syringe limit.

Ms. Hackworth expressed that she is not supportive of removing the limit; however she does support removing the sunset date.

Dennis McAllister, representing Express Scripts, noted that California is in the minority in requiring a prescription for needles. Mr. McAllister added that doctors often forget to write a prescription for syringes.

Steve Gray, speaking as an individual, commented that a prescription is not currently required for insulin needles and a pharmacist can already use his or her professional judgment to provide a syringe to a patient for a legitimate medical purpose. Dr. Gray also stated the 30 limit was completely arbitrary, and it would be better to simply allow a pharmacist to use his or her professional judgment to supply syringes.

Dr. Ratcliff clarified that according to Business and Professions Code section 4142, a prescription is required for a needle or syringe. 4145.5(a) allows a pharmacist to furnish a syringe to a patient that is *known* to them without a prescription.

**Committee Recommendation (Motion):** Support AB 1743.

Support: 6    Oppose: 5    Abstain: 1

**C. AB 2418 (Bonilla) Health care coverage: prescription drug refills**

Chairperson Lippe reported that AB 2418 would allow a patient to opt out of a health plan's mandatory mail order program if the patient prefers to obtain prescription drugs from a community pharmacy; would streamline prescription medications by placing a patient's medications on the same refill schedule; and would allow patients who run out of prescription eye medications because of accidental spillage or who use more than 70 percent of prescribed eye drops to be eligible for an early refill.

No comments from the board or from the public were made.

**Committee Recommendation (Motion):** Support AB 2418.

Support: 11      Oppose: 0      Abstain: 1

**D. SB 835 (Hill) Food animals: medically important antimicrobial drugs**

The committee took no position on SB 835. No comments from the board or from the public were made.

6. Other Legislation Impacting the Board or Its Regulatory Jurisdiction

**A. AB 1702**

Chairperson Lippe reported that existing law establishes various eligibility criteria needed to qualify for a license and authorizes the board to deny a license on the grounds that the applicant has been convicted of a crime substantially related to the qualifications, functions, or duties of the business or profession for which the application is made.

AB 1702 would provide that an individual who has satisfied any of the requirements needed to obtain a license while incarcerated, who applies for that license upon release from incarceration, and who is otherwise eligible for the license shall not be subject to a delay in processing the application or a denial of the license solely based on the prior incarceration, except when the incarceration, except as provided in Business and Professions Code section 480.5.

Anne Sodergren cautioned the board to consider if this legislation could limit the board's ability to consider the entire picture when making a licensing decision. The board expressed their concern that the bill may limit the board's discretion when making licensing decisions and may add confusion on what criteria the board could actual consider when making decisions.

Dr. Wong stated that it is important that the board considers giving applicants second chances when the members believe it is appropriate.

**Motion:** Oppose AB 1702

M/S: Brooks/Lippe

Support: 11      Oppose: 1      Abstain: 0

**B. AB 2396**

Chairperson Lippe explained that existing law permits a defendant to withdraw his or her plea of guilty or plea of nolo contendere and enter a plea of not guilty in certain circumstances. AB 2396 would prohibit a board from denying a license based solely on a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code.

Mr. Santiago clarified that if passed, the bill will not allow the board to use an expunged conviction as the sole reason for licensure denial.

The board members expressed their concern that AB 2396 would take away their discretion in making licensure decisions.

**Motion:** Oppose AB 2396.

M/S: Lippe/ Wheat

Support: 10      Oppose: 0      Abstain: 2

**C. AB 2147**

AB 2147 would require all state entities to provide the following disclosure in 12-point boldface type, in direct proximity above the button used to submit any form.

*By submitting this form, I acknowledge that this information is being collected by the state and may be shared with another state agency or a private party in accordance with Section 1798.24 of the Civil Code and the Information Practices Act of 1977 generally.*

Ms. Sodergren reported that the board already complies with the Information Practices Act. The intent of the legislation is to be sure the public is informed as to what information is public information. Ms. Sodergren added that this bill could have significant fiscal impact to the board as it could require reconfiguration of the BreZE system to comply.

Mr. Brooks noted that this bill does not allow for any flexibility. Mr. Brooks added that this bill is good in concept; however, the way it is currently written it has unintended consequences.

**Motion:** Oppose AB 2147.

M/S: Brooks/Lippe

Support: 10

Oppose: 0

Abstain: 2

**b. Regulation Report**

1. Regulations Approved by the Office of Administrative Law - Combined Rulemaking – Proposal to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 California Code of Regulations Related to Partially Fill of a Schedule II Prescription, Criteria for Rehabilitation, and to Define Unprofessional Conduct.

Chairperson Lippe reported that on February 24, 2014, the Office of Administrative Law approved the board’s rulemaking to amend Sections 1745 and 1769, and to add Section 1762 to Title 16 of the California Code of Regulations related to the Partial Fill of a Schedule II Prescription, Criteria for Rehabilitation, and to Define Unprofessional Conduct. The regulation went into effect April 1, 2014.

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

2. Board-Approved – Recently Noticed - Update on Rulemaking to Amend Section 1707.5 of Title 16 California Code of Regulations Regarding Patient-Centered Labeling Requirements

Chairperson Lippe reported that at the October 2013 Board Meeting, the board voted to modify the board’s patient-centered prescription label requirements at Section 1707.5 (a) (1) to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items to be printed in 12-point san serif typeface. At the January 2014 Legislation and Regulation Committee meeting, the committee motioned to make a recommendation to the board to initiate the rulemaking. At the January 2014 Board Meeting, the board approved a motion to initiate a rulemaking to amend Section 1707.5 to Title 16 of the California Code of Regulations.

Chairperson Lippe stated that the rulemaking was noticed on April 11, 2014, and the 45-day public comment period will conclude on May 26, 2014.

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

3. Board-Approved – Undergoing Administrative Review - Fee Schedule –Proposal to Amend Title 16 California Code of Regulations Section 1749

Chairperson Lippe reported that on April 24, 2013, the board approved a proposal to amend Title 16 California Code of Regulations Section 1749 to increase the board’s fees to the statutory maximum. At the July 2013 Board Meeting, the board approved the motion to direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law.

Chairperson Lippe announced that the board received notice that the Office of Administrative Law approved the board's rulemaking to amend Section 1749 to Title 16 of the California Code of Regulations related to Fee Schedule on April 14, 2014. The effective date of the regulation will be July 1, 2014.

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

4. Board-Approved – Awaiting Notice

*A. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements*

Chairperson Lippe stated that at the July 2013 Board Meeting, the board voted to approve the text to amend Sections 1702, 1702.1, 1702.2, and 1702.5 to Title 16 of the California Code of Regulations. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking. Chairperson Lippe briefly reviewed how each section would be amended.

No comments from the board or from the public.

*B. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1732.05, 1732.2, and 1732.5 related to Continuing Education*

Chairperson Lippe reported that the board previously approved a 45-day public comment period for three proposals related to continuing education. Due to the significant changes in pharmacy law as a result of SB 294 (Emmerson, Chapter 565, Statutes of 2013) and SB 493 (Hernandez, Chapter 469, Statutes of 2013) with regard to the changes to compounding and the addition of the advanced practice pharmacist, board staff recommended that the Legislation and Regulation Committee revisit the three continuing-education regulation proposals. At the January 2014 Legislation and Regulation Committee Meeting, the committee reviewed the board-approved language and deemed this language meets the board's requirements.

Chairperson Lippe briefly reviewed the three sections and highlighted how they would be amended.

Dr. Gutierrez noted that sterile compounding should be added as one of the continuing education content areas in 1732.5.

**Motion:** Amend 1732.5 to include a 6<sup>th</sup> section for sterile compounding continuing education.

M/S: Gutierrez/Lippe

Support: 12      Oppose: 0      Abstain: 0

*C. Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to "Section 100" Regulatory Actions*

Chairperson Lippe reported that at the October 2013 Board Meeting, the board voted to direct staff to initiate the formal rulemaking process to delegate to the executive officer the authority to adopt regulation changes that are deemed to be “without regulatory effect” in accordance with Section 100 of Title 1 of the California Code of Regulations. The board also directed staff to issue the amended text as discussed at this meeting for a 45-day public comment period. If no negative comments are received, the board directed staff to take all steps necessary to complete the rulemaking process.

At the time of the meeting, staff was preparing the required documents for notice. No comments from the board or from the public.

**IX. BOARD MEMBER OFFICER ELECTIONS**

The board conducted an election for the positions of board president, vice president and treasurer.

President

**Motion:** Nominate Stanley Weisser for the position of board president.

M/S: Lippe/Gutierrez

Support: 12 Oppose: 0 Abstain: 0

Vice President

**Motion:** Nominate Amy Gutierrez for the position of board vice president.

M/S: Law/Wong

Support: 12 Oppose: 0 Abstain: 0

Treasurer

**Motion:** Nominate Deborah Veale for the position of board treasurer.

M/S: Gutierrez/Butler

Support: 12 Oppose: 0 Abstain: 0

**X. CLOSED SESSION**

The board adjourned to closed session at 3:41 p.m.

**ADJOURNMENT FOR THE DAY**

## **THURSDAY, APRIL 24, 2014**

### **RESUMPTION OF OPEN SESSION**

**8:46 a.m.**

President Weisser conducted a roll call. Board members present: Stanley Weisser, Amy Gutierrez, Greg Lippe, Deborah Veale, Victor Law, Ryan Brooks, Rosalyn Hackworth, Albert Wong, Lavanza Butler, Allen Schaad, Gregory Murphy, Shirley Wheat and Ramon Castellblanch (arrived late). Board member not present: Ryan Brooks.

### **XI. ENFORCEMENT COMMITTEE REPORT**

Dr. Gutierrez provided a report on the Enforcement and Compounding Committee meeting held on March 27, 2014

#### **a. Enforcement Matters**

##### **1. Update on Implementation of AB 1136 (Levine, Chapter 304, Statutes of 2013) Regarding Warning Labels on Prescription Container Labels**

Chairperson Gutierrez reported that existing law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a drug (1.) if the drug poses a substantial risk to the person consuming the drug when taken in combination with alcohol, or the drug may impair a person's ability to drive a motor vehicle, whichever is applicable, and (2.) the drug is determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Chairperson Gutierrez explained that Assembly Bill 1136 (Levine), signed by the Governor on September 9, 2013, amends existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. She added that Section 1744 of the board's regulations provides the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where their patients' ability to operate a vehicle may be impaired.

Chairperson Gutierrez stated that at the March committee meeting both the committee members and the public expressed concerns about whether including a comprehensive list of drugs would essentially require a warning to be placed on all labels, thus making the warning ineffective.

Chairperson Gutierrez and Ms. Herold asked pharmacy schools to assist the board in compiling an updated list of drug classes that could impair your ability to operate a vehicle or vessel.

2. Discussion and Possible Action on the Request from UCLA Health System, Ronald Reagan UCLA Medical Center, for a Waiver Under California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Section 4128 et seq.

In 2012, the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are bar-coded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012). Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read.

Chairperson Gutierrez reported that at the March committee meeting Ronald Reagan UCLA Medical Center requested a waiver to forgo the specific labeling elements in section 4128.4 that requires that barcode to contain:

- (a) The date the medication was prepared
- (b) The components used in the drug product
- (c) The lot number or control number
- (d) The expiration date
- (e) The National Drug Code Directory number
- (f) The name of the centralized hospital packaging pharmacy

Ronald Reagan UCLA Medical Center's current computerized physician order entry (CPOE) system is not configured to do a bar code read of the elements in section 4128.4, but it can read the NDC number on the container with a reader to ensure the container is read at the patient's bedside it is the right medication in the right dose for the patient.

Chairperson Gutierrez reported that the committee recommended approval of the waiver at the meeting.

Ms. Herold reported that CSHP has a bill this year that will update the language to reflect current technology capabilities. Dr. Gray confirmed that CSHP is working with an author's office and board staff.

Chairperson Gutierrez noted that if doctors and nurses have to check multiple locations for information, it takes away from the patient care.

Katie Marconi, Director of Pharmacy at Doctor's Hospital, Manteca, noted that with the Affordable Care Act the goal is to have all medical records be electronic by 2015. She noted that a problem that she sees with the current barcoding system is that the "beep" that occurs upon scanning does not differentiate between correct or incorrect patient information.

**Committee Recommendation (Motion):** Approve the waiver request of UCLA for five years, identical to the requirements approved at the January Board Meeting.

Support: 12      Oppose: 0      Abstain: 0

3. Presentation by Eric Kastango, CEO of Clinical IQ and Industry Expert in USP Chapter Processes, On Sterility Testing in Compounding

**Note:** To accommodate his schedule, Mr. Kastango presented during the enforcement section of the board meeting rather than the compounding section.

Chairperson Gutierrez thanked Mr. Kastango for speaking with the board via phone. She asked Mr. Kastango to give a high-level overview of how to conduct sterility testing in compounding.

Mr. Kastango directed the board to an article found in the March, 2014 issue of *Pharmacy Purchasing & Products*. The article, titled "Understanding the Role of Sterility Testing in Compounding," was written by Dr. Scott Sutton and can be found at: [http://www.pppmag.com/article/1463/March\\_2014/Understanding\\_the\\_Role\\_of\\_Sterility\\_Testing\\_in\\_Compounding/?sutton](http://www.pppmag.com/article/1463/March_2014/Understanding_the_Role_of_Sterility_Testing_in_Compounding/?sutton)

Mr. Kastango provided a high level overview on sterility testing in compounding.

- The preferential methodology to do sterility testing is membrane filtration, not direct inoculation.
- If the drug that you need to test can be filtered - you must do membrane filtration.
- A major problem he often encounters is the sample size is not large enough.
- Sampling and testing needs to be done on *every* batch.
- For 1-100 doses you need to sample 10 percent, or at least four containers (whichever is greater).
- For 101-500 doses at least 10 containers need to be tested.
- Two-growth media, one broth specific for bacterium and one broth specific for fungi must be used when testing.
- The two broths must be incubated at different temperatures for 14 days.
- Sterility testing is a destructive test.
- Batches should not be re-tested if they are found to be contaminated, they should be discarded.
- Anytime you exceed the "beyond use date," as defined in the chapter, you must conduct sterility testing.
- If you make a batch of more than 25 high-risk level compounded sterile preparations (CSPs) you must conduct sterility testing.

Dr. Gutierrez clarified that this does not apply to "average" pharmacies that do not extend the expiration date past the beyond use date, or conduct any non-sterile to sterile compounding. Mr. Kastango confirmed.

Ms. Herold asked that the article by Dr. Scott Sutton be included as a background document in the compounding regulation file.

Holly Strom, former board member, asked how you can incubate a product for 14 days to conduct the sterility test if the product only has a 14-day chemical stability. For example, can you take a sample of the product to test and then freeze the rest? Mr. Kastango recommended that the compounder mix a seven-day supply and dispense it twice so that it is staying within the parameters of USP 797 and the chemical stability of the drug. Ms. Strom commented that doing so could be a problem if the compounder is shipping from another state into California. Mr. Kastango responded that companies can do overnight shipping and added that shipping a seven-day supply is a common process for many home infusion companies.

Larry Dalph, from Comprehensive Pharmacy Services, stated that several of its hospitals who use only barrier isolators for compounding, have asked for clarification on what should be tested for glove-tip sampling - since they don't actually don gloves. Mr. Kastango responded that USP 797 says that when you do sterile compounding you need to wear sterile gloves. When an isolator is used the operator needs to place a pair of sterile gloves into the inside chamber of the isolator and put them over the barrier gloves of the chamber. This allows the operator to conduct a fingertip sample of the gloves that came into contact with the sterile drugs.

Bruce Benson, Cedar Sinai, asked what endotoxin or pyrogen testing is required for low and medium-risk compounded drugs within the USP storage guidelines. Mr. Kastango responded that there was no testing requirement.

Chairperson Gutierrez asked if Mr. Kastango had any idea when USP 800 would be finalized. Mr. Kastango reported that USP 800 is currently in the public comment period, which is open until the end of July. He concluded that he would expect it to be another nine months to a year before USP 800 is official.

4. Discussion and Possible Action on the Availability to Provide Written Comments to the DEA on the Possible Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 21 Code of Federal Regulations Part 1308 [Federal Register, Docket No. DEA-389]

Chairperson Gutierrez reported that hydrocodone combination products are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are approved for marketing for the treatment of pain and for cough suppression. The Drug Enforcement Administration (DEA) recently published a notice of proposed rulemaking to reschedule hydrocodone combination products from Schedule III to Schedule II of the federal Controlled Substances Act. Written comments on the notice are due on or before April 28, 2014.

Chairperson Gutierrez also reported that in recent years, hydrocodone has been identified as a stepping stone drug, where individuals start with hydrocodone, like the feeling, take more and more of the widely available drug as they become habituated, and then move to stronger drugs

like hydromorphone and then to oxycodone. Then, when it becomes too expensive to obtain and purchase these drugs, individuals turn to heroin (which is much cheaper).

Larry Busch, pharmacist, commented that other states have moved hydrocodone to a Schedule II and asked if the board supported this. It was confirmed that this action item was to determine if the board should write a letter of support to the DEA to move hydrocodone from Schedule III to Schedule II.

Dr. Gray, representing Kaiser, commented that there is a concern that there are not enough alternative products in the market and suggested that the board request an implementation date that would allow enough time for doctors and patients to look for alternative treatments.

Dr. Ramon Castellblanch asked what health care providers are doing to anticipate this change. Dr. Gray responded that the medical board is implementing new pain management guidelines and a lot of other organizations are looking at their internal processes to see what changes need to be made.

Mr. Lippe asked how moving hydrocodone from Schedule III to Schedule II will impede patients from getting care – if it is prescribed because the patient needs it, the patient should get it no matter what schedule it is. Dr. Gray responded that there is a stigma attached to prescribing Schedule II products because they are scrutinized more heavily.

Dr. Gutierrez asked if there was a timeline for changing the schedule. Mr. Room responded that the board does not have control over the implementation date, but it could be as far as 18 months way.

Mr. Law commented that he supports moving hydrocodone to Schedule II.

Dr. Castellblanch reminded the board that there has been a significant increase in the number of deaths due to overprescribing.

Holly Strom, former board member, stated that when considering alternative treatments NSAID pain relievers often cannot be used in elderly patients because it increases the risk for GI bleeding. Jonathan H. Watanabe, University of California, San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences, and long-term care pharmacist, stated he was in support but stated the challenge will be to prevent the discontinuation of therapy and that when patients do need the therapy; they are able to get it. Sam Shimomura, Associate Dean of Western University School of Pharmacy, agreed with Ms. Strom's comment.

Dr. Castellblanch commented that there are other non-prescription alternatives such as massage, acupuncture, etc., to help manage pain.

**Committee Recommendation (Motion):** Submit comments to the DEA to support the rescheduling of hydrocodone from Schedule III to Schedule II.

Support: 10   oppose: 2   abstain: 0

**Motion:** Add language to the comments to the DEA requesting transition time.

M/S: Veale/Lippe

Support: 9   Oppose: 1   Abstain: 1

5. Discussion on Availability to Submit Comments on the Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Establishment of a Public Docket, Federal Register, Food and Drug Administration [Docket No. FDA-2014-N-0200]

The Food and Drug Administration (FDA) is establishing a public docket to receive information and comments on standards for the interoperable exchange of information associated with transactions involving prescription drugs to comply with the new requirements in the Drug Supply Chain Security Act.

Chairperson Gutierrez and Mr. Room clarified that there was not a need to submit comments on this item because it appeared to be more of a supply chain issue versus something that would impact the board's regulation.

6. Report on Alternative Process for Pharmacists to Become Registered to Access CURES

Chairperson Gutierrez reported that last year, SB 809 (DeSaulnier) was enacted to enhance the CURES prescription drug monitoring program. Part of the discussion associated with the bill's progression through the Legislature was the growing concern about the need for pharmacists and prescribers to access CURES before dispensing or prescribing controlled drugs. To access CURES to see the history of controlled drugs dispensed to a single patient over the last year, a prescriber or pharmacist must have been preapproved by the CA Department of Justice. Chairperson Gutierrez noted that an abysmally low number of prescribers and dispensers have applied for and been granted access to CURES.

Chairperson Gutierrez stated that provisions enacted in SB 809 require all prescribers and pharmacists to be registered with the DOJ to access CURES by January 1, 2016. However, the new computer system and funding for staffing for the DOJ to operate the CURES system will not be available until perhaps July 2015. Chairperson Gutierrez noted that as such, it appears likely that few, if any, DCA boards will be able to comply with the January 1, 2016 CURES registration deadline for licensees.

Chairperson Gutierrez reported that the current process for CURES registration is frustrating and laborious. Individuals must start an email contact with the DOJ, then fill out an application they download, and then copy various documents (driver's license, professional license) and have the whole package notarized and then mailed to the DOJ. Lacking staff, the DOJ is taking months to process this material. Chairperson Gutierrez stated that at their last meeting the Enforcement Committee expressed the need for the board to facilitate the enrollment by collecting and authenticating identification for the application process.

Ms. Herold reported that board staff has discussed with the DOJ a process whereby the board could authenticate the identity of a pharmacist and aid the DOJ in getting this individual registered. Details are still being worked out, but a general process has been drafted.

Ms. Herold stated that the current pharmacist enrollment in CURES has risen to 17 percent.

Ms. Hackworth commented that the DOJ has been working with her organization to attend their meetings and register the pharmacists in CURES. She noted that many of those trying to get registered reported having difficulty with the registration website.

Dr. Castellblanch noted that the Prescription Drug Abuse Subcommittee is also very concerned with the use and availability of CURES.

Chairperson Gutierrez reported that an article will be included in the *Script* indicating how the PDMP can be used, in addition to staff developing a Q&A document and sending a subscriber alert.

Chairperson Gutierrez noted that at the next enforcement meeting there is an agenda item addressing the need for pharmacist to have Internet access to the CURES system in all pharmacies.

Dr. Gray reminded the audience that *all* California pharmacists are required to register for CURES, even if they are a faculty member who is not currently dispensing. Dr. Gray asked if it was possible for interns to become registered in CURES. Ms. Herold responded that interns are not allowed access to the system.

Dr. Castellblanch commented that the use of CURES should be included in pharmacy school curriculum and added that the board should consider having an exam question related to the use of CURES.

#### 7. Summary of Discussion and Possible Action Regarding Reported Losses of Controlled Substances in California

Chairperson Gutierrez stated that a pharmacy or a wholesaler must report any loss of controlled substances to the board within 14 days.

Recently, the board's staff compiled some statistics regarding drug losses reported to the board in order to respond to press inquiries. Chairperson Gutierrez asked Ms. Herold to provide the most current statistics on drug losses. Ms. Herold provided that last calendar year 3.06 million units of controlled substances were reported to the board as lost. Ms. Herold noted that of those, 1.7 million units was from a major manufacturer who had a truck stolen. Mr. Room commented that these numbers are only estimates provided by the entity when they first realize there has been a loss. He feels that this number is most likely significantly lower than actual losses.

Chairperson Gutierrez reported that the committee expressed concern about the significant losses and the need for more stringent inventory controls to identify losses resulting from employee pilferage. Comments from the committee included developing steps for tighter

inventory controls, which could be done either by regulation, statute or policy and perhaps reconciling the top ten drugs for the pharmacy.

Katie Marconi, Director of Pharmacy at Doctor's Hospital, Manteca, commented that there is relatively inexpensive surveillance software that can help monitor and identify trends and losses.

Ms. Veale asked if the pharmacies would send reports of their monthly counts to the board. Ms. Herold clarified that they are not required to provide a report to the board, rather they conduct the counts as a self-monitoring mechanism.

The board asked that this item be sent back to the Enforcement Committee to draft language on monthly counts and reporting requirements.

Dr. Gray commented that reporting every loss, no matter how small, can dilute the importance of the reports received.

Janet Hanny, from Sutter Health, encouraged that board to consider the difference between hospitals and retail pharmacies when they create the language.

8. Summary of Presentation on "What We Find When We (the Board of Pharmacy) Inspect Pharmacies"

Chairperson Gutierrez reported that the board's executive officer continues to be asked to speak about pharmaceutical supply chain issues that have been discovered by the board. At the March committee meeting, a short PowerPoint presentation was given by Ms. Herold about what the board finds when inspecting pharmacies or reading the industry's journals.

Ms. Veale commented that she would like to have Ms. Herold provide this presentation to the full board.

9. Summary of Demonstration by Omnicell Regarding Technology Currently in Use for Pharmacies Providing Automated Drug Delivery Systems in Health Care Facilities Licensed Under Health and Safety Code Section 1205 (c), (d) or (k)

During the March committee meeting, Rich Hooper and Daniel Sanchez, representing Omnicell, provided a demonstration on restocking procedures of their automated dispensing cabinet (ADC) as it is used in long-term care for emergency/first dose medication.

Chairperson Gutierrez reported that the committee questioned the supervision of the restocking of the automated dispensing machine and was advised that there was no oversight of the restocking of the automated dispensing machine.

Chairperson Gutierrez provided that Omnicell was advised to formalize their request in writing to the board and to include exactly what they are requesting and to include in the proposal where the pharmacist is involved in the process.

10. Enforcement Statistics

Chairperson Gutierrez directed the board and the public to review the statistics provided in the meeting materials.

11. Third Quarterly Report on the Committee's Goals for 2013/14

Chairperson Gutierrez directed the board and the public to review the statistics provided in the meeting materials.

**c. Compounding Matters**

1. Summary of Discussion and Possible Action on the Board's Proposed Compounding Regulations

Chairperson Gutierrez reported that at the October 2013 Board Meeting, the board moved to issue the initial notice of proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45-day comment period ran from November 29, 2013 – January 13, 2014. A regulation hearing was held on January 16, 2014, to provide the public with an opportunity to provide comments in another forum.

Chairperson Gutierrez stated that during the notice period, the board received many written and oral comments. Board staff sorted all written and oral comments (approximately 200 pages) received by section number, to facilitate review all of related comments by section. This compilation document was available at the January 2014 board meeting and online.

Chairperson Gutierrez reported that at the January 2014 board meeting, the board made a motion to allow the sterile compounding workgroup to work through the comments received and submit a second version of the proposed text, based on comments.

Chairperson Gutierrez reported that after reviewing and considering the written and oral comments received, the Enforcement Committee recommends the board take the following action:

1. Withdraw the current rulemaking file originally noticed November 29, 2013.
2. Provide general guidance from the sterile compounding workgroup to develop new updated language based on substantive comments received by the board and notice the revised language as a new rulemaking.

Dr. Gray, representing CSHP, expressed his support of withdrawing the current rulemaking.

Mr. Room reminded the public that the current compounding regulations are still in effect and being enforced.

Chairperson Gutierrez thanked board manager Debbie Damoth for her work in compiling the comments.

**Committee Recommendation (Motion):** Withdraw the current compounding rulemaking, revise the language to incorporate many comments submitted in response to the initial regulation notice and notice the new language as a new rulemaking.

Support: 12    Oppose: 0    Abstain: 0

2. Update on Compounding Provisions Enacted by H.R. 3204, the Federal Drug Quality and Security Act and the Recent Meeting between the FDA and the States' Boards of Pharmacy

Chairperson Gutierrez reported that included as part of the federal Drug Quality and Security Act (HR 3204) are provisions that establish a federal regulation and oversight of large scale drug compounding by "outsourcing facilities." The federal law sets forth voluntary requirements for licensure and enforcement of these entities.

Chairperson Gutierrez stated that at the committee meeting Ms. Herold provided a high-level overview of the sterile compounding requirements of the new law and highlighted that California's law is more restrictive than the federal law in several areas.

Ms. Herold also noted that California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with the board and comply with California requirements as sterile compounding pharmacies.

Dr. Gray, representing CSHP, commented that some states do not license for 503B registered facilities and therefore would not be eligible for a license in California. Mr. Room and Ms. Herold confirmed.

Chair Gutierrez asked if the board is ready to conduct the out-of-state inspections. Ms. Herold confirmed that the board is currently securing the necessary requirements to travel out-of-state so that they can conduct the inspection.

Mr. Schaad asked if there would be a list on the board's website of all of the out-of-state facilities that had been inspected. Ms. Herold responded that there would not be a list, however, if a facility is issued an LSC license, then the pharmacy will have been inspected by the board.

3. Review of Data Collected on Violations Found During Compounding Inspections in California

Recently, the FDA convened a meeting of all states to discuss their activities with respect to compounding, principally sterile compounding, within their jurisdictions. Chairperson Gutierrez reported that Ms. Herold was asked to provide an overview of California's inspections and outcomes at this meeting. The presentation included the history of compounding in California, actions taken by the board to ensure public safety is not compromised by sterile compounding practices and the top ten violations found during compounding inspections.

Supervising Inspector, Dr. Ratcliff, provided the board with statistics on the compounding inspections conducted by the board.

- A total of 750 inspections need to be completed by the end of 2014.
- Inspectors first visited facilities with existing LSC licenses that expired before August 31, 2014. These inspections were completed by April 2014.
- For the sites with existing LSC licensure, 561 corrections were issued to 83 pharmacies and 127 hospitals.

- In order to complete the remaining inspections before June 15, 2014, each inspector will need to conduct 9 inspections
- There are 23 non-resident compounding locations that will need inspection.

Chairperson Gutierrez asked what are the main problems they are finding during their inspections of hospitals. Dr. Ratcliff responded that in hospitals the biggest problem has been inappropriate compounding attire.

#### 4. Summary of Update on the National Shortage of IV Solutions

A copy of the update provided by the California Hospital Association on the continuing shortage of essential IV solutions was provided in the meeting materials.

Chairperson Gutierrez commented that she has heard that the shortages are improving. Janet Hanny, representing Sutter, confirmed that the shortage has been improving.

Dr. Gray, CSHP, noted that the number of suppliers is very low and the use of just-in-time inventory has prevented the accumulation of reserves. He added that the creation of state-owned emergency stock-piles is being discussed.

The board recessed for a break at 10:57 a.m. and resumed at 11:18 a.m.

## **XII. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS**

Michael Santiago reminded the board that they may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting.

Pharmacist Larry Busch highlighted some challenges faced by pharmacists in the field. Mr. Busch commented that he would be sending the board members a letter outlining how his past citation was inappropriate and was not handled correctly by the administrative law judge.

## **XV. LICENSING COMMITTEE**

Chair Deborah Veale provided a report on the Licensing Committee meetings held on February 12, 2014 and March 19, 2014.

### **a. Summary of Presentation Made to Committee on the Duties and Operations of Third Party Logistics Providers in the Pharmaceutical Supply Chain**

Chair Veale reported that on March 19, 2014 representatives from International Warehouse Logistics Association, UPS Supply Chain Solutions, Exel and Saddle Creek Logistics provided the committee with a presentation on the duties and operations of third-party logistic providers and highlighted how they differ from wholesalers.

Chair Veale reported that the committee expressed that the board's main priority is to minimize the potential for diversion in the supply chain. The committee's concern is that due to the high

value of drugs, losses will continue to occur during transport. It was also noted that with the exception of 3PLs, the entire supply chain is licensed, the board views this as extremely problematic as it creates a potential for diversion in this unlicensed area. Chair Veale concluded that there was no action taken on this item at the meeting. The committee will continue to work with 3PLs and other stakeholders to develop the regulation language.

Ms. Herold stated that AB 2605 has been introduced. The board will be working with 3PLs to create a new licensing class what will be separate from wholesalers but with similar regulatory requirements.

**b. Summary of Presentation Made to Committee on an Update of Major ACPE Programs and Activities**

Chair Veale reported that the Accreditation Council for Pharmacy Education's (ACPE) Executive Director, Peter Vlasses, attended the March 19, 2014 meeting. Chair Veale stated that while no action was taken on this item, the committee found Dr. Vlasses' presentation to be very informative. The committee was particularly appreciative of Dr. Vlasses' review of ACPE's pharmacy school accreditation process, as it provided insight into the rigorous process schools of pharmacy undergo to ensure students receive a high-quality education that includes experience in practice settings.

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

**c. Summary of Presentation Made to Committee on Requirements for Intern Experience in ACPE Approved School of Pharmacy Curricula**

The Licensing Committee was asked to review the requirements for reporting intern hours experience required of students enrolled in ACPE-approved schools of pharmacy. Chair Veale reported that on March 19, 2014 Dr. Vlasses provided a presentation on ACPE's requirements for intern experience in ACPE-approved schools of pharmacy. Dr. Vlasses highlighted that ACPE accredited schools of pharmacy curricula must contain "real world" pharmacy experience. Dr. Vlasses also reviewed the process by which students shadow pharmacists and work in pharmacies to gain hands-on practice experience.

Chair Veale stated that the committee was particularly concerned with the preceptor screening and evaluation process and the hands-on knowledge students gain while in pharmacy school.

Chair Veale explained that she would report on agenda item d before opening the floor to board and public comments under agenda item e.

**d. Summary of Presentation by the California Schools of Pharmacy on the Intern Experience Earned by Students in California Schools of Pharmacy and the Reporting of Intern Hours to the California Board of Pharmacy**

Chair Veale stated that over the years, the board has been asked to change the reporting of intern hours to eliminate the specific requirement that 900 hours be earned in a pharmacy. Historically, the board has not agreed that such a change is in the public interest.

Chair Veale provided that the committee heard testimony stating that it is difficult for students to gain additional intern hours outside of the curriculum, as many of the jobs historically held by interns are now being filled by technicians. Chair Veale noted that deans from various schools of pharmacy asked the committee to change the intern requirement to deem any student who graduated from an accredited school of pharmacy after 2007 as having fulfilled his or her required intern hours.

Chair Veale reported that the committee asked legal counsel if a regulatory change would be required in order to accept the proposal as brought before the board. Mr. Santiago stated that a regulation change would be required to allow the schools to sign off on the entire 1,500 hours. The committee also asked if the board could eliminate the 1,500-hour requirement and simply require graduation from an ACPE accredited school. Mr. Santiago confirmed that the board could choose to go that way and stated that doing so would require a statutory change.

**e. Discussion and Possible Action to Update the Pharmacist Interns Hour Requirements from Business and Professions Code section 4209 and 16 California Code of Regulations Section 1728 and the Intern Hours Affidavit Form 17A-29**

Chair Veale reported that at the committee meeting Jon Roth offered CPhA's legislative support to make any statutory changes deemed necessary to change the reporting of pharmacy intern hours.

Chair Veale explained that it was the committee's desire to ensure that intern hour requirements are the same for all graduates of an ACPE-accredited pharmacy program. The committee asked board staff and counsel to ensure any statutory or regulatory changes made achieved equality in intern hour reporting requirements for both in-state and out-of-state applicants.

Chair Veale noted that at the committee meeting comments were made that it is easier for an out-of-state graduate to receive approval to sit for the board's exam. Mr. Santiago stated that at the committee meeting the comments were not addressed because there was no licensing staff present. Ms. Herold responded that the board does not probe into whether an out-of-state applicant was getting paid during the internship, but does validate that a licensed pharmacist signed off on the hours.

Mr. Room asked if the committee envisioned that statute would require that as part of the application, an applicant would have to submit a form signed by the dean of the school certifying that the intern completed the intern hours required in the ACPE curricula. Chair Veale responded that graduating from an accredited school essentially indicates that the intern has completed the necessary intern hours, the committee was looking to staff to determine if a certificate from the dean was necessary.

Mr. Room warned that in regards to compounding the board was previously willing to accept an accreditation body's approval in place of a board license and the board has since found that this was not sufficient. Chair Veale responded that unlike compounding accreditation there is only

one entity (ACPE) that accredits all schools of pharmacy. Additionally, she stated that the committee felt that ACPE was better able to monitor the programs and preceptors.

Mr. Room expressed that the board must be willing to accept any changes to the hourly requirements they may deem fit in the future – for example if they lower the requirement to 500 hours. Chair Veale agreed and commented that perhaps the board should create a floor that the hours could not go under.

Ms. Herold noted that the board would need to consider that there are foreign graduates who are currently required to complete a number of hours in the United States. Chair Veale responded that the committee would not change that requirement.

Ms. Herold asked to clarify if proof of graduation or a separate letter from the dean would be required to fulfill the intern hour requirement. Chair Veale stated that those details could be sent back to the committee and staff to work-out.

President Weisser commented that he is uncomfortable handing over the process to ACPE and worries that the importance of gaining hands-on experience may be lost. Chair Veale commented that she felt the same way previously; however, after hearing the various presentations she learned that ACPE closely monitors the schools and the preceptors.

Mr. Law commented that the board needs to require that the schools meet a certain hour requirement so that the scenario that Mr. Room described earlier could not occur.

President Weisser remarked that over the years he has wondered how much of an emphasis the pharmacy schools place on graduating students who have an appreciation for practice in community pharmacies versus clinical practice. Mr. Law responded that in top pharmacy schools 30 percent of graduates work in clinical settings and 70 percent of graduates work in community pharmacies.

Ms. Butler commented that like President Weisser, she was previously concerned about students gaining experience in community settings. However, after the committee meeting she felt assured that ACPE-accredited schools give students experience in all settings.

Dr. Wong commented that knowledge gained in clinical settings can be used in community pharmacy settings. President Weisser agreed.

Steve Gray, representing CSHP, commented that there is a perceived discrepancy in the requirements for California applicants and out-of-state applicants. Currently California applicants must have their hours signed off by the pharmacist who did the training or PIC of the location where they worked. However, out-of-state applicants do not have to submit the same documentation. Dr. Gray clarified that even if the board does not choose to accept graduation in place of intern hours, they should review the licensing processes to ensure that the requirements are being implemented equally for all applicants.

Dr. Gray also commented that CSHP is worried that current graduates of pharmacy schools are not entering the workforce practice ready and have a lack of maturity (no work experience). He

noted that many schools use simulations rather than real experience. Dr. Gray stated that ACPE is currently designing the new standards for accreditation and encouraged the board to participate in the process. Dr. Gray concluded that it is very difficult for current students to gain intern hours outside of their school.

Chair Veale asked Dr. Gray to clarify if CSHP supports the request made by the various schools of pharmacy to change the intern hour reporting. Dr. Gray confirmed that CSHP was in support of the proposal.

At the request of Mr. Schaad, Dr. Gray provided an overview of the use of simulations used in schools of pharmacy.

Ms. Herold clarified that every applicant, regardless of state, signs his or her application stating the completion of 900 hours of practice experience under the direct supervision of a pharmacist. Dr. Gray responded that the board requires California students to submit affidavits signed by the pharmacist that supervised them, while out-of-state applicants do not have to provide such documentation. Dr. Gray clarified that the difference in documentation required by the board is why CSHP feels that California students are being held to a higher standard.

Holly Strom, former board member, commented that many graduates leave school and are not ready for practice. She added that when she was a board member she attended an ACPE accreditation and was very impressed with the rigor that the schools are held to and encouraged current board members to attend them if possible.

Sam Shimomura, Associate Dean of Western University School of Pharmacy, commented that many times students go back to the location they completed the intern hours and the PIC or supervising pharmacist has left the pharmacy. Dr. Shimomura added that Western University finds simulations to be a helpful educational tool and recommended that the board consider adding a simulation portion to the CPJE.

At the request of Mr. Law, Dr. Shimomura explained that out of the approximately 140 graduates about 30-40 students choose to study clinical pharmacy and the rest study community pharmacy.

Dennis McAllister, representing ACPE, reported that the draft ACPE standards are now available for review online and they will be reviewed at the NABP meeting in Phoenix. Dr. McAllister explained that ACPE changed its standards to allow students to have 30 of their experience hours gained via simulation; the remaining 1,710 must be done in a pharmacy.

President Weisser asked Dr. McAllister, who currently serves on the Arizona Board of Pharmacy, if they have issues with pharmacists not conducting patient consultations. Dr. McAllister responded lack of consultation is hard to quantify, but seems to be a common problem in all states. He added that six or seven years ago the Arizona board took the stance that any issue resulting in the patient needing to file a complaint with the board or that caused patient harm and could have been prevented by proper consultation, would result in an automatic fine.

Mr. Law asked Dr. McAllister if ACPE would ever lower the number of experience hours a student needs to complete prior to graduation. Dr. McAllister responded that he does not anticipate ACPE would ever lower the hour requirement as they understand how important quality experience is to graduating practice ready pharmacists.

Representatives from the University of California San Francisco, University of San Diego, Touro University and the University of the Pacific expressed their support of the proposal to change the intern hour requirements as presented to the board. The representatives also provided the board with insight into the pharmacy experience gained while in the various schools.

John Garret, pharmacy student at the University of San Diego, provided the board with insight into the experience gained in school by current pharmacy students. He noted that students face new hardships, including increased tuition fees and a decrease in the number of jobs available.

Ms. Butler asked if the representatives felt that students left the schools ready to practice pharmacy. It was clarified that the students were ready to sit for the CPJE exam.

Sam Shimomura, Associate Dean of Western University School of Pharmacy, commented that their preceptors receive training and continuing education opportunities. Dr. Shimomuro added that schools have been expanding the number of clerkship hours required for students.

Ms. Herold suggested that staff provide different options to the board at the next meeting. Chair Veale asked that the board vote on the committee recommendation to change the requirements, and then if the motion passes, board staff can provide options on how to implement the change.

Dr. Castellblanch commented that he would like to receive more options from board staff and discuss the item again at a future meeting. Chair Veale responded that members who would like to receive more options rather than accepting graduation from an ACPE accredited school should vote the motion down so that the discussion can go back to committee.

**Committee Recommendation (Motion):** Direct staff to work with counsel to develop any statutory and regulatory changes necessary so that graduating from an ACPE accredited school of pharmacy meets the intern hours requirement for the application to the CPJE exam.

Support: 9      Oppose: 1      Abstain: 2

The board recessed for break at 1:03 p.m. and resumed at 1:49 p.m.

Dr. Gutierrez left the meeting at 1:45 p.m.

**f. Summary of Update on Discussion Regarding Application Questions Relating to “Prior Convictions”**

Chair Veale reported that DCA Staff Counsel Michael Santiago continues to work with staff on this assessment. The topic will be discussed at the next Licensing Committee Meeting.

**g. Summary of Presentation Made to Committee on Qualifications to Become an Advanced Practice Pharmacist**

Chairperson Veale reported that Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) makes a number of important changes to the services that pharmacists may perform. One major portion of the law establishes an “advanced practice pharmacist” category of pharmacist licensure, which allows such licensed pharmacists to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers.

Chairperson Veale stated that at the February 2014 Licensing Committee Meeting, the committee heard a presentation by the Board of Pharmacy Specialties on their certification programs. She noted that there was also lengthy discussion about routes of qualification.

Chairperson Veale said that Alex Adam, vice president of pharmacy with National Association of Chain Drug Stores, provided a presentation on advanced practice pharmacists at the March 19, 2014 meeting.

Chairperson Veale noted that the committee heard comments from the public supporting the multiple pathway approach, but asked the board to ensure that any certification program they approve meets the high standard of practice required by an APP.

Chairperson Veale reported that the committee asked staff to look at states with similar APP laws to see how they approached implementation and what type of programs they created. The committee will also examine the shortcomings of APP programs in other states so that California can avoid making the same mistakes. Chairperson Veale concluded that the committee does not want to create a sub-par program by rushing the implementation of SB 493.

**h. Update on the Implementation Schedule for SB 493 (Hernandez, Chapter 469, Statutes of 2013) Relating to Advanced Practice Pharmacist**

1. Summary of Presentation Regarding Development of Certification Programs and Existing Certification Programs by Board of Pharmacy Specialties

Chairperson Veale reported that Brian Lawson, PharmD, and Andrea Iannucci, PharmD, from Board of Pharmacy Specialties (BPS) provided the committee with a presentation on the existing certification programs for pharmacists offered by BSP.

2. Update on Development of Application and Renewal Requirements for Advance Practice Pharmacist

Chairperson Veale stated that the committee received a draft of the advanced practice pharmacist application at the March 19, 2014 meeting. The committee took no action on this item. A second version of the application is being developed by board staff and will be discussed at a subsequent committee meeting.

3. Summary of Discussion on the Development of Other Certification Programs

Chairperson Veale reported that the committee received public comment asking the board to remain open to accepting other certification programs in addition to BSP. Chairperson Veale noted that it was recommended that the committee examine the certification process in North Carolina to learn from its shortcomings.

**i. Summary of Discussion on Requirements for Pharmacists who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols**

Chair Veale stated that the Board of Pharmacy and the Medical Board of California will work together to create a protocol for self-administered hormonal contraception. This provision will apply to all pharmacists who possess the training, not only advanced practice pharmacists.

Ms. Herold noted that the draft protocol provided to the board by CPhA would need to be revised by the Medical Board and the Board of Pharmacy.

Chairperson Veale stated that the committee decided that a panel of experts should be established to review the protocol, and the panel should contain members from both boards as well as experts in the field of oral contraception.

**j. Summary of Discussion on the Requirements for Pharmacists who Initiate and Administer Immunizations Pursuant to Recommended Immunization Scheduled by the Federal Advisory Committee of Immunization Practices**

Chairperson Veale provided that Senate Bill 493 allows all pharmacists who possess the designated training to provide immunizations pursuant to the CDC's guidelines. Therefore, there was no action required by the committee on this item.

Ms. Herold noted that the board's inspectors will verify that pharmacists administering immunizations are adhering to the CDC's requirements. She added that perhaps the board should create a guidance document so that everyone knows what documentation is required.

**k. Summary of Discussion on the Requirements for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols**

Chairperson Veale reported that as with the oral contraceptive protocol, the nicotine replacement protocol must be developed jointly by the Medical Board and the Board of Pharmacy. Chairperson Veale added that the draft protocol provided by CSHP would require further review and development. The committee will continue to work with staff and other stakeholders on the development of the protocol.

Dr. Castellblanch asked if there is any effort to create requirements for advanced practice pharmacy on a national level. Chairperson Veale responded that there are a few states that have a similar license type; however, the rest of the country is looking to see what California

does. Ms. Herold stated that California is on the leading edge and there are many groups who are very interested in the development of the protocols.

Chairperson Veale commented that the board really wants to create a quality program, especially when they have seen that other states such as North Carolina have very few pharmacists who became licensed as an advanced practice pharmacist. Ms. Herold noted that she spoke with the executive officer of the North Carolina Board of Pharmacy and he said that because you have to qualify through the state's medical board, pharmacists are not inclined to seek licensure.

Ms. Butler commented that CPhA is providing continuing education on travel medications and hormonal contraception at their next meeting, and it is being advertised as being SB 493 compliant. Ms. Herold and Chairperson Veale commented that the board has not yet approved any continuing education programs.

#### **I. Competency Committee Report**

Chairperson Veale reported that effective April 1, 2014, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means that there is currently a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. Chairperson Veale added that the board expects to release the scores in June 2014, however, will release exam scores more quickly if the review is completed.

Chairperson Veale stated that the Competency Committee workgroups continues to meet throughout 2014 for examination development. Both Competency Committee workgroups will meet for the annual meeting in August to discuss examination development.

Chairperson Veale provided that the committee has also begun to develop a job analysis survey to be used to complete an occupational analysis with the board's contracted psychometric firm. Pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the examination. She added that the board anticipates releasing this survey to a random sample of pharmacists before the end of year. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE. Pharmacists who completed the job analysis survey in the past were awarded three hours of CE credit. Chairperson Veale stated that staff requests that the board again approve awarding the hours to acknowledge the important and time-consuming attention needed to review the duties pharmacists perform.

Dr. Wong asked how long the survey takes to complete. Ms. Herold reported that the survey takes at least a few hours to complete.

David Adler from the University of California, San Diego, commented that they will be conducting two summer research programs regarding hormonal contraception. One study will be assessing pharmacists' attitudes towards the new authority given to them in SB 493 and the other study will look at pharmacists' knowledge regarding hormonal contraception. Dr. Adler offered to share the data with the board.

**Committee Recommendation (Motion):** Approve three hours of CE credit to pharmacists who complete the job analysis questionnaire.

Support: 12    Oppose: 0    Abstain: 0

**m. Licensing Statistics**

Chairperson Veale briefly reviewed the licensing statistics provided in the meeting materials.

**n. Third Quarterly Report on the Committee's Goals for 2013/14**

Chairperson Veale reported that the board is meeting the acceptance parameters for Success Indicators 2C – Review received deficiency items to determine application completeness within five working days of receipt, 2D – Issue licenses within 3 working days of completed application, and 2E – Update information changes to licensing records within five working days.

Chairperson Veale noted that the board is not meeting the acceptance parameters for the following Success Indicators

- 2A – Cashier All Revenue Received within three working days
- 2B – Review Initial Applications within 30 working days

Chairperson Veale added that in these success indicators, board staff is working diligently to move towards the goal.

**XIII. PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE REPORT**

Chairperson Castellblanch provided a report on the Prescription Medication Drug Abuse Subcommittee meeting held on February 18, 2014.

**a. Summary of Presentation Made to Committee by the Placer County Task Force to Educate Parents, Teens, Educators, Law Enforcement, Medical and Pharmacy Professions About Prescription Drug Abuse**

Chairperson Castellblanch reported that a prescription drug task force from Placer County provided information to the committee on what they are doing to combat prescription drug abuse in their community. The task force representative, Sheri Crow stated that their task force has three main goals: to educate the community and medical professionals, to educate the public on the safe storage and proper disposal of prescription drugs and to work towards getting permanent disposal sites in local pharmacies. Chairperson Castellblanch stated that he found the presentation to be interesting as Placer County is a rural area that is making the most of their limited resources to combat the growing problem in their community.

**b. Information on April 26, 2014 DEA Sponsored Prescription Drug Disposal Day**

Chairperson Castellblanch commented that the next national DEA Drug Take Back Day is April 26, 2014. This is a free event and a solution for the public on how to dispose of unwanted medications. Chairperson Castellblanch added that the board will have a link on its website, as it has in the past, so the public can learn more about the event and find local take-back locations.

**c. Summary of Discussion with Mike Small, California Department of Justice, Administrator, CURES Program Regarding Processes to Facilitate the Enrollment of Pharmacists in CURES**

Chairperson Castellblanch reported that at the subcommittee meeting Mike Small, administrator of the CURES program at the DOJ provided a presentation. The subcommittee learned that even with the passage of SB 809 there will be no funds allocated to the CURES program until July 1, 2015.

Chairperson Castellblanch stated that the subcommittee looked at ways that the board could help the DOJ with the registration process; however, the committee learned that currently DCA does not require licensees to provide their email address, which is a necessary requirement for CURES registration.

Chairperson Castellblanch reported that there was one SB 809 stakeholders meeting in February; however, while members of the Medical Board and other entities were present, there were no Pharmacy Board members in attendance.

Chairperson Castellblanch noted that he was glad to hear earlier in the board meeting the CURES enrollment was up to 17 percent, however there is still a long way to go. He added that at the committee meeting they discussed ways to promote enrollment and CSHP offered to help.

Chairperson Castellblanch reported that at the subcommittee meeting there had been a motion to express the board's displeasure with the Attorney General's handling of the implementation of SB 809, especially in regards to the lack of funding currently being provided to the CURES system. He added that he did not feel that the minutes from the subcommittee meeting accurately reflected the motion and the subcommittee's serious concern with the Attorney General's lack of movement on the implementation of SB 809.

Ms. Herold added that the CURES feasibility study report had been reviewed in a recent meeting of DCA staff she attended and comments were provided back to the DOJ. Ms. Herold added that this is the first step in the process for going out to bid for the new CURES IT system.

Chairperson Castellblanch again expressed his concern that the AG's office will not provide funding to the system until July 1, 2015 – six months before all pharmacists are required to be registered in the system. Chairperson Castellblanch stated that this lack of funding is causing great difficulty for pharmacists trying to register for the system because there is only one CURES staff member for the entire state of California. Chairperson Castellblanch recommended that the board write a letter to the Attorney General stating its concerns with the lack of funding and the delay in implementation of SB 809.

The board decided that the best way to express its concerns to the Attorney General would be in a letter from the board president.

**Motion:** Express to the Attorney General the board's dissatisfaction with the current pace of the implementation of SB 809 and urging them to accelerate the pace of implementation.

M/S: Castellblanch/Hackworth

Support: 11    Oppose: 0    Abstain: 0

**d. Report on the Discussion and Identification of Effective Ways to Educate Pharmacists about Prescription Drug Abuse and Corresponding Responsibility**

Chairperson Castellblanch reported that at the May 28, 2014 subcommittee meeting in San Diego there will be a report from experts from the University of San Diego on what type of materials the board could provide on its website to better educate patients and licensees on opioid dispensing.

**e. Summary of Discussion on Pharmacists' Scope of Practice and Consultations for Opioid Dispensing**

Chairperson Castellblanch reported that the subcommittee discussed that a pharmacist has a major opportunity to advise patients when dispensing medication about precautions and appropriate use of opioids, related issues of prescription drug abuse, control and storage of the medication, and appropriate disposal of the medication. However, Chair Castellblanch stated that the subcommittee decided that this topic would best be handled by the Licensing Committee as it implements SB 493.

**f. Report on the Discussion of Activities to Promote March 2014 as Prescription Drug Awareness Month, Pursuant to Senate Concurrent Resolution 8 (DeSaulnier, Chapter 26, Statutes of 2013)**

Chairperson Castellblanch provided that the subcommittee reviewed various educational materials that would be used during Prescription Drug Awareness Month including the public service announcement prepared by board staff.

**g. Report on Review of Public Outreach Materials Developed and Shared by Southern California Community Groups**

Chairperson Castellblanch noted that the subcommittee reviewed the educational and outreach materials that had been developed by community groups in Southern California.

**h. Report on Review of Industry-Produced Educational Materials for the Public and Licensees**

Chairperson Castellblanch reported that the subcommittee heard from Kristi R. Dover, of Purdue Pharma, on the multiple educational materials that Purdue Pharma has developed.

**i. Report on the Review of Articles Documenting the Issues of Prescription Medication Abuse**

At the last subcommittee meeting, the members reviewed the articles provided in the meeting materials regarding prescription medication abuse. Dr. Castellblanch noted that the subcommittee was particularly interested in an article that stated that in Vermont prescription drug abuse has reached such an epidemic level that the governor dedicated his state of the state address to the subject.

**j. Report on Public Outreach to Address Prescription Drug Abuse**

Chairperson Castellblanch reported the subcommittee briefly discussed the two-day presentations on prescription drug abuse and corresponding responsibility sponsored by the board in January. The two sessions were provided in Orange County on January 22, 2014 and in Sacramento on January 31, 2014.

President Weisser noted that at the subcommittee meeting Chairperson Castellblanch stated that it is a statistical fact that the opioid epidemic is most prevalent in middle aged men. President Weisser asked what age range this included. Chairperson Castellblanch responded that overdoses are significantly higher in men ages 35-55, according to the Center for Disease Control.

**XIV. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE**

In the absence of Ryan Brooks, Rosalyn Hackworth provided a report on the Communication and Public Education Committee meeting held on April 1, 2014.

**a. Report on the Presentation to the Committee by Mpack Systems on New Product Design for Pharmacy Prescription Containers**

Ms. Hackworth reported that MPack is a packaging and automated system that uses flat, rectangular packages instead of pill bottles and its owners said the system cuts pharmacy staff expenses, fill times, medication errors and shipping costs. Committee members had a favorable response to the system, but stated the board is not able to endorse products.

**b. Update on the Committee's Assessment of California's Patient-Centered Labeling Requirement**

Title 16 California Code of Regulations section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. At the October 2013 Board Meeting , the board voted to amend two items of 1707.5(a) – requiring 12 point font for all elements of the patient centered label, and an express prohibition that nothing but the designated patient-centered elements appear in the 50 percent of the label space dedicated to the patient-centered labels.

Ms. Hackworth reported that the committee was tasked by the board to discuss the following items and other elements relating to patient-centered labels, and bring recommendations back to the board.

- Should Section 1707.5(a)(1)(B) Require Listing of the Manufacturer's Name in the Patient-Centered Clustered Area of the Label When a Generic Drug Is Dispensed?
- Should Changes Be Made to 1707.5(a)(1)(B) regarding the Name of the Drug and Strength of the Drug to Improve Patient Understanding of the Medication?

- When a Generic Drug Is Dispensed, Should the Generic Equivalent Drug Dispensed to a Patient Be Referenced Back to the Brand Name, e.g., Phrased as “Generic for (brand name)\_\_\_\_\_”?
- Should Purpose or Condition Be a General Requirement for Labels?
- Should the Existing Requirements for “Added Emphasis” in the Patient-Centered Area of the Prescription Label Be Modified?
- Translated Directions for Use Are Available on the Board’s Website. Should the Board Require Use of Them to Aid Patients with Limited English Proficiency?
- Should the Board Consider Technology Standards to Enhance the Patient-Centered Requirements?

Ms. Herold stated that at the beginning of the committee meeting Chair Brooks said that due to the diversity of opinions of the committee members, the public and the full board he would like to return these questions to the full board to be discussed. Ms. Herold added that the committee discussed having experts come before the board to talk about translations and patient-centered labels. The board agreed with the idea of having a special segment of a future board meeting dedicated to patient centered labels. The board directed staff to determine if this would take place at the June or July board meeting.

Mr. Law commented that he was unsure that the board needed to readdress every aspect of the patient-centered regulation as they had already handled the font size. Ms. Butler commented that that public in particular was concerned about including “generic for” on the labels to avoid confusion.

Dr. Castellblanch commented that he wants to be sure that these items, particularly the translation piece, are discussed as soon as possible.

The board members asked staff to use the website “Doodle” to help make board meeting scheduling easier.

**c. Report on the Availability of Options for Prescription Labels for Visually Impaired Patients**

Ms. Hackworth reported that the board was recently made aware of a new technology to aid visually impaired patients in taking their medications. The committee took no action on this during the meeting.

**d. Information on the Proposal by the Federal Food and Drug Administration on “Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products”**

The Food and Drug Administration late last year proposed a rule that would permit generic drug manufacturers, who are approved to manufacture a generic version of a brand-name drug, to distribute revised product labeling that differs in certain respects, on a temporary basis, from the labeling of its reference listed drug previously submitted to the FDA.

Ms. Hackworth reported that the committee was informed that the board was asked twice in a month what the board's position is on this – by CalPERS and the Governor's Office. In the past, when there has been a problem with a drug, it is the brand drug makers' responsibility to inform the public, not the generic drug maker. Ms. Hackworth noted that the committee was informed there may be some developing policy on this in the future; however, no action was recommended by the committee.

Ms. Herold added that the board's main concern is patient safety and clarified that the FDA wants generic manufacturers to be required to provide the same patient safety information as the brand-name manufacturers. The board expressed their support of the FDA's position.

**Motion:** In the event that there is rulemaking before federal authorities, the board will express its support of generic manufacturers being required to provide the same warning labels to consumers as the brand-name manufacturers are required to provide.

M/S: Law/Butler

Support: 11    Oppose: 0    Abstain: 0

**e. The National Association of Boards of Pharmacy's Launch of ".pharmacy" to Identify Legitimate Internet Web Sites for Prescription Drugs**

Ms. Hackworth reported that the committee was updated on where The National Association of Boards of Pharmacy is in the process of implementing ".pharmacy." It was requested that this information eventually be included on the board's website.

**f. Update on *The Script***

Ms. Hackworth reported that *The Script* is scheduled to go into design late in April. This edition focuses on new laws for 2014 and disciplinary actions. Ms. Hackworth added that staff intends to resume at least biannual production of this newsletter from this point forward.

**g. Updated on the Board's Public Service Announcement and Video Developed on Prescription Drug Abuse**

The board viewed the public service announcement video on prescription drug abuse developed by staff.

**h. Summary of Review of Board's Consumer Education Materials on Counterfeit Drugs and a Newsletter Article for the Medical Board's Newsletter**

Ms. Hackworth stated that a new online brochure on counterfeit drugs is in the design phase and is expected to be completed by the end of April. Ms. Hackworth added that staff also developed an article on patient-centered prescription labels to appear in the upcoming Medical Board newsletter.

**i. Update on Media Activity**

Ms. Hackworth briefly reviewed the board's media activity since the last board meeting.

Mr. Lippe and Mr. Law left the meeting at 3:14 p.m.

**j. Report on the Public Outreach Activities Conducted by the Board**

Ms. Hackworth provided a brief overview of the board's public outreach activities, highlighting the two DEA programs conducted in January 2014.

**k. Public Comment for Items not on the Communication and Public Education Committee Meeting**

Ms. Hackworth reported that committee members expressed their concern that the "Ask Your Pharmacist" posters have too much information on them and the type is too small to read.

President Weisser thanked Shirley Wheat, who is leaving the board, for all of her work on the board. Ms. Wheat thanked the board and staff for their support while she served on the board.

**ADJOURNMENT**

**3:21 p.m.**

DRAFT