



**California State Board of Pharmacy**

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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:** October 28-29, 2014

**LOCATION:** Sheraton Park Hotel  
1855 South Harbor Blvd  
Anaheim, CA 92802

**BOARD MEMBERS**

**PRESENT:** Stanley C. Weisser, President  
Amy Gutierrez, PharmD, Vice President  
Deborah Veale, RPh, Treasurer  
Greg Lippe, Public Member  
Gregory Murphy, Public Member  
Victor Law, RPh  
Allen Schaad, RPh  
Ramón Castellblanch, PhD, Public Member  
Albert Wong, PharmD  
Lavanza Butler, RPh  
Rosalyn Hackworth, Public Member (10/29/14 only)  
Ryan Brooks, Public Member

**BOARD MEMBERS  
NOT PRESENT:** Ramon Castellblanch, Public Member

**STAFF**

**PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Michael Santiago, DCA Staff Counsel  
Robert Ratcliff, Supervising Inspector  
Joshua Room, Supervising Deputy Attorney General  
Desiree Kellogg, Deputy Attorney General  
Laura Hendricks, Staff Analyst

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**Note:** A webcast of this meeting can be found at:

<http://www.pharmacy.ca.gov/about/meetings.shtml>

**Tuesday, October 28, 2014**

**Call to Order**

**9:02 a.m.**

**I. GENERAL ANNOUNCEMENTS AND OVERVIEW OF CURES REGISTRATION PROCEDURES FOR BOARD OF PHARMACY**

President Weisser called the meeting to order at 9:02 a.m. He announced that CURES registration would be taking place in the lobby both days of the board meeting from 9-11 a.m.

President Weisser conducted a roll call. Board members present: Gregory Lippe, Greg Murphy, Victor Law, Allen Schaad, Rosalyn Hackworth, Amy Gutierrez, Stanley Weisser, Lavanza Butler, Deborah Veale and Albert Wong. Board members absent: Ramon Castellblanch and Rosalyn Hackworth. Note: Amy Gutierrez arrived at 9:48 a.m.

President Weisser announced that former board members John Tilly, Holly Strom and Stan Goldenberg were in attendance.

**II. TRIBUTE AND RECOGNITION OF CLARENCE HIURA (1934-2014)**

The board honored Clarence Hiura. Clarence served on the board for 16 years and played a significant role in the development of the pharmacy profession. A plaque was provided to his family who was in attendance.

**III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JULY 30-31, 2014**

Motion: Approve the July 30-31, 2014 board meeting minutes.

M/S: Weisser/Law

Support: 8 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Brooks			x	
Butler	x			
Castellblanch				x
Gutierrez				x
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			
<b>Total</b>	<b>8</b>	<b>0</b>	<b>1</b>	<b>3</b>

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

Geneviève Clavreul noted that she is very concerned about the dramatic increase in the cost of prescription medications. Victor Law asked that this topic be placed on a future agenda.

#### **V. LEGISLATION AND REGULATION COMMITTEE**

Chairperson Lippe provided the Legislation and Regulation report as follows. He noted that there has been no meeting of the Legislation and Regulation Committee since April 2014.

##### **Part 1: Legislation Report**

##### **a. Board-Sponsored Legislation**

##### **1. SB 960 (Morrell) Pharmacy Licenses: Letters of Admonishment**

Chair Lippe reported that on August 22, 2014, the Governor signed Senate Bill 960 (Morrell), which contained board-sponsored provisions to authorize the issuance of a letter of admonishment (LOA) concurrently with a license to an applicant for licensure who has committed any violation of law that the board deems, in its discretion, does not merit the denial of a license or require a probationary status under section 4300 of the Business and Professions Code. Chair Lippe clarified that the LOA is not to be construed as a disciplinary action or discipline for purposes of licensure or for the reporting of discipline for licensure.

Ms. Herold stated that LAOs are public documents and are available upon request.

##### **2. 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 contains two board-sponsored provisions and was signed by the Governor on September 9, 2014. SB 1466 amends Business and Professions Code 4021.5 to change the definition of a correctional pharmacy. Chair Lippe also reported that the bill amends Section 4053 regarding designated representatives. As enacted, a designated representative of a wholesaler or veterinary food-animal drug retailer must be at least 18 years of age and meet other licensing requirements.

##### **3. SB 600 (Lieu) Repeal of E-Pedigree Requirements**

Chair Lippe stated that on September 20, the Governor signed Senate Bill 600 which contains the board's sponsored provisions to conform California law to federal law (the federal Drug Quality and Security Act) and repeals the inoperable e-pedigree provisions in Pharmacy Law. He added that in addition, SB 600 enacts provisions that declare that drugs obtained outside of the licensed supply chain (regulated by the FDA) are deemed misbranded, and provides for related penalties.

#### **4. AB 2605 (Bonilla) Requirements for Third Party Logistics Providers**

Chair Lippe reported that on September 20, 2014, the Governor signed Assembly Bill 2605 to ensure the appropriate and continued oversight of third-party logistics providers. As enacted, the legislation establishes requirements for application, licensure and renewal of three, new categories of licensure (third-party logistic provider premises, nonresident third-part logistic provider premises and designated representative –3PLs).

Joshua Room noted that simultaneous to the passage of AB 2605, the FDA noticed a guidance document on third party logistic providers. He recommended that the board provide comments on the document. Mr. Room concluded that comments were due by December 7, 2014.

#### **b. Chaptered Legislation**

##### **1. AB 1535 (Bloom) Pharmacists: Naloxone hydrochloride – Chapter 326, Statutes of 2014**

Chair Lippe reported that Assembly Bill 1535 added section 4052.01 to the Business and Professions Code 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 as enacted, AB 1535 authorizes the board to adopt emergency regulations to establish the standardized procedures or protocols.

##### **2. AB 1702 (Maienschein) Professions and Vocations: Incarceration – Chapter 410, Statutes of 2014**

Chair Lippe explained that existing law establishes various eligibility criteria needed to qualify for a license and also 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 application is made. As enacted, AB 1702 provides 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 because all or some of the licensure requirements were completed while the individual was incarcerated. Chair Lippe noted that the enacted version of the bill states that the provisions shall not be construed to limit the board's ability to deny a license pursuant to section 480 of the Business and Professions Code.

##### **4. AB 1743 (Ting) Hypodermic needles and syringes – Chapter 155, Statutes of 2014**

Chair Lippe stated that existing law authorizes a pharmacist or physician to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older. Chair Lippe reported that AB 1743 deleted the limitation (30 or fewer) and extended the provisions to January 1, 2021.

**5. AB 1841 (Mullin) Medical Assistants – Chapter 333, Statutes of 2014**

Chair Lippe explained that as enacted, Assembly Bill 1841 authorizes a medical assistant who works in a clinic licensed by the board (nonprofit or free clinics) to hand out prepackaged prescription drugs, so long as they are labeled in accordance with Section 4170 (prescriber dispensing). The bill states that in every instance, prior to handing the medication to a patient, an “appropriate patient consultation regarding use of the drug” shall be provided by a licensed physician and surgeon, a licensed podiatrist, a physician assistant, a nurse practitioner, or a certified nurse-midwife.

Chair Lippe reported that the board opposed this bill because the board felt the consultation provided to these patients did not require sufficient information to protect the patient from harm and is not consistent with the level of consultation a patient would receive in a pharmacy.

**6. AB 2396 (Bonta) Convictions: Expungement: Licenses – Chapter 737, Statutes of 2014**

Chair Lippe stated that Assembly Bill 2396 amends section 480 of the Business and Professions Code and prohibits a board within the DCA from denying a license based *solely* on a criminal conviction that has been withdrawn, set aside, or dismissed by the court. Chair Lippe reported that the board opposed the measure. It was noted that when considering the denial of an application, the board conducts an independent investigation of the behavior, circumstances and details of such a conviction for the purpose of sustaining the denial.

**7. AB 2720 (Ting) State Agencies: Meetings: Records of Actions Taken – Chapter 510, Statutes of 2014**

Chair Lippe reported that as enacted, Assembly Bill 2720 amends the Bagley-Keene Open Meeting Act to modify the definition of the term “action taken” to require that a state body publicly report any action taken and the vote or abstention on that action of each member present for the action.

President Weisser explained that due to this bill the board would now be reporting how each member votes during meetings. It was clarified that this bill only applies to open meetings; therefore, votes taken during closed sessions and mail voting would not be reported in the new manner.

**8. SB 1039 (Hernandez) Pharmacies: Furnishing Drugs – Chapter 319, Statutes of 2014**

Chair Lippe provided that as enacted, Senate Bill 1039 impacts an acute care health facility licensed pursuant to Health and Safety Code section 1250(a). The bill authorizes a pharmacy intern and a pharmacy technician, under the direct supervision of a pharmacist, to perform various functions to include the sealing of emergency containers for use in the hospital; and authorizes an intern pharmacist to perform monthly inspections of drugs in the hospital; and to stock, replenish, and inspect the drugs maintained in the emergency pharmaceutical supplies container and the emergency medical system supplies in the hospital.

Ms. Herold explained that the board identified a fiscal impact for this measure, and has requested one-half of an inspector position for the expected inspection workload and one half-

time limited-term AGPA. She noted that due to the board's current lack of funds, these two positions cannot be approved at this time.

**9. SB 1159 (Lara) Professions and Vocations: License Applicants; Individual Tax Identification Number – Chapter 757, Statutes of 2014**

Chair Lippe reported that this measure requires an applicant to provide the board with either a social security number or an individual taxpayer identification number.

**10. SB 1226 (Correa) Veterans: Professional Licensing – Chapter 657, Statutes of 2014**

Chair Lippe explained that this measure requires a board within the Department of Consumer Affairs, on or after July 1, 2016, to expedite the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the Armed Forces and was honorably discharged. Ms. Herold explained that applications are processed in date order. This bill will require staff to pull any military applicant and process it first.

**c. Vetoed or Failed Legislation**

**1. AB 2757 (Bocanegra) Centralized Hospital Packaging Pharmacies: Medication Labels**

Status: Failed

Chair Lippe reported that Assembly Bill 2757 was an effort to specify requirements for barcode and human-readable labels on drugs prepared by a hospital's centralize hospital packaging pharmacy. The bill would have specified that a barcode be readable by "barcode administration software" and what the software shall read from the barcode.

**2. SB 204 (Corbett) Prescription Drugs: Labeling**

Status: Vetoed

Chair Lippe reported that Senate Bill 204 would have required the board to conduct surveys of pharmacists and electronic health record (EHR) vendors to evaluate the use of standardized directions on prescription labels, to report the findings at its July 2016 Board Meeting, and to publish the findings on the board's website. The board identified estimated costs of approximately \$50,000 to contract for the mandated surveys, which would come out of the board's Contingent Fund. The Governor vetoed the bill because the board did not have the necessary resources to conduct the surveys.

**3. SB 1014 (Jackson) Pharmaceutical Waste: Home Generated**

Status: Failed

Chair Lippe stated that Senate Bill 1014 would have required the Department of Resources Recycling and Recovery (CalRecycle) and the board to jointly develop regulations authorizing a

voluntary program in pharmacies to collect and properly dispose of home-generated pharmaceutical waste.

#### **4. SB 1258 (DeSaulnier) Controlled Substances: Prescriptions: Reporting**

Status: Died - Held in Appropriations

Chair Lippe stated that SB 1258 would have permitted the oral and electronic transmission of controlled substances prescriptions, established dispensing limits, required the reporting of Schedule V controlled substances furnished to CURES, and allowed DCA investigators access to CURES data for specified investigations.

#### **5. AB 2058 (Wilk) Open Meetings**

Status: Vetoed

Chair Lippe explained that AB 2058 would have amended the definition of a “state body” to exclude an advisory body with less than three individuals, except for certain standing committees. The Governor’s veto message notes that an advisory committee does not have authority to act on its own and must present any findings and recommendations to a larger body in a public setting for formal action.

#### **6. AB 2147 (Melendez) Website: Information Practices**

Status: Failed

Chair Lippe reported that Assembly Bill 2147 would have required a state agency that uses an Internet web site to obtain information through electronic forms and that shares that information with another state agency to include a specific disclosure notice displayed in a minimum of 12-point boldface type and is clearly displayed in direct proximity to the “submit” button on the form.

#### **7. AB 2418 (Bonilla / Skinner) Healthcare Coverage Rx Drug Refills**

Status: Vetoed

Chair Lippe stated that Assembly Bill 2418 would have required health plans and insurers to apply a prorated, daily, cost-sharing rate to the refills of certain medications if the prescriber or pharmacist indicates it is in the best interest of the patient and it is for the purpose of synchronizing refill dates for the patient’s medications. The bill also allowed for early refills of covered eye products.

**d. Discussion of Legislative Proposals for 2015**

**Part 2: Regulation Report**

**a. Board Approved – Undergoing Administrative Review (Information Only)  
Update on Rulemaking to Amend Title 16 CCR Section 1707.5 Regarding Patient-Centered Labeling Requirements**

In 2013, 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 sans serif typeface.

Chair Lippe reported that the rulemaking was noticed on April 14, 2014, and following the 45-day comment period, adopted by the board in June. Staff compiled the rulemaking file and submitted it to the Department of Consumer Affairs to begin the administrative review process at the end of July 2014. As of October 17, 2014, the rulemaking file was being reviewed by the Department of Finance. Chair Lippe concluded that pursuant to the Administrative Procedure Act, and following review and approval by the Business, Consumer Services and Housing Agency, the rulemaking will be submitted to the Office of Administrative Law for final review.

**b. Board Approved – Awaiting Notice**

**1. Combined Rulemaking – Proposal to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements**

Chair Lippe reported that at the July 2013 Board Meeting, the board approved proposed text to amend sections 1702 and 1702.5 and to add sections 1702.1 and 1702.2 to Title 16 of the California Code of Regulations. He noted that staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

**2. Combined Rulemaking – Proposal to Amend Title 16 CCR Sections 1732.05, 1732.2, and 1732.5 Related to Continuing Education**

Chair Lippe reported that the board previously approved a 45-day public comment period for three proposals related to continuing education. Then, following the enactment of legislation that resulted in significant changes to pharmacy law in 2013(SB 294, Emmerson and SB 493, Hernandez) regarding changes to compounding and the addition of the advanced practice pharmacist provisions, the board again reviewed the proposal in January 2014. Chair Lippe concluded that further amendments to continuing education requirements would be discussed in detail later in his report.

### **3. Proposal to Amend Title 16 CCR Section 1703 Related to “Section 100” Regulatory Actions**

Chair Lippe stated that at the October 2013 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations section 1703 to delegate to the executive officer the authority to initiate a rulemaking to adopt “changes without regulatory effect.” Chair Lippe reported that staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

#### **c. Regulation Proposals – Possible Action Items**

##### **1. Recommendation to Amend Title 16 California Code of Regulations Sections 1715, 1735.2 and 1784 to Update the board’s Self-Assessment Forms 17M-13, 17M-14, 17M-26 and 17M-39**

Chair Lippe explained that Title 16 California Code of Regulations section 1715, 1735.2 and 1784 require pharmacists-in-charge (PIC) and designated representatives-in-charge (DRIC) to complete a self-assessment no later than July 1 of each odd-numbered year, and at other times as specified. Modifications made to the various forms are based on changes in pharmacy laws and regulations, and other laws that impact the practice of pharmacy. The purpose of a self-assessment is to promote compliance through self-examination and education.

Chair Lippe stated that the meeting materials contained proposed modifications to Title 16 California Code of Regulations sections 1715, 1735.2, and 1784, and to the self-assessment forms that are incorporated by reference in those sections. Below is a summary of each section.

**16 CCR § 1715** applies to the self-assessment of a pharmacy by the PIC. The regulation was established in 1997 and was last updated/approved by OAL in 2011. It incorporates by reference two self-assessment forms:

- **Form 17M-13** “Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment”
- **Form 17M-14** “Hospital Pharmacy Self-Assessment”

**16 CCR 1735.2.** This section applies to Compounding. The Office of Administrative Law approved changes to the Compounding Self-Assessment in 2012. The modifications made to the form reflect recent statutory changes.

- **Form 17M-39** “Compounding Self-Assessment”

**16 CCR § 1784.** This section applies to wholesalers. This regulation was established in 2007 and was last updated in 2011. It incorporates by reference the following self-assessment:

- **Form 17M-26** “Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment”

Ryan Brooks asked if self-assessment forms are submitted to the board and if so, can they be submitted online. Ms. Herold explained that the self-assessments are not submitted to the board.

When an inspection is conducted, the pharmacy must produce the self-assessment form. Dr. Steve Gray commented that there is a requirement for a “wet” signature by the PIC, thus it could not be submitted electronically. Ms. Sodergren noted that with the new BreEze system online submittal of self-assessment forms may be possible in the future.

**Motion:** Direct staff to initiate the formal rulemaking process to amend the text of 16 CCR sections 1715, 1735.2 and 1784 and to amend the Self-Assessment Forms incorporated by reference in those sections, as proposed, authorize the executive officer to make any non-substantive changes to the rulemaking package, and provide a 45-day public comment period. (The regulation text approved for advancement to rulemaking is available in the meeting materials.)

M/S: Lippe/Veale

Support: 10    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			
<b>Total</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>2</b>

**2. Recommendation to Further Amend Title 16 CCR Section 1732.5 Related to Renewal Requirements for Pharmacists – Continuing Education**

Chair Lippe explained that as mentioned earlier in his report, the board approved a 45-day public comment period for three proposals related to continuing education. Then, following the enactment of legislation that resulted in significant changes to pharmacy law (SB 294, Emmerson and SB 493, Hernandez) regarding changes to compounding and the addition of the advanced practice pharmacist provisions, the board again reviewed the proposal in January 2014.

Chair Lippe reported that at the July 2014 Board Meeting, the board voted to add “compounding education” as a sixth area of subject-specific continuing education. Thus, staff is recommending that the board further modify the language of section 1732.5 so that pharmacists renewing their licenses that expire on or after July 1, 2016, are subject to the requirements (versus those that expire on or after July 1, 2015). Ms. Sodergren explained that the 2016 implementation date reflects the time needed to promulgate the regulation.

**Motion:** Direct staff to initiate the formal rulemaking process to amend the text of 16 CCR section 1732.5, as described at this meeting; authorize the Executive Officer to make any non-substantive changes to the rulemaking package; and provide a 45-day public comment period.

M/S: Lippe/Law

Support: 10    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			
<b>Total</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>2</b>

The board recessed for a break at 10:05 a.m. and resumed at 10:15 a.m.

**VII. PRESCRIPTION MEDICATION ABUSE SUBCOMMITTEE**

In Chairperson Ramon Castellblanch’s absence, Lavanza Butler provided a report of the meeting held August 26, 2014.

**1. Report on California’s Opioid Misuse and Overdose Prevention Work Group Prescription Drug Work Group Headed by the Director of the State Department of Public Health**

Ms. Butler explained that the Prescription Opioid Misuse and Overdose Work Group was formed by the State Department of Public Health and is chaired by that department’s director. The work group is made up of representatives from various state agencies including the Medical Board, Dental Board, Pharmacy Board, Department of Public Health, Department of Health Care Services, Department of Justice CURES, Emergency Medical Services Authority, Department of Education and the California Conference of Local Health Officers. Ms. Butler noted that the goal of the group is to unify a focused policy that can be articulated by state agencies in efforts on opioid abuse education and prevention.

Ms. Butler reported that during the August committee meeting members asked if others could join the work group, but at this time it is only open to leaders of state agencies.

## **2. FOR INFORMATION: Report on 50-States Meeting Addressing Opioid Abuse Recently Held in Washington D.C.**

Ms. Butler reported that the executive officers of the Medical Board and Board of Pharmacy, along with a representative from the California Department of Public Health, recently attended a federal Department of Health and Human Services working meeting with state officials from across the country to share best practices and discuss how federal and state governments can work together to address the opioid abuse epidemic. During the meeting, national officials encouraged that prescription drug monitoring programs be fully implemented with operability across state lines.

Ms. Butler noted that at the August meeting committee members expressed concern because in California CURES is run by law enforcement - one of only three states doing that – and the system doesn't meet the needs of health care providers. The committee discussed the challenges of the CURES system including its difficulty to use and the lag time in reporting inputted data.

Ms. Veale asked why CURES is run by law enforcement in California. Ms. Herold explained that from its inception CURES was created and run by the Department of Justice. The concern is that because it is run by law enforcement some data elements that would be useful for pharmacist are not included in the system.

Mr. Room noted that California was one of the first states to create a prescription monitoring program; other states that came after were able to determine if their system would be better run by the board of pharmacy or law enforcement. He also noted that DOJ has the resources to manage such a large database, where currently the board does not.

Dr. Gutierrez said the NABP already has a system in place that operates across state lines. Ms. Herold explained that different states collect and report data differently. Mr. Brooks commented that the board should be cautious about integrating systems with other states that collect data in different manners, as the data output may be missing information.

Mr. Brooks asked if during the CURES meetings there is IT staff present. Ms. Herold confirmed that there are at least five IT experts at each meeting.

Dr. Gutierrez commented that despite the current difficulties, it is encouraging to see the increase in CURES registration (25 percent of pharmacists are currently registered).

Dr. Gray, representing Kaiser, commented that Kaiser is very supportive of the CURES system and has offered their expertise in making the system user friendly. Dr. Gray also noted that some states are unable to use the NABP system because they are not allowed to disclose patient information to a private organization.

Doug Hillblom commented that the NABP program does not use a HIPAA recognized standard, this may pose a problem for California. He also commented that there are privacy issues for some controlled substances as they relate to mental health status.

Holly Strom, former board member, commented when CURES was being established, the strongest opposition came from law enforcement. Ms. Herold explained that when CURES was established, the strongest organized opposition was from the Bureau of Narcotics Enforcement, which wanted to create its own program through federal grants.

Geneviève Clavreul commented that she does not find the CURES program to provide useful information. She noted that California has the longest turnaround time for inputting data. Ms. Clavreul also commented that CURES does not share data across state lines, which is a huge barrier for tracking doctor-shoppers.

**3. FOR INFORMATION: Report on CURES Data of Controlled Substances Dispensed in California and Controlled Substance Diversion for Fiscal Year 2013-14; and CURES Board Funds.**

Ms. Butler reported that board staff compiled CURES data on controlled substances dispensed and the number of pills dispensed per California adult; controlled substance drug loss; top drugs lost or stolen; and board expenditures on the CURES system. During the August meeting, the committee discussed that more than one billion hydrocodone pills were distributed to patients last year in California and that night break-ins, losses in transit and employee pilferage are the biggest reasons for losses reported by community pharmacies.

**4. FOR INFORMATION: Red Flags Video Regarding Corresponding Responsibility Produced by the National Association of Boards of Pharmacy (NABP)**

Ms. Butler reported that the NABP produced a video for pharmacists on red flags that could indicate abuse of prescription medications. The group then filmed the board of pharmacy executive officers introducing the video for viewing in their states.

The California version is now available on the board website at:  
<https://www.youtube.com/watch?v=jdeQ0GeJAM&feature=youtu.be>.

**5. FOR INFORMATION: Medical Board of California's Prescribing Task Force**

Ms. Butler reported that the Medical Board's Prescribing Task Force met in June 2014 to make revisions to the Medical Board's pain management guidelines. Ms. Herold reported that if the Medical Board approves the guidelines, there would be a campaign to promote awareness of the new guidelines.

**6. FOR INFORMATION: *Consumer Reports* Articles on the Dangers of Painkillers Presented by Doris Peter, PhD, Director of Consumer Reports Health Ratings Center**

Ms. Butler said that *Consumer Reports* recently published a special report on the dangers of painkillers. At the August committee meeting, Doris Peter, PhD, Director of Consumer Reports Health Ratings Center, presented by telephone information from their research. Dr. Peter reported that they take drug effectiveness reviews and translate complex information into

formats consumers can understand to provide information on options for treatment and effectiveness, safety and cost. She said they try to identify “best buy” choices for consumers. Dr. Peter said they also provide information on pain medications in the September issue of their magazine and included different options besides opioids for the treatment of pain.

Mr. Butler reported that the committee discussed that *Consumer Reports* gets no funding from the pharmaceutical industry and relies on independent grants and in-kind funding and the reports are provided for free to consumers.

Ms. Butler stated that at the August meeting there was discussion as to whether the board planned to include these materials on the board website. However, questions arose as to the article’s statement that there is a “small chance” of addiction if opioid medications are taken as directed because the American Journal of Public Health states it’s as high as 50 percent for those taking opioids long-term.

Geneviève Clavreul expressed her opinion that the *Consumer Report’s* article was inaccurate and discouraged the board from referencing it without first verifying the information contained in the report.

#### **7. FOR INFORMATION AND DISCUSSION: Recommendations Developed by National Council for Prescription Drug Programs (NCPDP) for Improving Prescription Drug Monitoring Programs (PDMP)**

Ms. Butler reported that at the committee meeting Nicole Russell, Government Affairs Specialist with NCPDP, presented their white paper by telephone. Ms. Russell reported that the National Council for Prescription Drug Programs formed a focus group whose goals and objectives were to identify the current and future issues and needs regarding the exchange of information for Prescription Drug Monitoring Programs (PDMPs).

At the committee meeting, Ms. Russell stated that NCPDP found that the current programs don’t effectively allow sharing of information across state lines and don’t relay information in real time. During the meeting, committee members suggested that it already may be too late to have a national tracking system because so many states already have PDMPs in place.

Ms. Veale and President Weisser asked if the committee’s stance was that it may already be too late to have a national tracking system. Mr. Room commented that it was the opinion of NCPDP that it may be too late to create a national tracking system. Ms. Herold commented that the committee discussed how difficult it would be to create a national tracking system.

Doug Hillblom commented that he worked on the NCPDP white paper. He stated that it was the opinion of NCPDP that it is too late to have a *singular* nationwide database.

**8. FOR INFORMATION: Presentation by Angela Crispo, PharmD, Pharmacy Resident, PGY2 Psychiatric, University of California San Diego Health System, on Counseling Tips for Pharmacists on Opioid Prescriptions**

Ms. Butler reported that the committee heard a presentation by Dr. Crispo on “Pharmacist Counseling Tips for Opioid Prescriptions” with information that pharmacists can use when counseling patients on new or changed opioid prescriptions. Ms. Butler noted that the committee discussed the increase in medication adherence with the type of consultation that Dr. Crispo presented.

**9. FOR INFORMATION: Opioid Addiction and Recovery and the Personal Experiences of Jason Smith**

Ms. Butler reported that the committee heard a presentation by Jason Smith, writer, business owner and pain medication addict, is in recovery and has been sober for two years. He recently wrote a series of three articles on heroin and opioid abuse and one of his articles chronicles the switch from pain medications to heroin.

Ms. Butler explained that the committee said Mr. Smith’s presentation showed another side of prescription drug abuse that had not been heard at the meetings. Committee members asked that Mr. Smith provide research studies that supported that connection between opioid abuse and heroin.

Dr. Wong asked if there is a list available of treatment services so that a pharmacist can provide the information to a patient they feel may need help. Ms. Herold commented that there is no one list as there are numerous variables depending on the location of the patient. Dr. Wong concluded that the board should look into resources available to patients in need.

Geneviève Clavreul commented that it has been shown that when patients are offered alternatives instead of pain medication, such physical therapy, they often recover quicker.

Dr. Gray commented that there are many pain management pharmacists in California that the board could use for their expertise in the area of pain treatment. He also commented that new studies show that opioids actually stimulate pain so that the body can get more of the mood effect that the opioids provide. Dr. Gray reported that there are new drugs being formulated that are abuse deterrent.

**10. FOR INFORMATION: Legislative Approval of Drug Overdose Prevention Bill (AB 1535, Bloom), Permitting Pharmacists to Furnish Naloxone**

Ms. Butler stated that as Assembly Bill 1535 was discussed during the Legislation and Regulation report, she would not discuss this item.

### **11. FOR INFORMATION: Joint DOJ and Board of Pharmacy CE Program in Santa Barbara**

Ms. Herold reported that about 160 people attended the free, joint training for pharmacists by the California State Board of Pharmacy and the Los Angeles Field Division of the Drug Enforcement Administration held on September 3 and 4 in Santa Barbara on “What every pharmacist should know to prevent drug diversion.”

Ms. Veale asked if there were plans to hold another CE program in the future. Ms. Herold responded that they are looking to hold one in the San Fernando Valley area. Mr. Law offered to help find a meeting location.

### **12. FOR INFORMATION: DEA Drug TakeBack on September 27, 2014**

Ms. Butler reported that drug take backs are normally held in April and October, but the DEA moved it to September this year. A link on the board’s website was available to find a nearby location for disposal on September 27. The DEA has stated that this may be the last DEA sponsored drug take back.

### **13. FOR INFORMATION: Public Outreach to Address Prescription Drug Abuse**

Ms. Butler reported that a list of outreach activities is available in the board packet.

The board recessed for a break at 11:10 a.m. and resumed at 12:48 p.m.

## **VIII. SB 493 IMPLEMENTATION COMMITTEE**

President Weisser provided a report of the committee meeting held August 6, 2014.

President Weisser reminded the board and the public that SB 493 creates a number of new opportunities for pharmacists to provide direct care to patients. He noted that there are essentially two levels of additional services authorized – one for all pharmacists, the second to create a new licensure category of advanced practice pharmacist to provide additional duties.

### **a. Review of a Proposed Project Plan for Implementation of SB 493**

President Weisser reported that the meeting held August 6 was the board’s third major committee meeting devoted to the implementation of SB 493. Since this meeting, board staff has met with the California HealthCare Foundation to secure their support for a staff person to work with the board’s staff and committee in developing work products for review and discussion.

President Weisser reported that the next two meetings of the committee are scheduled for:

- November 5 – Sacramento
- December 16 – Los Angeles

President Weisser encouraged the board and the public to review the board meeting materials as they outline what the November and December committee meetings will cover.

**b. Discussion Regarding Identification of Materials Where Board Guidance Is Envisioned, Discussion of the Requirements:**

1. For Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices

President Weisser reported that Senate Bill 493 allows a pharmacist to independently initiate and administer vaccines listed on routine immunization schedules of the CDC for persons three years of age or older.

President Weisser explained that to initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements,
- provide information to the patient’s primary care physician and into the CDPH’s immunization registry.

President Weisser noted that future enforcement checks of practitioners who provide immunizations under this provision will provide the board with evidence the pharmacists possess the required training and are submitting information to the immunization registry and the patient’s primary care physician.

President Weisser reported that at the August 6 committee meeting, Dan Robinson, dean of Western University, advised that a meeting of the eight accredited schools of pharmacy deans would be held in September. At that meeting there will be discussion of what certification programs are currently available in each curriculum and a standardized form will be created that can be submitted to the board showing completion of a certification program on immunization, travel meds, smoking cessation and hormonal contraception.

Ms. Herold reported that she attended the meeting with the deans and a form was developed. However, she stated that its contents and potential use would need to be discussed at the November 6, 2014, SB 493 Committee meeting.

President Weisser reported that at the committee meeting the reporting of immunizations to the California Department of Public Health (CDPH) was discussed. DCA Counsel Kristy Schieldge commented that SB 493’s language is open to interpretation and if the board wants to make reporting to CDPH a requirement, there would need to be a regulation to require this.

Mr. Brooks asked what the benefit was to reporting immunizations to CDPH. Ms. Herold responded that it provided a centralized database that practitioners and patients can use to track immunizations. She noted that it was particularly helpful for patients who may not have a primary doctor.

President Weisser concluded that this issue will be discussed further during the November committee meeting.

2. For Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

President Weisser reported that under SB 493 pharmacists may furnish prescription medications not requiring a diagnosis that have been recommended by the CDC for individuals traveling outside the U.S.

Only 5 percent of the traveling population sees a healthcare professional before traveling. President Weisser explained that SB 493 makes the process of getting travel medications much easier in a travel-clinic setting, something that has been historically difficult due to protocol requirements. However, he noted that at the August 6 meeting the committee discussed concerns that a board-produced protocol could be difficult to maintain because with travel medications, things can change overnight based on outbreaks and protocols would take time to modify. At the committee meeting, legal counsel commented that the board does not need to create a protocol for travel medicine.

President Weisser reported that at the committee meeting, legal counsel advised the committee to define what “not requiring a diagnosis” means and identify the CDC guidance document.

Dr. Gutierrez commented that the area of travel medications is so broad, it may be difficult for the board from an enforcement perspective. Under the umbrella of travel medicine, a pharmacist can dispense almost any medication. How is the board to determine if it is dispensed for someone who is traveling. Ms. Veale commented that the board would need to decide if the pharmacist would need to gather travel documentation from the patient prior to dispensing. Ms. Herold agreed that the pharmacist may want to collect information and the board would need to decide if this should be a requirement.

Mr. Brooks asked if the board is concerned that a patient may falsely claim they need medication for travel and then give the medication to someone else to use. Dr. Gutierrez responded that she is concerned someone will have a cold and instead of going to a doctor they will go to a pharmacy and falsely claim they are traveling in order to obtain antibiotics. Ms. Veale agreed that there is a real problem with antibiotic resistance and misuse. Mr. Law recommended that the board should require patients to show proof of travel, such as an airline ticket.

Dr. Gray commented that currently doctors who work in travel clinics do not require documentation of travel before they prescribe travel medication. He noted that they do not even have to see the person prior to prescribing travel medications.

Dr. Gutierrez asked if the centers are the same entity that dispenses the medication. Dr. Gray responded that they are affiliated with the entity that dispenses the medication and a patient can go anywhere to fill the prescription.

President Weiser concluded that there was much discussion on this topic at the committee meeting and it would be discussed again at future committee meetings.

### 3. For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

President Weisser explained that:

- All pharmacists can:  
Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescription, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, when available and as permitted by the prescriber.
- APP licensed pharmacists can:  
Order and interpret drug-therapy related tests.

President Weisser reported that the committee discussed the need for any guidelines developed to identify the professional standards pharmacists should follow when ordering and interpreting tests for monitoring the efficacy and safety of drug therapy.

President Weisser directed the board and the public to view the committee meeting minutes for a further summary of this agenda item.

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

President Weisser reported that during the August committee meeting, the committee discussed the requirements for the development of a protocol for self-administered hormonal contraception that must be approved by the Medical Board and the Board of Pharmacy. President Weisser noted that at least two public meetings will be scheduled to include the required groups and any other interested parties to develop the protocols, the self-assessment questionnaire and the fact sheet. These meetings will occur during November 5 and December 16 meetings. President Weisser stated that the committee will follow the same procedure as was used in the creation of the emergency contraception protocol with the Medical Board.

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

President Weisser explained that Senate Bill 493 provides that a pharmacist may furnish nicotine replacement products approved by the FDA for use by prescription in accordance with standardized protocols. Implementation of this provision requires:

- Certification of the pharmacist in smoking cessation therapy by an organization recognized by the board
- Development of a protocol developed and approved by this board and the Medical Board of California following development with other “appropriate entities”
- The pharmacist maintains records of all prescription drugs and devices furnished for at least three years
- The patient’s primary care provider is notified of any drugs or devices furnished, or information is added to a shared patient record. If the patient has no primary care provider, the pharmacist provides the patient with a written record and advises the patient to consult a physician of the patient’s choice
- The pharmacist completes one hour of CE on smoking cessation therapy biennially.

President Weisser noted that as with the hormonal contraception protocol, a series of at least two public meetings be scheduled and should include the required groups.

President Weisser reported that at the committee meeting members discussed if the board could allow recent graduation from pharmacy school to qualify the pharmacist to begin furnishing nicotine replacement products, rather than making pharmacists take a certification program.

Ms. Veale commented that at the meeting the committee discussed if there should be a limit to how far back the board would accept graduation in lieu of a certification program (i.e., graduation within the last five years). Mr. Brooks asked why the board was concerned with how long ago a pharmacist graduated. Ms. Veale responded that they want to ensure that the pharmacists’ education is current on the subject. Mr. Law suggested that the committee receive a report from the schools of pharmacy to determine what should be accepted.

President Weisser stated that for those pharmacists who will need to complete a certification program or complete continuing education, various professional associations have offered to work with the schools of pharmacy to expand the programs currently available.

**e. Summary of the Discussion on Application Requirements of the Advanced Practice Pharmacist License**

President Weisser explained that a pharmacist must satisfy of any two of the following criteria to become licenses as an APP:

- (A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
- (B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

- (C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

President Weisser stated that at the committee meeting it was clarified that a pharmacist's license must be in good standing, i.e., not on probation, in order to qualify.

President Weisser reported that at the committee meeting legal counsel encouraged the committee to determine if they would like to require certification programs to apply to the board or if the board would simply list the entities they will recognize.

President Weisser stated that at the committee meeting Ms. Veale asked if a pharmacist would be allowed to count the hours they spent completing their postgraduate residency as required in item (B) to complete the one year of clinical services under a collaborative practice agreement as required in item (C). Or if they would be required to complete the year of clinical services *after* they complete their residency. Legal counsel stated that the committee could interpret it either way.

President Weisser reported that Brian Warren commented during the committee meeting that originally, the bill only required fulfillment of one of three criteria. As part of the negotiation with the Senate Business and Profession Committee, it was changed to require fulfillment of two criteria.

President Weisser explained that at the meeting the committee discussed if ASHP-accredited residency programs would fulfill the requirement in item (B) or if the board would need to analyze each applicant's residency work to ensure that at least 50 percent of the experience included direct patient care services with interdisciplinary teams. Legal counsel discouraged the committee from this approach and recommended that the burden be on the school to certify that the residency meets the criteria.

#### 1. Board of Pharmacy Specialties Certification Programs

President Weisser reported that at the February 2014 Licensing Committee Meeting, the board heard a lengthy presentation by the Board of Pharmacy Specialties on their certification programs.

President Weisser explained that the Board of Pharmacy Specialties (BPS) has developed certification programs for eight pharmacy practice areas. The eight specialties are:

- Ambulatory care pharmacy
- Critical care pharmacy
- Nuclear pharmacy
- Nutrition support pharmacy
- Pediatric pharmacy
- Pharmacotherapy

- Psychiatric pharmacy
- Oncology pharmacy

President Weisser concluded that the committee felt that the requirements for BPS certification are high.

## 2. Other Certification Programs (e.g., Commission for Certification in Geriatric Pharmacy)

President Weisser reminded the board that at the June SB 493 Implementation Committee meeting, the board heard a presentation from the Commission for Certification in Geriatric Pharmacy (CCGP) on their certification program.

## 3. Other Programs Envisioned or Under Development

President Weisser reported that at the August committee meeting Dr. Kroon briefly described the certification program offered by the Canadian Pharmacists Association and encouraged the board to consider the program.

President Weisser stated that the BPS, CCGP and the Canadian programs are not accredited by ACPE, as ACPE does not accredit certification programs. He explained that both certification programs are accredited by the National Commission for Certifying Agencies (NCCA). He noted that at the August meeting the committee asked if a legislative change would be required to accept NCCA accreditation. Legal counsel responded that it would not require a legislative change; the board would simply need to recognize them.

President Weisser concluded that at this time the committee recommends that the board recognize NCCA as the accreditation body for certification programs for APP licensure. Ms. Herold commented that this is just the first step, in the future the board will need to create an application process, establish a fee for licensure, etc.

Mr. Law asked to clarify if BPS and CCGP are accredited by the NCCA. President Weisser confirmed that they were.

Brian Warren, of CPHA, reported that they are still determining if they will have their programs accredited by NCCA or ACPE. He noted that NCCA accreditation takes longer than ACPE accreditation.

Dr. Gutierrez asked if the board knew all of the entities that NCCA accredits. Ms. Veale responded that so far the committee has only heard from BPS and CCGP, both of which are accredited by NCCA. Ms. Herold added that before the regulation language is finalized the board will be provided a list of all NCCA accredited entities.

**Motion:** Direct staff to draft requirements for rulemaking for the acceptance of NCCA as a qualifying route for APP licensure.

M/S: Weisser/Lippe

Support: 10    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			
<b>Total</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>2</b>

**f. Development of Elements for Advanced Practice Pharmacist Licensure**

President Weisser reported that a draft APP application was included in the meeting materials. He stated that he would like the board to approve this application for the use of APP licensure.

**Motion:** Approve the draft application form as provided in the board meeting materials to be used for the purpose of applying for APP licensure.

M/S: Weisser/Law

Support: 10    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			
<b>Total</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>2</b>

The board recessed for a break at 1:50 p.m. and resumed at 2:00 p.m.

#### **IV. ENFORCEMENT AND COMPOUNDING COMMITTEE**

Chairperson Gutierrez provided a report of the committee meeting held September 16, 2014.

##### **Part 1: Enforcement Matters**

##### **a. Discussion and Possible Action to Modify 16 California Code of Regulations Section 1744 Regarding Required Warning Labels on Prescription Container Labels**

Chair 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 if 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.

Chair Gutierrez explained that Assembly Bill 1136 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 noted that the required label may be printed on an auxiliary label that is affixed to the prescription container.

Chair Gutierrez stated 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 a patient's ability to operate a vehicle (and now a vessel) may be impaired. As this section has not been revised in a number of years, the schools of pharmacy were asked to provide comments to the list of medications listed in this regulation.

Chair Gutierrez reported that the committee reviewed the comments provided by pharmacy schools and it was recommended to keep the language as broad as possible as the drugs will change over time. Chair Gutierrez noted that this would allow the pharmacist to use his or her professional judgment. It was also suggested to include a portion of the language in the statute as part of the introduction to 1744.

Dr. Gutierrez stated that the committee made the following recommendation (motion): Adopt the revisions to section 1744 of the Title 16 California Code of Regulations as provided below.

#### 1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription. If a pharmacist exercising his or her professional judgment determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel.

- (a) The following classes are examples of drugs that may impair a person's ability to drive a motor vehicle, vessel or operate machinery when taken alone or in combination with alcohol:
- (1) Muscle relaxants.
  - ~~(2) Analgesics with central nervous system depressant effects.~~
  - (3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines.
  - (4) Antidepressants with central nervous system depressant effects.
  - (5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
  - (6) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~
  - (7) Anticholinergic agents and other drugs which may impair vision.
- (b) The following are examples of drugs which may have harmful effects when taken in combination with alcohol. These may or may not affect a person's ability to operate a motor vehicle:
- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
  - (2) Mono amine oxidase inhibitors.
  - (3) Nitrates.

(4) Cycloserine.

(5) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

Mr. Law commented that this should be a wake-up call to all pharmacists; they should not have needed to pass legislation to make pharmacists provide proper consultations.

Michael Santiago, DCA legal counsel, commented that some of the proposed language is lifted directly from Business and Profession Code 4074. He warned that the Office of Administrative Law may have a problem with this because the language is duplicative. Ms. Sodergren commented that the committee recognized that the language may be duplicative; however, they felt it was important that the public had all of the information in one place.

Mr. Santiago expressed concern that not all of the drugs that would require a warning are listed in the language. Dr. Gutierrez responded that a list of drugs that could cause drowsiness is so extensive that it could not be listed in its entirety. Mr. Santiago argued that the pharmacists need to know for which drugs the board expects them to provide warnings.

Ms. Veale asked if classes of drugs could be listed instead of specific drugs. Mr. Santiago agreed that this was a possibility as long as the list of drug classes was comprehensive. He stated that the phrase “examples of drug classes” would need to be removed as it implies that there are more drug classes not listed in the regulation.

Chair Gutierrez commented that the committee had a lengthy discussion on what drugs or drug classes should be listed; however, they concluded that the language should be broad so that it allows a pharmacist to use his or her professional judgment. Mr. Santiago commented the board must provide a list of drugs that *always* require a warning; a pharmacist has the ability to use their professional judgment to provide warnings on drugs above and beyond what the board requires.

Robert Stine commented that the way the classes of drugs are listed in the draft regulation, the language seems to be duplicative and perhaps could be simplified.

The board chose not to vote on the committee’s recommendation (motion) and sent the language back to the committee for further discussion and review.

**b. Discussion and Possible Action to Seek Repeal of Health and Safety Code Section 11164.5(a), Approval to Receive Electronic Prescriptions for Controlled Substance Prescriptions**

Chair Gutierrez explained that Health and Safety Code section 11164.5(a) requires the approval of the Board of Pharmacy and the CA Department of Justice (DOJ) before a hospital or pharmacy may receive electronic data transmission prescriptions or computer entry prescriptions or orders.

This provision was enacted before the Drug Enforcement Administration (DEA) promulgated their e-prescribing requirements several years ago.

Kaiser Permanente recently requested the board's position on whether this provision is operative and how the board is complying with it. Chair Gutierrez reported that at the committee meeting a presentation was given by representatives of Kaiser, who requested approval to allow Kaiser to electronically prescribe controlled substances once approved by the DEA, provide Kaiser with an exemption, or provide additional guidance so that Kaiser could proceed in a lawful manner.

Chair Gutierrez stated that board staff does not believe that there is any need to retain this provision since the DEA has promulgated the required regulations to permit e-prescribing, and the staff recommend amending subdivision (a) out of 11164.5.

Dr. Gutierrez asked Mr. Room whether the board needed its own provisions or if the board could just comply with the federal regulations. Mr. Room responded that he felt the board no longer needed this provision.

Ms. Herold stated that the board should make conforming changes to 11164.5 if subdivision (a) is removed. President Weisser asked if the board needed to take this back to the committee to remove the additional items. Ms. Herold responded that legal counsel could help with this and approving the change now would allow the board time to find an author for the bill.

Mr. Law asked if making this change would allow Kaiser to receive electronic prescriptions for Schedule II drugs. Mr. Room responded that all Kaiser would need to do is comply with the DEA requirements to e-prescribe controlled substance.

Mr. Lippe noted that the committee recommendation provided in the meeting materials was: *"The committee recommends that section 11164.5(a) of the Health and Safety Code be eliminated and to include in the language that the board does not need to enforce this section while the legislation is pending."*

Mr. Lippe asked if *"and to include in the language that the board does not need to enforce this section while the legislation is pending"* was really necessary in the motion as historically it has never been enforced. Other board members agreed that the language would be unnecessary as the board has not historically enforced the provision and was voting to eliminate it all together.

Tony Wong, of Kaiser, commented that Kaiser would recommend keeping the non-enforcement language in the motion so that there is documentation that the board would not enforce the provision until it can be removed.

President Weisser stated that he felt uncomfortable having a motion that stated the board would not enforce a certain provision. Mr. Room responded that as the board has never enforced the provision it would not be inappropriate to state it publically.

The board decided to first vote on the committee’s recommendation (motion) including the non-enforcement language and, if it did not pass, make a subsequent motion excluding the non-enforcement language.

**Committee Recommendation (motion):** Recommended that section 11164.5(a) of the Health and Safety Code be eliminated and to include in the language that the board does not need to enforce this section while the legislation is pending.

Support: 3    Oppose: 7    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks		X		
Butler		X		
Castellblanch				X
Gutierrez		X		
Hackworth				X
Law		X		
Lippe	X			
Murphy		X		
Schaad		X		
Veale	X			
Weisser		X		
Wong	X			
<b>Total</b>	<b>3</b>	<b>7</b>	<b>0</b>	<b>2</b>

Mr. Brooks and Dr. Steve Gray ask that the meeting minutes reflect the board’s discussion to exclude the non-enforcement language was due to the fact that historically the provision has not been enforced and the board would continue this non-enforcement policy.

**Motion:** Recommend that section 11164.5(a) of the Health and Safety Code be eliminated.

M/S: Gutierrez/Law

Support: 10    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Castellblanch				X
Gutierrez	X			
Hackworth				X
Law	X			
Lippe	X			
Murphy	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			
<b>Total</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>2</b>

**c. Discussion and Possible Action on a Proposed Regulation for Community Pharmacies Aimed at Reducing Losses of Controlled Substances**

Chair Gutierrez reported that at the March 2014 Enforcement and Compounding Committee, she led a discussion of losses of controlled substances reported to the board as required by California Pharmacy Law. Subsequently, board’s staff compiled some statistics regarding drug losses reported to the board over the last few years.

The following tables display the losses of controlled substances reported to the board.

Year	2009	2010	2011	2012	2013	2014 (6 mo.)
Number of Reports	614	749	536	639	1224	678
<b>Loss Type</b>	<b>Total Count Reported</b>					
Armed Robbery		70,786	35,773	106,787	80,464	
Customer Theft		9,550	4,598	5,684	13,175	
Employee Pilferage		252,225	452,877	372,926	125,305	
Lost in Transit		13,239	412,168	*1,657,875	22,310	
Night Break In		505,016	80,971	689,925	154,156	
Other		121,635	532,441	518,432	94,267	
<b>Totals</b>		<b>972,450</b>	<b>1,518,828</b>	<b>3,351,628</b>	<b>489,677</b>	

\* In transit losses

### DEA 106 Reports by License Category

<b>Category</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
Pharmacy	376	460	943	551
Hospital	115	104	230	97
Wholesaler	33	35	58	35
Out of State				
Distributor	1	6	8	4
Correctional Facility	10	5	2	5
Clinic	1	2	0	0
Non Resident				
Pharmacy	0	1	0	0
Drug Room	0	0	1	0
Other	0	0	2	1
<b>Total</b>	<b>536</b>	<b>613</b>	<b>1244</b>	<b>693</b>

Chair Gutierrez highlighted that in 2013, 3.06 million dosage units of controlled substances were reported to the board as lost. This includes 1.7 million units reported by a major manufacturer who had a truck stolen.

Chair Gutierrez reported that at the March 2014 Enforcement and Compounding Committee Meeting, it was noted that these numbers were only estimates provided by the entity when they first realize there has been a loss. As such, the reported numbers are most likely significantly less than actual losses. The committee expressed concern about the significant losses and the need for more stringent inventory controls in pharmacies to identify losses resulting from employee pilferage. Comments from the committee included developing steps for inventory controls, which could be done either by regulation, statute or policy and perhaps reconciling the top ten drugs for the pharmacy.

Chair Gutierrez reported that at the April 2014 board meeting when this topic was discussed, the board asked the Enforcement Committee to draft regulation language to require monthly counts of a pharmacy's fastest selling controlled substances as a form of inventory control. When the Enforcement Committee met in September 2014, the committee heard comments from the public wherein it was noted that requiring hospital pharmacies and clinics to perform monthly counts would be too difficult. The committee suggested that the regulation focus on community pharmacies and add hospitals and clinics to the regulation at a later date.

Mr. Law agreed that drug losses is a huge issue; however, he felt that monthly inventory may cause undue hardships for small community pharmacies. He suggested that only pharmacies with high volume narcotic sales be required to conduct monthly inventories. Mr. Brooks agreed with Mr. Law.

Ms. Veale and Dr. Gutierrez commented that when the inventories are conducted it should be done on a strength basis. For example you wouldn't just count morphine as one item; you would break it out and count it by the different strengths.

Ms. Veale commented that pharmacies already have to count each individual Schedule II pill. It was clarified that this was only required once every two years.

Ms. Veale noted that the board has seen cases where an employee was purposefully diverting a "non-top ten" drug in order to evade detection. She noted that she is worried that the employees will know how to find a loop-hole in the inventory.

The board discussed if conducting an inventory of the dispensed controlled substances would be effective, as often the drugs are diverted when they are delivered (and in some cases prior to their delivery). The board concluded that it would be more effective for the inventory to be conducted on the controlled substances purchased each month rather than dispensed each month.

Chair Gutierrez noted that when she reviewed the DEA-106 loss reports only provided estimates of the losses because the pharmacy had no idea how long the diversion had been occurring. Mr. Room commented that often the numbers reported are only what the employee will admit he or she diverted.

Mr. Law commented that employees are more likely to divert from a pharmacy with a high volume of narcotics passing through it each day. He again recommended that the board create a threshold for the number of drugs purchased so that small pharmacies would not have to conduct inventories. Chair Gutierrez responded that if the board creates a threshold then pharmacies will simply place orders under the threshold to avoid inventories.

Mr. Brooks asked if the pharmacist-in-charge places the controlled substance orders. Ms. Herold responded that often it is staff person that places orders.

Dr. Wong commented that he felt that the board should change the inventory requirement from the top ten controlled substances to all Schedule II drugs.

Anne Chung, from Rite Aid Pharmacy, stated that Rite Aid conducts an annual count of all controlled substances and a monthly count of Schedule II drugs. She also reported that Rite Aid uses a perpetual inventory system that is reconciled during the monthly inventory. Ms. Veale asked if Schedule III, IV and V are counted in the same way. Ms. Chung responded that they were not.

Brian Warren, from CPHA, recommended that this topic be sent back to the committee for further discussion. He recommended that the committee look at what the top ten diverted drugs are, so that the board requires the appropriate drugs be counted.

John Cronin, pharmacy attorney, asked the purpose of the proposed regulation. Chair Gutierrez responded that it is an attempt to get a handle on the long, ongoing diversion that is happening without the pharmacy being aware of it. Mr. Cronin stated that the use of a perpetual inventory system would accomplish this goal without requiring such a detailed regulation.

Mr. Cronin asked what type of loss the category “other” covered in the statistics. Ms. Herold responded that the category “other” is used when a pharmacy reports a loss but has no idea how the loss occurred.

Mr. Brooks commented that the board needs to find a balance between creating a barrier for diversion without creating an undue burden for pharmacies.

Ms. Veale asked if there is already a requirement for a pharmacist to be in control of drug security.

Dr. Ratcliff, supervising inspector, commented that 16 CCR section 1714(b) requires the business to have security in place to discourage theft and 1714(d) requires the individual pharmacist to be responsible for drug security.

Ms. Veale asked if there is a requirement for pharmacies to conduct monthly inventories. Dr. Ratcliff responded that at this time there is no requirement. Ms. Veale stated that the board should create a regulation that requires a monthly inventory and leave it up to the individual pharmacy as to how they will accomplish this.

Dr. Law asked if there is a requirement for a pharmacy to have a perpetual inventory system in place for Schedule II drugs. Dr. Ratcliff stated that while it is a good practice, currently there is no state or federal requirement for a perpetual inventory system.

Karen Unbee, pharmacist at Cedar Sinai Hospital, reported that their hospital requires a monthly inventory of all schedule II-IV drugs.

Mr. Brooks asked how the board would handle a pharmacy that created written policies, but they were not adequate and diversion still occurred. Mr. Room stated that the board has found that rather than creating policies, pharmacies have simply purchased procedures from an online source. The board has also seen cases in which the pharmacy had written policies but they were not implemented by staff. Mr. Room stated that simply requiring policies and procedures would not be enough without specifying both what has to be in the policies, and how you have to comply with the policies.

Mr. Brooks commented that while he does not believe in overregulation, the statistics clearly indicate the pharmacies are not taking steps to prevent diversion, which should be a priority for all pharmacies.

Rebecca Cupp, from Ralph’s, commented that they have been doing perpetual inventory on Hydrocodone for seven years because their statistics showed that it was one of their top diverted

drugs. Ms. Cupp offered to share with board members Ralph's diversion policies and procedures. President Weisser asked if Ralph's has seen improvement since the implementation of their policies. Ms. Cupp responded that they have seen dramatic improvement.

Dianne McKellan, from PIH Hospital in Whittier, warned that pharmacies need to be sure that if they use a perpetual inventory system that they go back far enough to catch medications that have not been dispensed in a while.

Dr. Gutierrez recommended that this topic be sent back to the committee for further discussion, she also asked that chain pharmacies come to the committee meeting to discuss their anti-diversion efforts. Mr. Brooks asked that the committee also consider how the regulation will affect community pharmacies. Mr. Room recommended that the board vote down the committee recommendation (motion) so that the topic could be sent back to the committee.

**Committee Recommendation (motion):** Adopt the proposed language to add as section 1715.65 to 16 California Code of Regulations, for community pharmacies only, as follows:

**1715.65 Monthly Inventory Counts of Fastest Moving Controlled Substances**

- (a) Every June 30<sup>th</sup>, each pharmacy licensed by the board shall identify its top 10 controlled substances dispensed by the licensee as measured in dosage units in the prior 12 months (July 1 – June 30).
- (b) Effective July 1 and each month thereafter until the next June 30 (for a total of 12 months), the pharmacy shall count and reconcile the inventory of the top 10 controlled substances identified pursuant to subdivision (a). This reconciliation shall include for each of the controlled substances:
  - (1) The inventory recorded on the first of the preceding month
  - (2) The additions to inventory made in the preceding month (e.g., purchases, transfers in, will-call items that were never handed out that were counted as dispositions the prior month)
  - (3) The dispositions (e.g., dispensing, saleable returns to a wholesaler, drugs provided to a reverse distributor for destruction) from inventory made in the preceding month
  - (4) The drugs in quarantine waiting for the reverse distributor,
  - (5) The final inventory count on the first of the month
  - (6) The pharmacy shall attempt to reconcile overages or shortages. Shortages must be reported to the board.
  - (7) The name of the individual conducting the inventory and date the inventory required by this subdivision was performed
- (c) Losses of controlled substances identified from the monthly audit shall be reported to the board as required by section 1716.5 and Business and Professions Code section 4104.
- (d) The pharmacist-in-charge shall sign each monthly inventory performed under this section indicating he or she has reviewed the inventory taken.

The pharmacist-in-charge shall perform a quality assurance review of the monthly and annual inventories and take appropriate actions to maintain secure methods to prevent losses of all dangerous drugs.

Support: 0    Oppose: 10    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks		X		
Butler		X		
Castellblanch				X
Gutierrez		X		
Hackworth				X
Law		X		
Lippe		X		
Murphy		X		
Schaad		X		
Veale		X		
Weisser		X		
Wong		X		
<b>Total</b>	<b>0</b>	<b>10</b>	<b>0</b>	<b>2</b>

**d. FDA Guidance on Drug Supply Chain Security Act**

Earlier this month, the FDA issued a guidance document regarding its future plans for implementation of the federal Drug Quality and Security Act. This law was enacted on November 27, 2013, and instituted new product tracing requirements for prescription drugs preempted any then existing state requirements for tracing prescription drugs (including California’s e-pedigree requirements) established minimum licensure requirements for wholesalers and required separate licensure of third-party logistics providers if states regulated them as wholesalers.

Mr. Room clarified that as of November 27, 2013, federal law prohibited states from regulating third-party logistics providers (3PLs) as drug wholesalers. As this is how the board has historically regulated 3PLs, the board secured enactment of new requirements for 3PLs with AB 2605.

Mr. Room also reported that the FDA will be creating federal regulations. Once they are enacted, the board will need to review and modify its regulations to ensure California’s requirements are not inconsistent with, less stringent than, directly related to or covered by the federal regulations. It was again clarified that while the federal regulation are being created, the board has ensured that 3PLs remain regulated through AB 2605.

Mr. Room reported that there has been a docket opened to allow comments on the federal 3PL requirements. Mr. Room and Ms. Herold recommended that the board submit comments by the December 7, 2014 deadline.

**e. Publication of a Board Appeal Decision Involving License Revocation Involving Fraud**

Mr. Room reported that a request was submitted and approved to the Court of Appeals to publish the Court’s opinion in the case of: *Tu Ngoc Hoang v. California State Board of Pharmacy*, California Court of Appeal, Fourth Appellate District Division Three, Case No. G0419275.

Mr. Room explained that publishing the decision allows the board to use it as precedent in other cases.

Mr. Room explained that the court's opinion rejected Plaintiff's argument that revocation is only reserved for dangerous conduct. This was a case involving fraud where there was no patient harm, but there was unscrupulous conduct. The court reiterated the board's authority to suspend or revoke for unprofessional conduct without requiring patient harm.

**f. Discussion Regarding the Future Demonstration of the Use of Automated Technology in Hospitals and Skilled Nursing Facilities and the Tools for Identification of Medication Diversion from These Units**

Dr. Gutierrez reported that at the American Society of Health-System Pharmacists meeting in Anaheim, board members will have an opportunity to receive a private demonstration of new auto-mated technology.

President Weisser encouraged board members to attend if possible.

**g. Discussion Regarding the Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication**

Chair Gutierrez reported that on September 9, 2014, the DEA released its regulations on the take back of controlled substances from the public.

Chair Gutierrez explained that the Final Rule authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registrations with the DEA to become authorized collectors. All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection receptacles at long-term care facilities.

Ms. Herold stated that the board will need to have some kind of regulations in place for this program. The Enforcement Committee will have a draft of proposed language at a future committee meeting.

Mr. Law commented that he supports this program, but cautioned that the board will need to ensure there are appropriate safeguards in place.

Dr. Gray commented that when the regulation was created it was intended to be a voluntary program. He expressed concern that when counties do not get enough participation they will stake steps to mandate participation.

#### **h. Discussion of the Federal Rescheduling of Hydrocodone to Schedule II**

Chair Gutierrez reported that on October 6, 2014, all hydrocodone combination products (HCP) were up-scheduled from Schedule III to Schedule II. The board sent out a subscriber alert with important information on the scheduling change.

Dr. Gutierrez explained that the DEA has stated that it will allow refills on HCPs written and initially filled before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014. Dr. Gutierrez noted that she has seen reports that most pharmacies will not be allowing refills after October 6, regardless of the date the prescription was initially written and filled.

Ms. Herold stated that the board received a lot of phone calls on the rescheduling. Many of the chain pharmacies reported that they would not be providing refills; however, they would be contacting the prescriber ahead of time to minimize the impact of the change on the patient.

Dr. Gutierrez commented that many computer systems used in pharmacies would not allow for refills once HCP products were changed to Schedule II.

Dr. Gray encouraged the board to move forward with legislation to reconcile the differences in the scheduling of controlled substances on the federal and state level.

#### **i. Discussion of the Federal Rescheduling of Tramadol to Schedule IV**

Chair Gutierrez explained that tramadol is a centrally acting opioid analgesic that has been on the market since the mid-1990s. Subsequently, the FDA approved for marketing generic, combination, and extended-release tramadol products as dangerous drugs, but not as controlled substances.

Chair Gutierrez noted that over the years, the board and other entities have identified instances where tramadol was misused in part because as a dangerous drug, it was more readily available than a controlled substance would be.

In mid-August, the DEA secured the scheduling of tramadol into Schedule IV of the controlled substances schedule. The board sent out a subscriber alert with information on the rescheduling.

#### **j. Update on the Alternative Process for Pharmacists to Become Registered to Access CURES**

Chair Gutierrez explained 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.

Chair Gutierrez stated that the current process for CURES registration is frustrating and laborious. In an attempt to expedite registration, board staff has implemented a process whereby the board

can authenticate the identity of a pharmacist and aid the DOJ in getting this individual registered. Chair Gutierrez reported that the board began accepting applications in July 2014 and has to date received approximately 150 applications.

Chair Gutierrez reported that currently there are 9,268 pharmacists registered with CURES or about 25 percent of all pharmacists.

Dr. Wong commented that he registered recently and was pleased that the process was relatively quick.

**k. Summary of a Presentation by Rita Shane, PharmD, FASHP, FCSHP on Medication Reconciliation in Health Care Facilities**

Chair Gutierrez explained that medication reconciliation is intended to ensure the accuracy of a medication list of drugs taken by a patient. It involves the review, update and reconciliation of medications at each encounter.

Chair Gutierrez reported that at the committee meeting, Dr. Rita Shane provided a PowerPoint presentation regarding medication reconciliation in health care facilities. Chair Gutierrez noted that the committee found the presentation to be very insightful and suggested sharing the data with the California Hospital Association Medication Safety Committee.

**l. New Committee Issues Scheduled for Board Discussion at This Meeting (Not Discussed at the September 2014 Meeting)**

**1. DEA Release of Drug Take-Back Regulations**

Chair Gutierrez reported that the board will need to promulgate regulations on this in the future. She asked that the Enforcement Committee draft language to bring to the board.

**2. National Transportation Safety Board and its “Drug Use Trends in Aviation: Assessing Pilot Impairment**

Chair Gutierrez reported that the National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs.

Chair Gutierrez noted that overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of study pilots increased from 46 to 57 years over the study period.

Chair Gutierrez reported that the NTSB issued two recommendations to California healing arts boards, specifically the Medical Board, Nursing Board, Pharmacy Board and Osteopathic Medical Board. The safety recommendations include the following:

*(I-14-1) Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effects their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation.*

And;

*(I-14-2) Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.*

Chair Gutierrez asked that this information be included in a future article of *The Script*.

#### **m. Enforcement Statistics, 1<sup>st</sup> Quarter 2014-15**

Chair Gutierrez directed the board and the public to review the meeting materials for details on the first quarterly report of the committee's goals, enforcement workload statistics, and SB 1441 Program Statistics for the fiscal year.

Chair Gutierrez noted that, regrettably, the board is not meeting its success indicators for its enforcement related activities. This is in part because of a number of vacancies within the office as well as the training of new inspector staff. Ms. Herold reported that the board recently hired two new supervising inspectors, one who has experience in compounding and the other who has experience in drug diversion to oversee the ten new inspector positions created July 1 in the state budget for 2014/15.

#### **Part 2: Compounding Matters**

##### **a. Discussion Regarding FDA's Expectations for Human Drug Compounders**

Chair Gutierrez reported that the Food and Drug Administration (FDA) is proposing to amend its regulations to revise the list of drug products that may not be compounded under the exemptions provided by the Federal Food, Drug, and Cosmetic Act (FD&C Act) because the drug products have been withdrawn or removed from the market after the drug products or components of such drug products were found to be unsafe or not effective.

Chair Gutierrez reported that at the committee meeting the press release and article from the Federal Register were reviewed and the members did not feel there was any action needed by the board.

##### **b. Results of the Board's Implementation and Inspections of California Sterile Compounding Facilities and Data on Violations Found During Out-of-State Compounding Inspections**

Chair Gutierrez reported that during the committee meeting, Dr. Ratcliff highlighted the top ten violations found during compounding inspections which included lack of compounding self-

assessment, quality assurance issues, facility issues, adequate compounding attire, general compounding quality assurance issues, process validations issues, insufficient or nonexistent policies and procedures, substandard equipment and lack of training.

Chair Gutierrez asked how many out-of-state inspections have been completed to date. Ms. Herold responded that the board has completed approximately 50 out-of-state inspections. Ms. Herold reported that so far the board has found one facility whose California license will not be renewed because they did not comply with California's code.

Ms. Herold reminded the public to be sure that when they are dealing with an out-of-state outsourcing facility, that the facility is appropriately licensed in California.

Michael Bennett asked if the board was still accepting comments on provisions in the compounding regulation. Ms. Herold responded that any comments would need to be made at the November 4, 2014, regulation hearing. It was clarified that any comments received during the comment period would be included in the January board meeting materials.

Michael Bennett asked if a naval installation would need to be licensed to ship drugs into California. Ms. Herold responded that federal institutions and tribal lands can purchase independently without being licensed.

Mr. Bennett commented that many entities are frustrated with the vagueness of the federal compounding regulation. Ms. Herold responded that there currently are no federal regulations as the FDA has not yet promulgated them. She added that a facility doing non-patient specific compounding at a level that requires them to be licensed by the FDA as an outsourcing facility, still has to compound to a level that meets California's requirements.

#### **d. Recalls of Compounded Drugs Throughout the United States**

Chair Gutierrez reported that between November 8, 2013 and September 11, 2014, the board posted seven subscriber alerts related to compounding drug recalls.

#### **e. Future Meeting Dates**

Chair Gutierrez stated that the committee will select meeting dates for 2015. Once established, these dates will be posted on the board's website under the board meetings tab.

### **X. CLOSED SESSION**

Pursuant to Government Code Section 11126(c)(3), the board met in closed session to deliberate on disciplinary matters. President Weisser recessed the board to closed session at 4:03 p.m.

## **Wednesday, October 29, 2014**

President Weisser called the meeting to order at 9:06 a.m. and conducted a roll call. Board members present: Ryan Brooks, Debbie Veale, Stan Weisser, Allen Schaad, Greg Murphy, Lavanza Butler, Greg Lippe, Albert Wong, Victor Law and Rosalyn Hackworth. Note: Amy Gutierrez arrived late. Ramon Castellblanch was not present.

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

President Weisser recognized Warren Ficke for 50 years of service as a pharmacist.

### **XIII. LICENSING COMMITTEE REPORT**

Chair Veale stated that there has been no Licensing Committee Meeting since June 26, 2014. Chair Veale reported on the following board licensing activities.

#### **a. Request from West Coast University Possessing ACPE “Pre-Candidate” Accreditation for Recognition by the Board of Pharmacy Under Section 16 CCR § 1719 for Purposes of Issuing Intern Licenses**

Chair Veale reported that there are three levels to full ACPE accreditation status for new schools of pharmacy: pre-candidate status, candidate status and full accreditation. A school may be granted candidate status once the school has produced its first class of graduates. At this point, section 1719 allows the board to issue intern licenses to current and future students. However, before possessing candidate status and while students are moving through the program at a new school, the school may have pre-candidate status with ACPE. This means that the school is progressing to meet the ACPE accreditation standards, but has not yet completed the process nor graduated its first class. In such cases, the board must recognize the school for purposes of issuing an intern license.

Chair Veale noted that ACPE does not award pre-candidate status to new schools that are not adequately progressing toward full accreditation.

Dr. Nicholas Blanchard, Dean of West Coast University School of Pharmacy, provided an overview of their pharmacy program.

Chair Veale noted that she has visited their campus and was very impressed.

Ms. Butler commented that she was very impressed with their school and it was a privilege to sit in on their accreditation review.

Dr. Wong asked what the job outlook would be for graduates as the number of pharmacy schools have increased. Dr. Blanchard responded that with the Affordable Care Act and the new APP license, there will be new and exciting opportunities for graduates.

Mr. Law asked how their students gain experience hours. Dr. Blanchard responded that they always try to partner with facilities where their faculty is employed. He noted that they have not had any issues with getting their students the required experience.

President Weisser stated that communication is key for pharmacists to provide quality patient care. He asked how the school teaches communication skills. Dr. Blanchard responded during the interview process that they try to find students who are excited about pharmacy and have good communication skills.

**Motion:** Approve the request from West Coast University for recognition by the board under Section 16 CCR section 1719 for purposes of issuing intern licenses. Direct staff to maintain contact with ACPE to ensure that the school continues to move towards full ACPE accreditation status.

M/S: Veale/Law

Support: 10    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Castellblanch				X
Gutierrez				X
Hackworth	X			
Law	X			
Lippe	X			
Murphy	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			
<b>Total</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>2</b>

The board recessed for a break at 9:28 a.m. and returned at 9:35 a.m.

**b. Discussion and Possible Action on Requests for Waiver of California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, California Business and Professions Code Sections 4128 et seq., From Palomar Medical Center**

Chair Veale explained that Business and Professions Code section 4128 establishes the general functions for a Centralized Hospital Packaging Pharmacy (CHP). Business and Professions Code section 4128.4 establishes the required elements of the barcode that must be affixed at the time of packaging to be readable at the patient’s bedside.

Chair Veale reported that 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 barcoded.

Chair Veale stated that the measure's provisions included the requirement that the unit dose medications filled by the centralized hospital packaging license must be barcoded to be readable at the patient's bedside and specifies the information that must be retrievable when the barcode is read. Chair Veale noted that the board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals.

Chair Veale reported that on July 22, 2104, the board received an application for a CHP license from Palomar Health. As part of the application, Palomar Health also submitted a request seeking a waiver of the requirements contained in Business and Professions Code section 4128.4. Chair Veale stated that consistent with the requirements of the law, the application was submitted and is complete.

It was noted that the board has previously granted similar waiver requests to other institutions all seeking licensure as a CHP.

Mr. Law asked if the location had been recently inspected. Ms. Sodergren confirmed that it has been inspected and there were no issues found that would prevent the board from approving the waiver.

Note: Mr. Brooks left the meeting at 9:41 a.m. and returned at 9:52 p.m.

**Motion:** Approve a five-year waiver for Palomar Medical Center that as long as the required labeling elements appear on the label, the lot number is provided on the label and the required data elements are otherwise retrievable, waive the requirement that the data elements in section 4128.4 be retrievable at the patient's bedside by way of a barcode.

M/S: Veale/Lippe

Support: 9    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Castellblanch				X
Gutierrez				X
Hackworth	X			
Law	X			
Lippe	X			
Murphy	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			
<b>Total</b>	<b>9</b>	<b>0</b>	<b>0</b>	<b>3</b>

**c. Discussion and Possible Action to Seek Amendments to Business and Professions Code Section 4209 Relating to Intern Experience Requirements, and to Title 16 California Code of Regulations Section 1728. Also Relating to Intern Experience Requirement**

Chair Veale explained that Business and Professions Code section 4200 establishes the requirements an applicant for the Pharmacist Licensure Examination must satisfy, including 1500 hours of pharmacy practice or the equivalent. Business and Profession Code section 4209 establishes the parameters for the pharmacy practice experience that is required and how an applicant must document compliance with these requirements

Chair Veale added that California Code of Regulations section 1728 (a) (1) provides further specificity on the pharmacy practice experience that is required including the requirement that pharmacy practice experienced must be obtained in both the communicate and institution pharmacy practice settings as well as a minimum of 900 hours of pharmacy practice experience must be obtained in a pharmacy.

Chair Veale stated that over the years the board has reviewed its requirements for pharmacy practice experience and the documentation requirements to support completion of such experience. The board currently accepts verification of pharmacist licensure in another state for one year to satisfy the 1,500 hours of pharmacy practice experience.

Chair Veale reported that during the April 2014 board meeting, the board determined it should revise its current process for the reporting of pharmacy practice experience for individuals graduating from an ACPE school of pharmacy to qualify to take the CPJE. Under current law, a candidate for the CPJE must submit an intern hours affidavit documenting the number of hours completed, or request that hours earned in another state be transferred to California. In addition, the board also accepts self-certification from the applicant confirming that pharmacy practice experience was gained in the community and institutional practice settings, as well as certification that a minimum of 900 hours of practice experience was earned in a pharmacy.

Chair Veale explained that this proposal would allow the board to accept transcripts (that contain the degree posted and date conferred) as sufficient documentation that a student who graduates from an ACPE school after January 2016, has appropriate documentation to verify completion of the requirements for pharmacy practice experience.

Chair Veale reported that during the July 2014 board meeting, the board voted to table the item to allow staff the opportunity to review the proposal with the legal office and determine what documents would need to be submitted with applications. Board staff has confirmed with counsel that as long as the degree is posted and the date is conferred, the transcript could be used as sufficient documentation that the pharmacist practice experience was completed.

Chair Veale explained that the proposed amendments to B&PC section 4209 and 16 CCR section 1728 have been modified slightly to implement the board's desire to accept the PharmD degree from an ACPE accredited school as documentation that an individual has completed the pharmacy practice experience requirements, not just the 1,500 hours. Chair Veale added that the language in CCR 1728 was amended to also reflect the name change of the National Practitioner Databank.

**Motion:** The Board of Pharmacy pursue legislation to amend Business and Profession Code 4209 to amend the intern experience requirements as provided in the board meeting materials.

**4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam**

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education (ACPE) or with regulations adopted by the board.

(3) This experience shall include a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist and must also include pharmacy practice experience in both the community and institutional pharmacy practice settings.

(b) An intern pharmacist shall submit proof of his or her pharmacy practice experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. ~~Intern hours~~ Pharmacy practice experience earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of ~~intern experience~~ pharmacy practice, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice

experience in a pharmacy as a pharmacist and has pharmacy practice experience in both the community and institutional pharmacy practice settings. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

(d) An applicant for the examination who has graduated after June 30, 2016, from an ACPE approved college of pharmacy or department of pharmacy of a university recognized by the board shall be deemed to have satisfied 1500 hours of pharmacy practice experience.

### **1728. Requirements for Examination.**

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Satisfactory Proof proof of 1500 hours of pharmacy practice experience pursuant to the requirement of Business and Professions Code Section 4209.~~that meets the following requirements:~~

~~— (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.~~

~~— (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.~~

~~— (C) Experience in both community pharmacy and institutional pharmacy practice settings.~~

~~— (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.~~

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144. (4) A signed copy of the examination security acknowledgment.

(5) A sealed, original Self Query Report from the National Practitioner Data Bank-~~Healthcare Integrity and Protection Data Bank~~ (NPDB-~~HIPDB~~), dated no earlier than 60 days before an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Authority cited: Sections 851, and 4005, Business and Professions Code. Reference: Sections 144, 851, and 4200, Business and Professions Code.

M/S: Veale/Butler

Support: 9    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Castellblanch				X
Gutierrez				X
Hackworth	X			
Law	X			
Lippe	X			
Murphy	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			
<b>Total</b>	<b>9</b>	<b>0</b>	<b>0</b>	<b>3</b>

**d. Status of Implementation of Recently Enacted Legislation Impacting Licensing Programs for the Board**

Chair Veale reported that several pieces of legislation were signed this year which impact application requirements and will require implementation by board staff. Below is a brief synopsis of each measure as reported by Chair Veale.

AB 2605 (Bonilla) Pharmacy: Third-Party Logistics Providers

This measure was board-sponsored to ensure the appropriate and continued regulation over third-party logistics providers. Specifically the measure creates three new licensing classifications for the board as well as establishes the requirements for application, licensure and renewal. The specific new licensing classifications include:

- Third-Party Logistics Provider
- Nonresident Third-Party Logistics Provider
- Designated Representative-3PL

Implementation of these provisions will require changes to the existing licensing and application computer system used by the board, which is more complicated than previously thought because of the department’s efforts to convert to the new BreZE computer system. Staff has requested a freeze exemption.

At the next committee meeting, the committee will discuss how to transition currently licensed wholesalers that will, effective January 1, 2015, become third-party logistics providers under the law.

SB 1159 (Lara) Professions and Vocations: License Applicants: Individual Tax Identification Number

This measure requires an applicant to provide the board with either a social security number or an individual taxpayer identification number. Implementation of this provision will require updating application and instruction forms as well as slight modifications to the licensing and application computer systems. As this legislation impacts all boards and bureaus within the DCA, staff does not anticipate the need to submit separate requests for these changes.

SB 1226 Veterans: Professional Licensing

This measure requires the board, on or after July 1, 2016, to expedite the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the Armed Forces and was honorably discharged. Implementation of this provision will require updating application and instruction forms.

SB 1466 (Omnibus) Business and Professions

SB 1466 contained two provisions that impact board licensing programs. The first amends the definition of a correctional facility. Implementation of this provision will require updating application and instruction forms, as well as securing changes to the existing licensing and application system. The board will need to secure a freeze exemption. Board staff will work with the department to secure the necessary changes. SB 1466 also changes the requirements for an applicant designated representative to require that the individual be at least 18 years of age. This provision only requires a procedural update.

There were no comments from the board or from the public on any of the legislation reviewed by Chair Veale.

**e. Proposed Amendment to Title 16 California Code of Regulations Section 1793.5 to Update the Pharmacy Technician Application Form**

Chair Veale explained that 16 California Code of Regulations section 1793.5 details the requirements for the pharmacy technician application and also incorporates, by reference, the application itself.

Chair Veale reported that at the request of the DCA Legal Office the Licensing Committee and board considered changes to the questions asked on applications for licensure. This request was made in an effort to provide uniformity throughout the DCA boards and bureaus.

Chair Veale stated that as part of the discussion, the board noted that, unlike other professions regulated under the department, working in a pharmacy or drug wholesaler gives individuals direct access to dangerous drugs, including controlled substances. The committee and board discussed information and suggested language from various attorneys regarding changes to the conviction question.

Chair Veale reported that during the July 2014 Board Meeting, members voted to amend specific questions on various applications, including question seven on the pharmacy technician

application. Subsequently, board staff updated the question and made a few non-substantive changes to question seven.

Chair Veale explained that in addition to those changes, staff is asking for consideration of the board to make a few additional changes designed to provide more clarification to applicants on what is required. Because the application form is incorporated by reference in 16 CCR section 1793.5, the board will need to initiate a rulemaking to modify the application form.

**Motion:** To propose modifications to the text of 16 CCR section 1793.5, and to modify the pharmacy technician application (Form 17A-5), as proposed, which is incorporated by reference in that section. Direct staff to take all steps necessary to initiate the formal rulemaking process; authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and provide a 45-day public comment period.

M/S: Veale/ Lippe

Support: 10    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Castellblanch				X
Gutierrez				X
Hackworth	X			
Law	X			
Lippe	X			
Murphy	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			
<b>Total</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>2</b>

**f. Competency Committee Report and Examination Statistics**

Chair Veale reported that the competency committee held its annual meeting in August as well as workgroup meetings in September and October to fulfill examination development related duties.

Chair Veale reported that examination scores for the CPJE and NAPLEX are released twice a year, generally in spring and fall. Ms. Herold stated that the results were just recently received from the vendor, so the statistics will be available at the January board meeting.

Mr. Law commented that he has attended some of the Competency Committee meetings and he is impressed with how much work the committee does. President Weisser agreed with Mr. Law. Ms. Herold commented that the Competency Committee is currently looking for more members.

Mr. Law commented that he felt that some of the questions are too narrow for general practice pharmacists. Ms. Herold responded that as the board only provided one type of pharmacist license the test is designed to cover all areas of pharmacy.

#### **g. Licensing Statistics**

Chair Veale reported that as of September 30, 2014, the board has 140,182 licensees, including approximately 45,000 pharmacists and 74,000 pharmacy technicians. The board has received more than 5,500 applications and issued over 4,100 licenses during the first quarter.

Chair Veale stated that processing times for most areas of licensing are much higher than in prior years in part because of vacancies, as well as the necessary redirection of staff to implement the significant expansion of sterile compounding. Board staff is working to reduce the processing times. Staff expects by the end of the year all licensing times to be reduced to less than 90 days from the date an application is received.

Dr. Wong noted that the number of technician applications seems to be increasing exponentially. He asked if the board could set a limit on the number of technician licenses it will issue. Ms. Herold responded that the board has no way to restrict a qualified applicant from obtaining licenses.

Mr. Law commented that many technician applicants have prior criminal convictions and thus they are denied licensure by the board. Mr. Law asked if there is any way the board could educate the technician schools on what types of convictions would disqualify and applicant from licensure. Ms. Herold responded that most of the technician schools do have a feel for the type of convictions that would disqualify an applicant. She concluded that this topic would be agenzized for a future Licensing Committee Meeting.

John Cronin, pharmacy attorney, commented that the 90-day minimum pharmacy application timeframe is unacceptable and causes significant financial hardships on the applicant. Ms. Herold responded that while the board has had staffing and workload challenges she agreed that the current processing times are unacceptable. Mr. Herold committed that by the end of the year the board will be back within its normal processing times. Ms. Herold also stated that any applicants who need help expediting their application can contact her directly.

#### **XIV. COMMUNICATION AND PUBLIC EDUCATION COMMITTEE**

Chairperson Hackworth provided a report of the committee meeting held September 18, 2014.

**a. Discussion Concerning the Parameters for Patient Consultation as Required by 16 California Code of Regulations Section 1707.2**

Chair Hackworth explained that requirements for patient consultation were adopted by the board in the early 1990s and have not been revised since.

Chair Hackworth reported that the committee discussed the importance of patient consultation by a pharmacist and agreed that consultations are still not being conducted as they should be, despite studies that have shown there is better medication adherence with consultation.

Chair Hackworth stated that the committee members discussed that consultation should include items of importance that aren't always on the label, such as storage requirements and number of refills left; and should never be just a recitation of what is already printed on the label. Chairperson Hackworth added that the committee felt pharmacists are in a position to dispel bad information that patients might find on the internet and since pharmacists are considered health care providers, the public expects more and pharmacists need to engage their patients.

Chair Hackworth also noted that the committee discussed that 25 years ago, when the board adopted patient consultation requirements, the board extended implementation by 18 months to allow for legislation that permits pharmacy technicians to "free" the pharmacist to perform consultation.

Chair Hackworth reported that during the committee meeting it was stated that pharmacy schools must do more to train their students on how to do a proper consultation and not leave it up to the students to learn during their internships. Evidence of this is a past study that indicated California pharmacists are not comfortable doing consultations because they weren't trained on how to do them.

Chair Hackworth stated that the committee will keep this item on the agenda for future meetings.

President Weisser expressed the importance of consultations and called on the pharmacy schools to better train their students on consultation. He added that as the scope of pharmacy is increased, communication between pharmacists and patients will become even more important.

Chair Hackworth asked if the board should conduct a survey of recent pharmacy grads to see what type of training the schools provide and if the students felt the training adequately prepared them for practice.

Ms. Herold commented that the board is still working with the district attorneys' office in three counties to conduct undercover prescription buys to determine if proper consultations are being given when the medication is dispensed. She reported that in one of the large chains only 50 percent received the required consultation. Ms. Herold added that two large chains have already paid fines under the Unfair Business Practices statutes.

Ms. Herold commented that pharmacists often say that they are not compensated for providing consultations. She added that the public does not know the wealth of knowledge that pharmacists have because they do not talk with their pharmacist.

Dr. Wong asked if the board could require schools to make consultation part of their core curriculum. Ms. Herold responded that it already is part of the curriculum. The board asked that at the January Board Meeting, schools of pharmacy come and report to the board on their current consultation curriculum, how it has changed over the years and if the Internet has changed consultations practices.

Mr. Brooks asked if the board could publicize the pharmacies that did not provide consultations. Ms. Herold responded that the two chains that have already paid their fines have been publicized through subscriber alerts and press releases. She added that the two chains also signed agreements saying they will provide consultations as required in California. Ms. Herold noted that if the DA goes into these pharmacies and finds that consultations are still not being provided, then additional fines could be assessed.

Mr. Brooks asked if the board could work with counsel to determine if schools of pharmacy could be required to notify their students that any criminal convictions will increase the chance that the board will deny them licensure. Ms. Herold stated that she would work with DCA counsel to create language and bring it to the Licensing Committee for discussion.

Ms. Butler commented that pharmacists are educated to provide consultations. She noted that in the problem is pharmacists are so busy that they are not providing the consultations.

Dr. Ratcliff described the process inspectors use to determine if a pharmacy is providing appropriate consultations. Inspectors often find that the pharmacy technicians screen for consultations in order to help keep the lines short in the pharmacy.

Dr. Ratcliff commented that in his opinion consultations often lack substance. He noted that the Indian Health Service offered an excellent training program on consultations.

Dr. Ratcliff explained that he often finds that pharmacies are understaffed which leads to pharmacists not providing required consultations.

Dr. Wong commented that another factor in providing consultations is that the reimbursement rates are so low that pharmacies have to fill a certain number of prescriptions per day to stay in business.

Ms. Herold reported that recently all of the board inspectors came to Sacramento for training. During the training, she reminded the inspectors that they need to be looking at consultations when they go into pharmacies.

Doug Hillblom commented that at the next CHPA Exchange Meeting, they will agendaize a discussion on consultation. He added that he will look to see if they could also offer a continuing

education course during their meeting. Dr. Gutierrez asked if there was a possibility of providing a web-based presentation. Mr. Hillblom confirmed that they had the technology to do this.

Chair Hackworth commented that the board should consider creating a consultation video that could be available on the board website.

Holly Strom commented an effective technique for consultations is to first ask what the patient already knows about their medications. Often a patient's information is incomplete or incorrect; the pharmacist can then provide the patient with complete and accurate information. Ms. Strom also provided the board with personal experiences that illustrated how much of a positive impact consultation can have on a patient's health.

A pharmacist commented that he believes that similar to other states, California should be an "offer to counsel" state. This would allow a pharmacy technician to ask a patient if they would like a consultation. Mr. Brooks responded that he strongly disagrees with the pharmacist's opinion that staff should be able to screen patients for consultation. Mr. Brooks explained that patients often go online to gain information about their medications, but this information is often inaccurate or incomplete. By screening for consultations the patient will leave the pharmacy with inaccurate information about their medications, and this is a recipe for disaster. Mr. Brooks concluded that he does not care that other states allow screening, as California should be a leader in this area.

John Cronin, pharmacy attorney, commented that consultation should be a topic on future agenda items for additional discussion. He added that economics makes it difficult for pharmacists to offer consultations. Mr. Cronin encouraged the board to look at all sides of issue, including economics. Mr. Cronin concluded that when asked patients are not willing to pay for consultations. He said it begs the question as to how much consumers value consultations. Mr. Brooks agreed that economics should be part of the discussion, but he disagreed that patients should have to pay for consultations.

Robert Lee, area supervisor for Walgreens, commented that Walgreens does not time their pharmacists. They expect that for new prescriptions their pharmacists provide the appropriate consultation.

Ms. Herold commented that patients don't value consultation because they don't get them often enough and when they do, it may be just the pharmacist reading them the label.

Mr. Cronin encouraged the board to publicize the next time consultations will be discussed.

Note: Mr. Schaad left the room at 10:47 a.m. and returned at 10:54 a.m.

Neshoba McCarum, pharmacist, commented that since she graduated fourteen years ago she has seen a culture change in regards to the value that is placed on consultations. She reported that now when she works in a pharmacy she has to specifically tell the technicians not to screen for

consultations. Ms. McCarum stated that in her opinion the shift in culture was the result of the board announcing that they would no longer be doing random inspections.

Rebecca Cupp encouraged the board to continue the discussion on this topic. Ms. Cupp reported that Ralph's has a system in place that ensures pharmacists provide consultations for all new therapy.

Mr. Law commented that in his opinion a major issue contributing to the lack of consultation is the reimbursement rate decreasing each year. This puts pressure on pharmacy owners to fill as many prescriptions as possible each day.

**b. Development of the Draft of a Board Policy Statement Recommending the Elimination of Tobacco and E-Cigarette Sales from California Pharmacies**

Chair Hackworth reported that at the July 2014 board meeting, board members voted to adopt a policy to recommend the elimination of tobacco and e-cigarette sales from California pharmacies and referred the item to this committee for follow-up.

Chair Hackworth stated that at the September committee meeting, members agreed that making a recommendation against tobacco sales in pharmacies was good for public health. However, they also discussed that the recommendation could encourage other groups in the future to demand that pharmacies stop selling items like alcohol and junk food. Chair Hackworth stated that the committee concluded that other products have some redeeming values, but tobacco and tobacco products do not. They also discussed whether the recommendation should also be directed at supermarkets and box stores that may sell tobacco in another part of the store and they decided those stores should also be included.

Mr. Brooks agreed that tobacco is unhealthy; however, he expressed his concern in creating policy in this area.

Chair Hackworth stated that this is just a recommendation, not a mandate. A pharmacy still has the right to decide if they would like to continue to sell tobacco products.

Dr. Gutierrez commented that with the passage of SB 493 pharmacists can now provide smoking cessation products to customers it seems inconsistent to concurrently sell tobacco products.

Mr. Brooks commented that he does not like non-binding resolutions or recommendations.

**Committee Recommendation (Motion):** Adopt a policy statement that: The California State Board of Pharmacy recognizes that pharmacists are health care providers and pharmacies are in the business of improving customer health; therefore the board recommends that pharmacies and chain stores that include pharmacies eliminate the sale of tobacco, e-cigarettes and tobacco products, as these products are known to cause cancer, heart disease, lung disease and other health problems.

Support: 9    Oppose: 2    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks		X		
Butler	X			
Castellblanch				X
Gutierrez				
Hackworth	X			
Law	X			
Lippe	X			
Murphy	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong		X		
<b>Total</b>	<b>9</b>	<b>2</b>	<b>0</b>	<b>1</b>

**c. Discussion and Possible Action on the Resumption of the Board’s Assessment of California’s Patient-Centered Labeling Requirement**

Chair Hackworth explained that Title 16 California Code of Regulations section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, there was much public comment from numerous stakeholders. As such, the board included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5, which directed the board to promulgate regulations for improved prescription container label design that would be patient-centered.

Chair Hackworth reported that numerous presentations on patient-centered labels were made at the July 31, 2014, Patient-Centered Prescription Label Forum.

Chair Hackworth provided that 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 elements. Chair Hackworth noted that at the January 2014 board meeting, these two changes were moved to notice for public comment to initiate a rulemaking.

Chair Hackworth explained that the following items one through four, were discussed at the September committee meeting and are now being brought before the board for consideration.

1. 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?

Chair Hackworth explained that current statutory law for prescription container labels requires that if a generic drug is dispensed, then the manufacturer’s name must also appear somewhere

on the label. If a brand name is dispensed, then no manufacturer's name is required on the label.

Chair Hackworth reported that at a prior board meeting, the committee had recommended to the board the removal from the patient-centered area of the label in 1707.5 (a)(1)(B) of "and the name of the manufacturer" when a generic is dispensed. However, there was disagreement as to whether the manufacturer's name needed to be in the patient-centered section and the item was sent it back to the committee for further discussion.

Chair Hackworth reported that at the September meeting the committee discussed the importance of having the manufacturer's name on the label because pill sizes, colors and shapes vary between manufacturers; and critical recalls would require knowing the manufacturer's name. The committee determined that while the manufacturer's name needs to be on the label, it does not need to appear in the patient-centered portion of the label.

Chair Hackworth stated that possible language to remove the manufacturer's name from the patient-centered area is:

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
  - (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface and listed in the following order:
    - (A) Name of the patient
    - (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name ~~and the name of the manufacturer.~~

Chair Hackworth reminded the board that the manufacturer's name is still required by Business and Professions Code section 4076 to appear *elsewhere* on the label every time a generic is dispensed.

**Committee Recommendation (Motion):** Change section (B) to read as follows: Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name. ~~and the name of the manufacturer.~~

Support: 10    Oppose: 1    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Castellblanch				X
Gutierrez				
Hackworth	X			
Law		X		
Lippe	X			
Murphy	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			
<b>Total</b>	<b>10</b>	<b>1</b>	<b>0</b>	<b>1</b>

2. When a Generic Drug Is Dispensed, Should the Brand Name of the Generic Equivalent Be Included on the Label Phrased as “Generic for \_\_\_\_\_”?

Chair Hackworth reported that the committee has previously discussed this issue, but has not taken action to require that when a generic drug is dispensed that “generic for [insert brand name]” is required on the label to ensure patients do not mistakenly take both forms of the medication. For example “Alendronate Tab 70 mg. generic for Fosamax.”

Chair Hackworth stated that at the September meeting the committee discussed the importance of including the generic name on the label so that if a drug from a different manufacturer is dispensed and the patient has both the old and new version of the same drug that they don’t take both by mistake.

Chair Hackworth reported that the committee requested that draft language be brought to the board for discussion and possible action. As requested, board staff determined that one possible solution could be to include “generic for \_\_\_\_\_” and include the brand name, and to require the brand name be listed for a period of time (e.g., five years after patent’s expiration), or leave it up to the professional judgment of the pharmacist. Language to do this is provided below:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point san serif typeface and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the statement “generic for \_\_\_” where the brand name is inserted into the parentheses. If it has been at least five years since the expiration of the brand name’s patent or if in the professional judgment of the pharmacist the brand name is no longer widely used, the label may list only the generic name of the drug and the name of the manufacturer.

Mr. Law asked if abbreviations would be acceptable. The board agreed that abbreviations would be acceptable.

Brian Warren commented that in the previous motion the board approved moving the manufacturer name out of the patient centered portion of the label. He noted that this language requires the manufacture be listed if the brand name is no longer widely used. The board agreed that this contradicted the previous motion and updated the last sentence of the proposed language as follows: If it has been at least five years since the expiration of the brand name’s patent or if in the professional judgment of the pharmacist the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, the name of the manufacturer.

Brian Warren asked if the board would be handling all of the patient-centered labeling requirements with one rulemaking. Ms. Herold responded that the board chose to move forward with 12 point font, but the remaining items would all be part of one rulemaking.

**Motion:** Change section (B) to read as follows: Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the statement “generic for \_\_\_\_” where the brand name is inserted into the parentheses. If it has been at least five years since the expiration of the brand name’s patent or if in the professional judgment of the pharmacist the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, the name of the manufacturer.

M/S: Hackworth/Lippe

Support: 11    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Castellblanch				X
Gutierrez	X			
Hackworth	X			
Law	X			
Lippe	X			
Murphy	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			
<b>Total</b>	<b>11</b>	<b>0</b>	<b>0</b>	<b>1</b>

### 3. Should Purpose or Condition Be a General Requirement for Labels?

Chair Hackworth reported that the addition of this component as a required element to the label has been discussed periodically for years.

Chair Hackworth stated that committee members, especially those who have cared for an elderly parent, concurred that it is important to have purpose on the label; however, prescribers are not required to include it and may choose not to because of off-label use of medications.

Chair Hackworth noted that the committee also discussed whether or not a pharmacist could include purpose on the label, even though the prescriber didn't include it, if the patient requests it. This question was referred to legal counsel. It was also discussed that pharmacists should ask patients the purpose of the medication because that could prevent a medication error and the inclusion of purpose will be a new requirement for e-prescriptions.

Chair Hackworth concluded that the committee asked that draft language be presented at the next board meeting to determine whether there should be regulation/legislation and to see if there is support to proceed. As requested the draft language is below.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, ~~if requested by the patient or patients.~~ unless the patient requests that this information not be added to the prescription.

Mr. Brooks asked what would happen if the drug was prescribed for HIV. Ms. Hackworth replied that the patient could "opt-out." Mr. Brooks expressed his concern that a patient might not be aware that they have the right to opt-out.

Ms. Veale asked if a pharmacist would need to call the doctor if the purpose was not written on the prescription. Ms. Herold responded that the pharmacist could.

Mr. Santiago commented that if it was not provided by the doctor, the pharmacist would need to call the prescriber or talk to the patient to determine the purpose. Ms. Veale expressed her concern that requiring a pharmacist to call the doctor each time they receive a prescription will cause a significant delay in dispensing medication to patients.

Ms. Sodergren commented the proposed language only changes Business and Professions Code 4040, which talks about the requirements for writing the prescription. According to Business and Professions Code 4076, a pharmacist only has to include the purpose if it is included on the prescription. Ms. Sodergren concluded that in her opinion, a pharmacist would not have to call a prescriber if they did not include the purpose on the prescription. Dr. Gutierrez and Ms. Veale disagreed.

Ms. Veale commented that she agrees that purpose should be on the label, however, she does not want pharmacists to have to become the police for how doctors write prescriptions.

The board asked that this item be sent back to the committee for additional discussion.

Mr. Brooks again expressed his concern that patients have to opt-out.

Doug Hillblom commented that a doctor is not required to provide the diagnosis for electronic prescriptions.

The board recessed for a break at 11:48 a.m. and returned at 11:58 a.m. Note: Mr. Brooks returned at 12:03 p.m.

4. Should the Existing Requirements for “Added Emphasis” in the Patient-Centered Area of the Prescription Label Be Modified?

Chair Hackworth reported that at the January 2014 committee meeting, there was no committee or public discussion on this item. It was again included on the September committee agenda to ensure the committee had no interest in modifications to this element. Chair Hackworth concluded that the committee decided that this element should be left as is.

There was no comment from the board or from the public.

**d. Translations on Labels**

Chair Hackworth reported that the committee discussed the two questions below at their September meeting.

1. 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?

2. Should There Be a Specific Requirement for Labels to Be Translated? If So, What Components Are Needed (e.g., Also printed in English, Only Directions, and Exemption from Liability for Translation Errors)?

Chair Hackworth explained that the committee agreed that patients benefit when translated instructions are provided in their native language; however, there are liability issues for pharmacists when they cannot read or write the language on the label or in ancillary information.

Chair Hackworth reported that the committee discussed that requiring translations could first begin by requiring the use of the vetted instructions on the board’s website, which appear in English and five different languages; and then addressing the issue of liability through legislation. There was also discussion about section 1716, which holds a pharmacist responsible for deviating from a prescription.

Ms. Herold provided the board with draft language to consider, it was noted that the language specifically took the liability off the pharmacist if the pharmacist used the translations provided on the board's website.

President Weisser asked if the patient-centered label requirements apply to mail order. Ms. Herold responded that all prescriptions coming into California, including mail order, must use the patient-centered format.

Mr. Brooks asked if the translated languages would fit on the label in 12-point font.

Dr. Wong commented that requiring translations will be difficult for many pharmacies and will negatively affect the workflow. Dr. Wong expressed his opinion that requiring translations would be over-regulation and encouraged the board to allow the market to dictate the need.

Dr. Wong asked if the board had data on the number of people requesting translation services. Ms. Herold responded that when the board conducted a survey two years ago, approximately 70 percent of the pharmacies indicated they had a system to provide translations. Ms. Herold noted that staff does not have any data on the demand for translations.

Mr. Brooks asked if there are any problems for law enforcement or emergency medical workers when they arrive at a scene and the medication labels are not in English. Gregory Murphy, board member and peace officer, stated that not having a label in English would prolong an investigation, as the officer on the scene would have to contact someone to translate the label. Ms. Herold stated that she would discuss this with law enforcement and emergency personnel. Dr. Gutierrez commented that the requirement is for the label to be in both English and the translated language, so this shouldn't be a problem.

Ms. Herold explained that the intent is to have pharmacists use the standardized directions for use which are on the board's website and are translated into five languages. She briefly explained how a pharmacist would use the translations on the web site and noted that translations would only be required for *standard* directions for use.

Mr. Brooks asked if the translations on the board's web site are accurate. Ms. Herold responded that the California Endowment vetted the translations; however, the board has found that no one is using the translations.

Ms. Veale asked if a pharmacist would have to translate the disease state. Ms. Herold responded that the pharmacist would not be required to translate the disease state, only the standard directions for use.

Ms. Herold stated that the goal of the proposed language is not to provide translations for every language and for every possible type of prescription with complicated directions for use. The goal is to provide translations for the 90 percent of medications that are dispensed with standard directions for use in the five languages spoken by the majority of Californians.

Ms. Herold stated that 40 percent of patients cannot read their prescriptions and this poses a real threat to their health.

Desiree Kellogg commented that the proposed language states that a pharmacist would not be held liable for providing an incorrect translation as long as they used the translations provided on the board's web site and were not grossly negligent.

Dr. Gutierrez commented that there may be an issue for some pharmacies providing translations due to their IT system capability.

Dr. Wong expressed his concern for the space available on the label and again stated that the market should determine what translations a pharmacy offers.

Mr. Law agreed that the board should not mandate translations and noted that some of the translations on the board's Chinese poster are incorrect.

Dr. Gutierrez asked if the board does not address the issue of translations will it be handled by the legislature. President Weisser responded that if the board does not address it, another entity will.

Note: Mr. Brooks left the meeting at 12:24 p.m.

Ms. Veale asked if the committee could discuss this item further, specifically regarding the issue of the translations fitting on the label. She also asked the committee to consider allowing a pharmacy to have their own translation system in place rather than being required to use the board's web site.

Mr. Law asked the committee to determine if there is really a need for the board to mandate translations. Mr. Lippe commented that the board has heard multiple times from the public that translations are needed.

Ms. Veale commented that the board should consider encouraging the use of the translations on the board's web site, rather than mandating it. Ms. Butler agreed that the board should encourage rather than mandate the use of translations.

Ms. Herold commented that pharmacies are not currently using the web site translations because they are worried about liability.

President Weisser asked the board members with expertise in this area to attend the next committee meeting to offer input. He also asked that members of the public attend the next committee to provide input.

Carrie Sanders, from the California Pan-Ethnic Health Network, commented that their organization is willing to work with the board on developing language. Ms. Sanders expressed frustration with the board's comments that there is not a need for translations as there has been

data provided showing that there is a need. She also commented that if the board does not address this issue there will be attempts by other organizations to do so.

President Weisser asked Ms. Sanders to attend the next committee meeting to provide additional input.

A pharmacist in the audience agreed with Dr. Wong that translations should not be mandated.

**e. Should the Board Adopt Liquid Measurement Standards as recommended by NCPDP?**

Chair Hackworth explained that the National Council for Prescription Drug Programs in March 2014 released liquid dosing instructions to provide recommendations and guidance for standardizing the dosing designation (the amount and volumetric units) used on prescription container labels of oral liquid medications dispensed from community pharmacies. The goal is to improve patient safety and outcomes by decreasing the potential for errors when patients and caregivers take and administer these medications.

Chair Hackworth reported that the committee members noted that the board's regulations are silent on the issue of liquid dosing and proper liquid measurement is very important, especially for infants who are the most dose-sensitive.

Chair Hackworth concluded that the committee directed staff to include an article in *The Script* newsletter to begin to inform pharmacists about liquid measurements.

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

**f. Should the Board Consider Technology Standards to Enhance the Patient-Centered label?**

Chair Hackworth reported that at past committee meetings, the committee has discussed that some pharmacies are able to provide pictures of the pill on the prescription label, instead of the verbal description of the medication -- which is a statutory requirement for all labels. Chair Hackworth noted that the committee has not determined that requiring items like a picture of the pill on the label to replace the description is technologically feasible at many pharmacies.

Chair Hackworth reported that the committee discussed that there is no standardization in technology available at different pharmacies to create requirements. For example, some pharmacies can use a color printer and can include a color photo of the pill on the label, while other pharmacies only have black and white printers.

Chair Hackworth stated that there was no desire by the committee at this time to consider technology standards to enhance the patient-centered label. However, as technology evolves it may become feasible in the future.

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

**g. Update on The Script**

Chair Hackworth reported that the next edition of *The Script* is expected to be completed before the end of the year and will highlight new California laws.

Dr. Gutierrez asked if there is a regular publication schedule. Ms. Herold responded that the goal is to publish it quarterly, due to staffing it is currently twice a year.

**h. Update on the Board's Consumer Education Brochure on Counterfeit Drugs**

Chair Hackworth reported that final edits were being made to a new brochure on counterfeit drugs when the board meeting materials were being prepared. Ms. Herold commented that the brochure is now completed and will be distributed at the next committee meeting.

**i. Update on Media Activity Public Continuing Education Training Session by the California State Board of Pharmacy and DEA Held September 2 and 3, 2014, in Santa Barbara**

Chair Hackworth reported that the Board of Pharmacy and the DEA held two continuing education training sessions on September 2 and 3 in Santa Barbara on diversion prevention titled "Pharmacy Diversion Awareness Conference." The event was attended by 142 people – 81 on the first day and 61 on the second day.

Chair Hackworth stated that the committee discussed that the board continues to have a demand for these training sessions and the board is also registering pharmacists into CURES at these events. Chair Hackworth also reported that for the first time at one of these educational programs, 75-80 percent of the attendees raised their hands when asked who was registered to use CURES.

**j. Update on Media Activity**

Chair Hackworth reported that media coverage included advanced practice pharmacy, patient-centered labels, prescription drug abuse, compounding pharmacies and board enforcement cases. Media outlets covering these issues included the *Los Angeles Times*, *Sacramento Bee*, National Public Radio and television stations.

**k. Report of Public Outreach Activities Conducted by the Board**

Chair Hackworth reported that the board continues to participate in community outreach events that inform consumers about such issues as prescription drug abuse and concerns for seniors. The board also participated in informative meetings with government officials on advanced practice pharmacists and prescription drug abuse prevention.

Chair Hackworth highlighted the board's participation in a state work group that is working to create a unified message on prescription drug abuse and overdose prevention.

A full list of public outreach activities was included in the meeting materials.

Chair Hackworth stated that at the committee meeting members discussed the possibility of the Board of Pharmacy and the Medical Board teaming up to provide a presentation for the dental association on prescription drug abuse, as dentists are one of the top three prescribers of hydrocodone.

Chair Hackworth reported that staff said there is great concern regarding the rescheduling of hydrocodone because patients may present at pharmacies and request refills that may no longer be available. At the committee meeting, staff reported that the board sent a subscriber alert in advance of the October 6 rescheduling of hydrocodone to educate licensees. Copies were also sent to other prescribing boards in the department to share with their licensees. Ms. Herold reported that while the board received phone calls regarding the rescheduling, the transition was smoother than anticipated.

#### **I. Review and Discussion of Articles on Issues of Interest**

Chair Hackworth reported that many articles of interest were provided for the committee to review. The committee was particularly interested in an article on the “100 Most Prescribed Drugs;” and another article on how seniors are medicated in nursing homes.

#### **m. Discussion of the 43rd Annual Report of the Research Advisory Panel of California**

Chair Hackworth explained that California law, pursuant to Health & Safety Code sections 11480 and 11481, requires proposed research projects using certain opioid, stimulant and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office. The Board of Pharmacy has an appointee on the panel.

Chair Hackworth reported that the Research Advisory Panel primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the study. The Panel members evaluate the scientific validity of each proposed project and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research.

Chair Hackworth stated that the committee members said they wanted to hear a full presentation of this item and directed staff to add it to an upcoming agenda and invite guest speakers.

### **XV. ORGANIZATIONAL DEVELOPMENT COMMITTEE**

**Note:** Several ad hoc teleconference meetings of the Organizational Development Committee have occurred to discuss items that required immediate attention.

**a. Future Board Meeting Dates for 2015**

President Weisser reported that the board has scheduled the meetings for 2015. As the locations are finalized they will be posted on the board's web site.

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

**b. Budget Update/Report**

1. Budget Report for 2014/2015

President Weisser reported that the new budget year began July 1, 2014. The board's spending authorization for the year is \$19,414,000, which is a 7 percent increase from the prior year.

President Weisser briefly reviewed the budget charts that were provided in the meeting materials.

2. Final Budget Report for 2013/2014

President Weisser reported that Fiscal Year 2013/14 are finally available.

Expenditures: \$16,892,184  
Revenue Collected: \$15,162,625

President Weisser reported that 54 percent of the board's expenditures was attributed to personnel; 20 percent was related to enforcement; and 16 percent was attributed to prorata.

President Weisser explained that 81 percent of the revenue for the year came primarily from application and renewal fees; with citation and fines accounting for approximately 15 percent.

President Weisser noted that included in the revenue for FY 2013/14 was the repayment of a \$1M loan made to the state's General Fund several years ago.

3. Fund Condition Report

President Weisser reviewed the fund condition as summarized below.

2013/14	12,020,000	7.4 months in reserve
2014/15	8,014,000	4.9
2015/16	3,627,000	2.2
2016/17	-1,166,000	-0.7

President Weisser stated that the board will need to pursue a fee increase due to the decline in the months in reserve.

4. Fee Audit Underway

President Weisser reported that as the fund condition demonstrates, the board will need to pursue a fee increase to sustain operations. If this is required, it would need to be done through legislation.

President Weisser explained that a precursor to making such a determination is completion of a fee audit. The board has secured a contract with Macias Consulting Group to complete this independent audit for the board. Work is underway and a draft report should be completed by the end of December. President Weisser concluded that the Organizational Development Committee will review the draft report and will provide an update during the January board meeting and bring forward a recommendation as appropriate.

5. Update on BreEZe, DCA's New Computer System

Ms. Sodergren reported that there has been a work stoppage for the BreEZe system while the department considers the best option for the board moving forward.

6. Board Member Reimbursement and Mail Vote Information

President Weisser directed the board and the public to review the meeting materials for mail vote and reimbursement information.

**c. Personnel Update**

1. Board Member Update

President Weisser reported that the board currently has one public member vacancy. This position was previously held by Shirley Wheat, who resigned from her position as a board member after concluding her term.

## 2. Board Staff Update

Ms. Herold briefly reviewed the board's staffing changes as provided in the meeting materials.

Ms. Herold highlighted the departure of manager Debbie Damoth after 17 years with the board of pharmacy.

Ms. Herold also highlighted the retirement of senior inspector Bob Venegas. Dr. Venegas worked for the board for 20 years and was integral in the creation of the board's drug diversion investigations. Ms. Herold stated that Dr. Venegas will be missed and leaves an incredible legacy with the board.

## **XVII. EXECUTIVE OFFICER'S REPORT**

### **a. Medical Board Update**

Ms. Herold reported that the board is working closely with the Medical Board on many crosscutting issues.

As Ms. Kirchmeyer was unable to attend the meeting in person she provided a written report which has been provided immediately after these minutes.

Ms. Herold noted that the board will be working with the Medical Board on the development of protocols for hormonal contraception, nicotine replacement products and naloxone hydrochloride. Ms. Herold stated that a portion of the next SB 493 Implementation Committee meeting would be dedicated to work-shopping the draft protocols that have been developed by staff.

Mr. Law asked if Ms. Herold has discussed the inclusion of purpose on prescriptions they write. Ms. Herold responded that several Medical Board members have expressed support on including purpose on the label.

### **b. PEW Trust Meeting on Compounding**

Ms. Herold reported that she attended the PEW Trust Meeting on Sterile Compounding processes in Washington D.C. At the meeting, draft sterile compounding guidelines were developed and will be released in the near future.

### **c. NABP Hosts Its Executive Officer Conference**

Ms. Herold reported that she attended the NABP Executive Officer Conference where she provided information on the board's sterile compounding program as well as the work they are doing on corresponding responsibility.

Ms. Herold reported that like the board, the NABP is addressing prescription drug abuse and is working with the Federation of American Medical Board and the National Nurses Association.

**d. Board Inspector Meeting Held October 6-9, 2014, Including a Joint Meeting Between Board Inspectors and CDPH Consultants**

Ms. Herold reported that the board held an all-inspector meeting in early October. At the meeting the inspectors also met with California Department of Public Health consultants. Ms. Herold noted that one item that was discussed was the need to look for appropriate consultations during inspections.

Ms. Herold concluded that staff will be holding another inspector meeting in February.

Mr. Law asked how many inspectors the board has. Ms. Herold responded that currently there are 39 inspectors filling 48 positions.

**e. Duty Inspector Reinstated**

Ms. Herold reported that the board has reinstated the duty inspector. She explained that the inspector takes calls from 9 a.m. -11 a.m. on Monday, Wednesday and Friday.

Mr. Law asked if someone screens the calls. Ms. Herold reported that a member of the office staff answers the phone and determines if the caller needs to talk with the duty inspector or if they have an issue that would be better handled by board staff.

Ms. Herold explained that the goal is to direct the caller to the appropriate information; however, no legal advice will be given.

Ms. Herold reported that the program has been in place for two weeks, during which time the board received 51 calls. Of those calls there were 16 pharmacists, 11 prescribers and seven consumers.

Dr. Wong asked if calls should be limited to only health care professionals. Ms. Herold responded that currently they are accepting calls from anyone. If the statistics show that it is a problem to permit inspectors to respond to all callers, then the board could change the parameters.

Dr. Gutierrez asked if the board is monitoring how long the inspector takes to provide responses. Ms. Herold responded that the inspector has to respond to all questions the same week they are received.

Ms. Herold provided statistics on what type of questions were received.

Dr. Gutierrez asked if the board will be advertising this in a subscriber alert. Ms. Herold responded that they will; however, they are going to wait in order to work out the major problems first.

**f. 2015 Meeting Calendar for Committees Under Development**

Ms. Herold stated that board members will be contacted to determine committee meeting dates for 2015. When the dates are finalized they will be posted on the board's website.

**g. Changes for Board Members Making Travel Arrangements**

Staff member Laura Hendricks reported that all agencies are converting to an online booking web site called the Cal Travel Store. The web site will be used for all future hotel, flight and rental car booking. Ms. Hendricks explained that board members will no longer be able to book their own travel directly with hotels or airlines, as all travel must be booked through the Cal Travel Store in order for it to be reimbursed.

Ms. Hendricks reported that board staff will now be using an online program to submit travel claims for reimbursement. This will make it easier for staff to submit the claims and monitor them for payment. Ms. Hendricks explained that board staff would automatically prepare the claims after each meeting and then provide it to the board member for review and approval.

Ms. Herold reported that she and Dr. Gutierrez would be attending the CSHP convention on October 30 and 31, 2014, to provide presentations on compounding and pharmacy law updates. Ms. Herold added that there will be an opportunity for attendees to register for CURES.

President Weisser adjourned the meeting at 1:26 p.m.