



**California State Board of Pharmacy**

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

**DATE:** May 3-4, 2017

**LOCATION:** Department of Consumer Affairs  
1<sup>st</sup> Floor Hearing Room  
1625 North Market Blvd.  
Sacramento, CA 95834

**BOARD MEMBERS  
PRESENT:** Amy Gutierrez, PharmD, President  
Deborah Veale, RPh, Vice President  
Victor Law, RPh, Treasurer  
Lavanza Butler, RPh  
Greg Lippe, Public Member  
Valerie Muñoz, Public Member  
Ricardo Sanchez, Public Member  
Allen Schaad, RPh  
Stanley Weiser, RPh  
Albert Wong, RPh

**BOARD MEMBERS  
NOT PRESENT:** Ryan Brooks, Public Member

**STAFF  
PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Laura Freedman, DCA Counsel  
Kristina Jarvis, Deputy Attorney General (May 3)  
Joshua Room, Deputy Attorney General (May 4)  
Laura Hendricks, Staff Analyst

**Call to Order**

**9:02 a.m.**

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

President Gutierrez called the meeting to order at 9:02 a.m. Board members present: Greg Lippe, Lavanza Butler, Valerie Munoz, Stanley Weisser, Victor Law, Amy Gutierrez, Albert Wong, Ricardo Sanchez and Allen Schaad. Note: Deborah Veale arrived at 9:11 a.m. and Ricardo Sanchez arrived at 9:27 a.m.

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

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

**III. Approval of the January 24-25, 2017, and February 17, 2017 and March 30, 2017 Board Meeting Minutes**

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

**Motion:** Approve the January 24-25, 2017, board meeting minutes.

**M/S:** Weisser/Lippe

Support: 9    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**Motion:** Approve the February 17, 2017, board meeting minutes.

**M/S:** Lippe/Law

Support: 9    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**Motion:** Approve the March 30, 2017, board meeting minutes.

**M/S:** Lippe/Law

Support: 9    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

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

The board recognized Kathleen Walters for 50 years of service as a pharmacist.

Deborah Veale Arrived at 9:11 a.m.

**V. October 26-27, 2016, Board Meeting Minutes – Revisions to Previously Approved Minutes**

Staff analyst Laura Hendricks explained that on pages 66-68 of the October board meeting minutes the board was discussing CCR 1780 and motioned to approve proposed language to amend 1780. However, in the minutes CCR 1709 was incorrectly provided as the draft language the board voted on. She explained that the minutes need to be corrected in order to accurately reflect the language the board motioned to approve.

**Motion:** Modify the October 26-27, 2016, board meeting minutes to accurately reflect the boards motion to approve the proposed regulation language in CCR 1780. Approve the corrected October 26-27, 2016, board meeting minutes.

**M/S:** Lippe/Law

Support: 9    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**VI. Update from the Department of Consumer Affairs**

Dean R. Grafilo introduced himself as the new director of the Department of Consumer Affairs. Mr. Grafilo explained that he has spent most his career working for various Assembly members working on complex issues such as consumer protection for patients, immigrant rights, working families. He noted that he has also worked in union organizing campaigns in Washington and Hawaii.

Mr. Grafilo thanked the board for its work and stated that he was looking forward to working with the board to fulfil its consumer protection mandate.

**VII. Board Officer Elections**

**Motion:** Nominate Amy Gutierrez for board president.

**M/S:** Schaad/Weisser

Support: 9    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Munoz	X			
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

The board thanked President Gutierrez for her dedication to the board.

**Motion:** Nominate Victor Law for vice president of the board.

**M/S:** Lippe/Weisser

Support: 9    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Munoz	X			
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

The board thanked Deborah Veale for her service as the board’s vice president.

**Motion:** Nominate Allen Schaad as the board’s treasurer.

**M/S:** Weisser/Gutierrez

Support: 9    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Albert Wong asked if the board should consider having a two-year term limit for the position of president.

Staff noted that currently the Board Member Administrative Procedure Manual does not include term limits for any elected position on the board and noted that the board updated the procedure manual as part of the Sunset Review process.

The board agreed to revisit the issue the next time the Board Member Administrative Procedure Manual is updated.

**VII. Executive Officer’s Report**

a. Semi-Annual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics

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

Ms. Herold reported that the Semi-Annual CPJE statistical report for October 1, 2016, through March 31, 2017, reflects that the overall pass rate for the CPJE is 57.2 percent. She added that the pass rate for graduates from the California schools of pharmacy is 66.4 percent. The overall pass rate for the NAPLEX is 88.0 percent.

Note: The full Semi-Annual CPJE Statistical Report is provided in the board meeting materials.

Ms. Herold noted that the board has seen an increase in the number of interns that drop out of pharmacy school. She added that the Deans of the schools of pharmacy have expressed difficulty in finding quality candidates.

Stanley Weisser noted that the pass rate for the NAPLEX is significantly higher than the pass rate for the CPJE. Ms. Herold explained that this has historically been true and noted that even the NAPLEX has seen an increase in their fail rate. She added that the board has taken steps to ensure that the exam is psychometrically valid and to minimize candidate information sharing.

Mr. Weisser stated that there is a significant difference in the fail rate between schools of pharmacy. Victor Law stated that students taking the exam in fall/winter have already taken the exam and failed it their first time. Mr. Weisser expressed his concern that the bar is being lowered at schools of pharmacy.

Ms. Herold stated that many of the schools are looking to offer remedial education for students prior to taking the CPJE.

Allen Schaad expressed concern that perhaps the board is making the CPJE too difficult and reminded that board that the purpose of exam is to determine if the candidate meets the minimum qualification standards.

Lavanza Butler stated that historically the California exam has always been more difficult.

Ms. Herold offered to have board members attend the exam development meetings.

The board asked that the chairperson of the Competency Committee attend the next board meeting and provide a report to the board (in closed session).

b. Discussion and Consideration of NABP's Letter to Congress Regarding the Dispensing of Non-United States Food and Drug Administration Approved Medicines to Patients in the US from Online Pharmacies

Ms. Herold stated that one of the proposals being offered in Washington D.C. to offset the increase in the price of drugs is to encourage the purchase of medication on the internet from non US websites where drugs are lower in price.

Ms. Herold reported that over the years the National Association of Boards of Pharmacy (NABP) has reviewed nearly 11,500 online drug outlets and found 96% appear to be operating in conflict with pharmacy laws and practice standards. Such conflicts include pills that contain drywall and rat poison and cases involving patients' personal and financial information being stolen. In the worst cases, people have died from receiving counterfeit medications. She added that the World Health Organization estimates that between 100,000 and 1 million people die each year from counterfeit medications.

Ms. Herold stated that the NABP has drafted a letter to Congress regarding the dispensing of non-United States Food and Drug Administration (FDA) approved medicines to patients in the US from online pharmacies and the dangers it poses to consumers.

Mr. Weisser asked if the pharmaceutical industry has a position on this subject. Ms. Herold stated that the pharmaceutical industry opposes allowing patients to purchase medications from illegitimate internet sites.

Mr. Schaad expressed concern that the letter from the NABP is biased and stated that there are legitimate websites in Canada that offer medications at a cheaper cost than those that can be purchased in the U.S.

Mr. Weisser stated that the board needs to protect consumers who are unknowingly purchasing counterfeit drugs online.

The board discussed its concern with the amount of recalls the board issues through its subscriber alert system and asked if there is a way to make consumers more aware of medications that have been recalled. President Gutierrez asked board staff to gather information on recalls (broken out by manufacturer) and report it at the next Enforcement Committee meeting. Ms. Herold stated that the board should consider if publicizing manufacture recalls would have the unintended consequence of discouraging manufactures from issuing voluntary recalls.

Ms. Veale stated that while she shared Mr. Schaad’s concern with the growing cost of medications, at this time there is no way for patients to be sure that the drugs they purchase online are safe. Gregory Lippe added that until there is an international pedigree for medications there is no way for consumers to know that their medications are coming from a safe source. Mr. Schaad agreed that consumer protection is paramount and that at this time there are not many safe options for patients purchasing medications online.

**Motion:** Send the NABP letter (with modifications if necessary) to the appropriate California lawmakers.

**M/S:** Veale/Weisser

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Ms. Butler asked if Ms. Herold knew anything about the “.Pharmacy” domain name. Ms. Herold explained that the .Pharmacy domain name is offered by the NABP and indicates that the website meets all of the pharmacy laws in the areas in which they are operating in (they also

must pay a fee to continue to use the domain name). She added that she is a member of the NABP's .Pharmacy committee.

Ms. Herold reported that she would be attending the NABP's Annual Meeting in Florida.

### **VIII. Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications**

President Gutierrez explained that traditionally pharmacies have refilled prescriptions only upon the request of the patient or the patient's prescriber. However, in recent years computer programs have been developed that allow pharmacies to enroll patients in automatic refill programs ("auto refill"). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto refill programs are limited to drugs identified as maintenance medications. She explained that the argued benefit of auto refill programs is that they increase patient compliance with drug therapy by refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

President Gutierrez reported that from late 2012 through 2013, the board received over 100 complaints directly related to auto refill programs due to the media attention.

President Gutierrez stated that at the January 25, 2017, board meeting, the board discussed the draft policy developed by staff on automated refill programs and heard public comment. As part of the discussion the draft policy was revised and the members asked that the auto refill language be brought back to the full board after it was refined by staff based on board's discussion. Below is the revised language.

#### **Title 16. Board of Pharmacy Proposed Text**

**Add section 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

##### **1717.5 Automatic Refill Programs**

- a) A pharmacy may offer an automatic refill program (program) for prescription medication for patients provided the following conditions are met:
  - 1) Written notice regarding the program shall be given to the patient or patient's agent. Notice shall include instructions on how to withdraw a prescription medication from the program.
  - 2) The patient or patient's agent shall provide written consent to participate in the program. If available, consent may be given through an online enrollment option. The pharmacy shall keep enrollment acknowledgement on file for one year from date of dispensing.
- b) A pharmacy shall have written policies and procedures in place that outline specifics of the program. Policies and procedures shall reference medications that are eligible for inclusion in the program.
- c) A patient or patient's agent shall have the option to withdraw from the program at any time.
- d) A drug regimen review shall be completed on all prescriptions filled as a result of the program.
- e) Each time a prescription is refilled, a reminder notification shall be included confirming that the prescription medication is enrolled in the program.



f) The pharmacy shall provide a full refund to the patient, patient's agent or payer on any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy was notified regarding withdrawal of enrollment in the program.

President Gutierrez asked if the written notice required in 1717.5(a)(1) must be translated. Ms. Herold responded that the regulation currently does not require it, but it is something that the board could consider.

President Gutierrez asked for clarification on the notification requirement in section (e). Ms. Sodergren explained that often patients did not remember that they are was enrolled in an auto refill program. The intent of section (e) is to provide the patient a reminder (either on the label or on the receipt) that the medication is being provided as part of an auto refill program. President Gutierrez stated that the intent is unclear. Ms. Freedman recommended modifying the language as provided below. The board agreed with her recommendation.

Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient's agent confirming that the prescription medication is enrolled in the program.

Mr. Law stated that any written notification should be provided in alternate languages if the patient needs it. The board agreed that the requirement should be consistent with the current translation requirements. Ms. Freedman recommending adding an additional provision to clarify the translation requirements. The board agreed with her recommendation.

Ms. Freedman stated that she would like to reorganize the language (possibly renumber) to make it more clear and easier to read. The board agreed with her recommendation.

The board asked Ms. Freedman if the language would need to be brought back before the board for approval given that the changes are relatively minor. Ms. Freedman stated that as long as the board provides clear direction to staff on the modifications it does not have to come back before the board before moving forward in the rulemaking process.

Lauren Burton from CVS Health asked the board to consider allowing the written notice to occur electronically and to consider allowing telephone consent to be provided for patients who may not have access to online consent forms. Ms. Burton asked the board to remove the drug regimen requirement in section (d). Ms. Burton asked the board to consider exempting patients who are in long term care facilities.

Mr. Weisser asked for additional public comment regarding the exemption of long term care patients.

Mark West, from Pacific Care Pharmacy, agreed that patients in long term care facilities should be exempt from this requirement in order to avoid possible delay in therapy. After discussion, the board agreed with the recommendation to exempt long term care patients.

Paige Talley, representing the California Council for the Advocacy of Pharmacy (CCAP), recommended defining long term care facilities using Health and Safety Code section 1250 so that it covers all the various types of long term care facilities. The board agreed with the recommendation.

**Motion:** Modify the proposed regulation text as discussed at the meeting (and provided below). Move forward in the rulemaking process and delegate authority to the executive officer to make changes consistent with the board’s policy discussion if necessary to complete the rulemaking file.

- Allow board staff and DCA counsel to reorder the regulation to provide clarity.
- Modify (e) to read as follows: *Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient’s agent confirming that the prescription medication is enrolled in the program.*
- Add a subdivision to clarify that any written notifications must be translated as required in state or federal law.
- Add a subdivision to exempt patients in a long-term care facility (as defined in Health and Safety Code section 1250) from the requirements in the regulation.

**M/S:** Weisser/Sanchez

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**IX. Organizational Development Committee**

**a. Budget Update/Report**

1. Fund Condition Report

President Gutierrez reviewed the fund condition report as provided below. She noted that the fund condition includes the midyear augment the board received to ensure sufficient funding to ensure continuity in enforcement related activities.

<b>Fund Condition: With Fee Increase Effective July 1, 2017</b>		
Fiscal Year	Fund Balance	Months in Reserve
2015/2016	\$10,518,000	5.6
2016/2017	\$5,945,000	3.1
2017/2018	\$8,338,000	4.3
2018/19	\$10,331,000	5.2

## 2. Budget for Fiscal Year 2016/2017

President Gutierrez reported that on June 27, 2016, the governor signed the budget for FY 2016/17. The new budget year began July 1, 2016. The board's spending authorization for the year was adjusted from \$20,652,000 to \$19,464,000 in the governor's final budget released on January 10, 2017.

As discussed at the last board meeting, this reduction reflects a change in how statewide pro rata payment is billed. The statewide pro rata of \$1,165,000 will no longer be reflected as an expenditure line item on the budget and will now be a direct withdrawal from the board's reserve fund. As mentioned under the prior agenda item, the board requested a midyear budget augment of almost \$1.8M to ensure sufficient funds to continue administrative case work through both the Office of the Attorney General and the Office of Administrative Hearings. (The board has made similar requests for the past several years.)

Budget information for the current fiscal year is available through March. During the first nine months of the fiscal year, the board received \$16,237,900 in revenue originating from the following:

<b>Revenue Sources</b>		
<b>Source</b>	<b>Amount</b>	<b>Percentage</b>
Licensing	\$13,968,100	86%
Citation Fines	\$1,400,600	9%
Cost Recovery	\$822,100	5%
Interest	\$47,100	0%

The board has expended \$15,312,900 -- about 79% of its authorized budget -- during the first nine months of the fiscal year. The largest expenditure categories are detailed below.

<b>Expenditures</b>		
<b>Source</b>	<b>Amount</b>	<b>Percentage</b>
Personnel	\$9,852,400	64%
Enforcement	\$2,346,800	15%
Prorata	\$1,890,300	13%

## 3. DCA Distributed Cost Allocations

President Gutierrez explained that the board closely monitors its budget and receives quarterly budget reports. She stated that the board pays about \$2.75 million in pro rata to the state, a portion of which is for services provided by DCA, including the development and maintenance of the department's new BreEZe system.

President Gutierrez reported that the committee continues to monitor the money paid to the department for services and has requested specific cost allocations for the various offices within the department. Ms. Sodergren stated that the cost allocation information has still not been provided by the department.

Ms. Herold reported that the board is currently working on implementing a program to allow for payment via credit card. Ms. Sodergren reported that the board is currently third in line to implement the program. The board asked staff to provide a timeline for implementation at the next board meeting.

**b. Board Member Reimbursement Information**

President Gutierrez explained that board members may seek reimbursement for expenses and per diem payments. Board members are paid for each day of a board meeting but, in accordance with board policy, may also submit hours for work performed doing additional board business. President Gutierrez noted that these figures only represent hours where reimbursement was sought. It is not uncommon for board members to waive their per diem payments.

There were no comments from the board or the public.

**c. Personnel Update**

Board Member Updates

President Gutierrez announced that Amjad Mahmood Khan was appointed to the California State Board of Pharmacy by the Speaker of the Assembly in April 2017. Mr. Khan is partner at Brown, Neri, Smith & Khan LLP in Los Angeles, where he focuses on complex commercial litigation. He is also Adjunct Professor of Law at UCLA Law School, where he teaches "Fundamentals of U.S. Contract Law." He graduated *summa cum laude* from Claremont McKenna College with degrees in English Literature and Government and earned his law degree from Harvard Law School. He is also an elected term member of the Council on Foreign Relations. His term will expire in 2021.

President Gutierrez stated that the board currently has one vacancy. The position is a public member appointment which was formerly held by Greg Murphy.

Staff Updates

Ms. Herold provided a brief staff update as provided below.

*Recent Hires/Transfers/Promotions*

- Tom Lenox joined the board in April as the Chief of Enforcement over the Probation Monitoring/Drug Diversion for Self-Use team, the Prescription Drug Abuse team and the two Drug Diversion & Fraud teams.
- Margaret "Peg" Panella-Spangler was promoted to Supervising Inspector on the new Outsourcing team.
- Anita Von Aesch accepted a permanent position as an Office Technician in the Administration Unit A.
- Brazil Smith was hired as a Seasonal Employee in the Administration Unit A.
- Shekeya Strong was hired in a training and development assignment for the Program Technician III position in Licensing Unit A.
- Office Technician Keshia Mallard transferred to Licensing Unit B.

### *Departures*

- Sandra Rodriguez left the board in March.

### *Recruitments*

- One AGPA for the Prescription Drug Abuse Prevention Team in the Complaint Unit.
- One Staff Program Analyst in the Administration Unit B.
- One permanent, intermittent Office Technician in the Enforcement unit.
- One permanent, intermittent Office Technician in Licensing Unit B.
- One Seasonal employee in the Administration Unit A.
- One Inspector for the Compliance/Routine Inspection teams.
- One Inspector for the Prescription Drug Abuse team.
- Two Inspectors for the Outsourcing team.

#### **d. Board Member Attendance Information**

President Gutierrez reported that the Department recently contacted the board requesting board member attendance for the last four years. She stated that the detail of each board member's attendance was provided in the meeting materials.

Mr. Law asked why the department requested the information. Ms. Herold responded that periodically the department or the appointing offices will request the information. Ms. Sodergren added that this year there was legislation regarding board member attendance.

There was no comment from the public.

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

President Gutierrez reviewed the future board and committee meeting dates as proved below. She noted that the hope is that by scheduling meetings far in advance, it will help improve board member attendance.

##### **1. Future Board Meeting Dates for 2017**

- July 25-26, 2017, *the Sheraton Park, 1855 South Harbor Blvd. Anaheim, CA 92802.*
- November 8-9, 2017, *Location to be determined.*

##### **2. Future Board Meeting Dates for 2018**

- Full Board Meetings
  - February 6-7, 2018
  - May 2-3, 2018
  - July 24-25, 2018
  - October 23-24, 2018
- Petitioner Board Meetings
  - March 27, 2018
  - June 6, 2018
  - September 6, 2018
  - December 12, 2018

### 3. Future Committee Meeting Dates for 2018

- Communication and Public Education Committee
  - January 31, 2018
  - April 25, 2018
  - July 11, 2018
  - October 11, 2018
  
- Enforcement and Compounding Committee
  - March 28, 2018
  - June 7, 2018
  - September 5, 2018
  - December 13, 2018
  
- Licensing Committee
  - January 16, 2018
  - April 19, 2018
  - June 26, 2018
  - September 26, 2018
  
- Legislation and Regulation Committee
  - January 17, 2018
  - April 24, 2018
  - July 10, 2018
  - October 20, 2018

The board recessed for a break at 10:45 a.m. and resumed at 11:01 a.m.

### X. Enforcement and Compounding Committee Related Items

President Gutierrez provided a report of the April 18, 2017, Enforcement Committee Meeting.

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

- a. Discussion and Consideration of the University of California, San Diego's Experimental Program/Research Study to Permit Patients to Access Medications From an Automated Drug Delivery System (ADDS) Without Compliance with All Provisions of Title 16, California Code of Regulations, Section 1713

President Gutierrez reported that at the April 2015 board meeting, the board approved an 18-month pilot study under the auspices of the University of California, San Diego (UCSD), School of Pharmacy involving use of an automated drug delivery system (ADDS) for prescription medication from which staff of Sharp Hospital in San Diego and their families who opted in could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for first-time fills.

President Gutierrez reported that the committee has received quarterly updates on the study, including patient use of the system. As authorized by the board, UCSD has collected data

through the first quarter of 2017 and will report its findings at this board meeting. She added that the board has permitted UCSD to continue operating the kiosk until the board makes a decision about the expanded use of the ADDS. The board could make this decision at this meeting.

Ms. Herold reported that staff has reviewed the preliminary report from UCSD and has determined that the report is not yet ready to be provided to the board. Ms. Herold added that staff will work directly with UCSD to refine the report so that it is ready to be presented to the board at its July meeting.

Ms. Freedman explained that the board would need to approve the extension of the pilot program so that patients can continue to receive their prescription medication from the machine.

Ms. Butler expressed concern with the patients not being able to get their questions answered by the pharmacist when they picked up their prescriptions at the machine.

Mr. Weisser stated that the machine did not meet his expectations for patient consultation. He added that it is not the board's responsibility to correct the report so that the pilot program can be approved by the board. Ms. Herold responded that the data in the report was presented in a way that was difficult to understand, and staff wants to ensure that the data is presented in a way that the board can review and make a determination.

Members of the board expressed concern with the small sample size of the study. Mr. Lippe commented that the board approved the study and knew the sample size would be relatively small because it was only open to employees.

Mr. Law commented that younger generations may want to use automated dispensing machines to get their refills; however, older generations may still wish to go to a pharmacy. He added that it is the board's responsibility to ensure that patients are safe wherever they get their prescriptions.

Mr. Sanchez stated that he is concerned that the study shows that patients did not know who to call if they had questions while using the dispensing machine.

**Motion:** Extend the study through July 2017 so that patients can continue to receive their prescription medications.

**M/S:** Lippe/Veale

Support: 8      Oppose: 1      Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Gutierrez	X			
Law		X		
Lippe	X			
Munoz	X			

Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

b. Update on CURES 2.0 Prescription Drug Monitoring Program

President Gutierrez reported that the CA Department of Justice, which operates CURES, converted to the exclusive support of only CURES 2.0 at the beginning of March. The new CURES 2.0 system contains features that were not available to pharmacists in the prior system. She noted that at the January Enforcement Committee meeting, the Department of Justice provided an overview of the new system and highlighted the new features that can be accessed by pharmacists. For example, enrollment in CURES is now a much simpler and fully online registration process.

President Gutierrez stated that at the January 2017 board meeting, the board identified multiple items for future changes with respect to the CURES program and for staff to pursue statutory changes. These changes are:

1. Include the days' supply of medication dispensed in the patient activity report (PAR).
2. Permit prescribers to view the prescriptions where they are identified as the prescriber.
3. Reduce the period within which a dispenser must report data following dispensing to within 48 hours.
4. Add Schedule V prescriptions for reporting to the CURES system.

President Gutierrez reported that number 1 (including the days' supply of medication dispensed in the PAR) has already been changed.

Ms. Herold explained that numbers 2-4 would require legislation to change. She added that she will be meeting with the Medical Board and the American Medical Association to attempt to incorporate these changes into a bill this year.

Ms. Herold noted that another change that the board should pursue is sharing data with at least the three neighboring states of California. The board requested that Mike Small, from the Department of Justice, present at the July Board Meeting on the challenges of sharing information and how the board can work with the DOJ to accomplish this goal.

Ms. Butler noted how useful CURES is for staff in emergency rooms and pharmacies, and she would like the board to continue to improve the system.

c. Summary of a Presentation by Stericycle of a New Device for Destruction of Controlled Substances in Healthcare Facilities

President Gutierrez reported that the committee was provided with a brief presentation by Stericycle of a new process/device for use in health care facilities to destroy controlled substances. She noted that as part of the presentation, the committee was advised that the



new device is tamper-proof and contains a carbon-based solution that renders the contents unpalatable.

Mr. Law asked how much the service cost. Mr. Schaad responded that it is not yet available in California, but it will be part of a service they offer to safely dispose of the controlled substances and used sharps.

d. Discussion and Consideration of the Use of Automated Drug Delivery Systems (ADDS)

President Gutierrez explained that Business and Professions Code (BPC) section 4186 establishes the provisions under which a community clinic can use an automated drug delivery system (ADDS).

President Gutierrez stated that Health and Safety Code (HSC) section 1261.6 establishes the provisions under which a pharmacy can use an ADDS in a skilled nursing facility.

President Gutierrez reported that in February 2017, the board convened a special board meeting to focus on new technology that has been introduced to provide medications to patients. Many ADDS devices today offer features not addressed in pharmacy law. Accordingly the board invited vendors to present information about technological features and how the devices are affected by existing statutes. She explained that the board's goal was to seek ways to allow pharmacies to provide better quality care and service to patients while maintaining security and protecting the public from diversion of controlled substances and other prescription drugs.

President Gutierrez explained that in general, ADDS machines must "collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy and accountability." Key regulatory provisions specify who is responsible for stocking an ADDS with medication and how restocking may be prepared outside the health facility where an ADDS is installed.

President Gutierrez reported that as part of its discussion, the committee discussed the options and features currently available as well as the refilling of ADDS in a skilled nursing facility. She noted that the committee focused its discussion in two areas - medications that are administered (such as in a skilled nursing facility) and medications that are dispensed (such as in a community clinic).

President Gutierrez reported that the committee was advised that based on counsel's review of the provisions contained in HSC 1261.6, an ADDS may be stocked by a health care professional who is licensed to administer drugs, at a skilled nursing facility - if all the following conditions are met:

1. The ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers.
2. The stocking of those removable containers is performed by or under the direct supervision of a pharmacist.
3. The containers are transported between the pharmacy and the facility in a secure, tamper-evident container.
4. The pharmacy and facility have developed policies and procedures to ensure that the

containers are appropriately placed in the ADDS.

The board was advised that a newsletter article will be written to clarify the conditions under which individuals other than pharmacy personnel may stock an ADDS.

**Note:** The article on ADDS was included in the June 2017 issue of *The Script* and may be found using the link below. [http://www.pharmacy.ca.gov/publications/17\\_jun\\_script.pdf](http://www.pharmacy.ca.gov/publications/17_jun_script.pdf)

President Gutierrez noted that there are also other types of automated drug delivery machines that are not in skilled nursing facilities where patients are directly receiving the drugs from the machine (such as in the UCSD study). Ms. Herold stated that currently these devices are only allowed in clinic settings.

Ms. Herold stated that at some point in the future the board will need to closely look at the use of these machines outside of clinic settings and determine what direction the board wants to take.

President Gutierrez asked if a physician can use these machines in their offices. Ms. Herold responded that they can, and the board has no jurisdiction in this area. She added that the drugs are only to be provided to that doctor's own patients and the doctor must hand the patient the medication. Mr. Weisser expressed his concern that patients are not receiving consultations in this setting.

President Gutierrez asked if the board should expand the use of ADDS owned and operated by a pharmacy to locations currently not allowed under pharmacy law -- for example, a setting similar to that of the UCSD study.

Ms. Veale responded that she can see the need for these machines in rural areas, but she expressed concern with patients not receiving the same quality of care when they use these machines.

Ms. Sodergren stated that board staff can prepare policy questions for the next Enforcement Committee meeting. The board agreed with this suggestion and decided to discuss some of the questions staff had already provided in the board meeting materials.

Note: Below is a summary of each question the board reviewed.

- Should someone other than an employee of the pharmacy access the system for purposes of replenishing the drugs? Could replenishing of the system be done via a remote camera with pharmacist review?
  - Some members of the board stated that the restocking of the machines should be done by a healthcare provider using the same criteria as the restocking of machines in skilled nursing facilities. Other members stated that they would like the machines to be restocked by pharmacy staff.
- Should the board allow the machines to be in locations that are not healthcare facilities (such as shopping centers)?
  - The board decided that as a first step the machines should only be in licensed healthcare facilities (pharmacies, hospitals, clinics, etc.).

After discussing the two questions above Mr. Lippe asked if the board should wait until the UCSD study is completed to discuss expanding the use of ADDS.

Ms. Munoz stated that there is a need for these machines in underserved communities, but she would like to see the final results of the UCSD study before making a determination.

The board agreed that it should first consider the outcome of the UCSD study before deciding if automated dispensing machine use should be expanded and how the board would regulate their use.

e. Discussion and Consideration of a Proposed Regulation to Add Title 16 California Code of Regulations Section 1715.65 Related to Inventory Reconciliation of Controlled Substances

President Gutierrez explained that throughout pharmacy law, there are requirements established to provide for the security of drugs. Some specific sections include:

- BPC section 4116 limits access to the pharmacy area and specifies that a pharmacist is responsible for any individual that enters premises. This section further requires the board to establish regulations requiring reasonable security measures.
- BPC section 4117 limits pharmacy access where controlled substances, dangerous drugs or dangerous devices are stored.
- Further, Title 16, CCR section 1715.6, requires the owner of a pharmacy to report within 30 days of discovery of any loss of controlled substances, including their amounts and strengths.

President Gutierrez reported that for over one year, the board has been discussing proposed new regulation requirements to ensure pharmacies more closely monitor and periodically count controlled substances as a means to reduce drug losses and to identify any losses sooner. The regulation in its current form requires a physical count and reconciliation of all Schedule II controlled substances every 90 days.

President Gutierrez stated that at its meeting the committee discussed proposed modifications to the section and identified additional changes to be included. The committee also discussed the current requirement for a pharmacy to notify the board of any loss of a controlled substance. The committee noted that DEA requirement for reporting a drug loss states “significant” loss.

President Gutierrez reported that after discussion and public comment, the committee requested that the language be changed as outlined below.

- Moving the requirement of including identification of possible causes of overages from section (e) where it was a standalone requirement into the reporting requirements in section (c) relating specifically to the inventory reconciliation reporting activities for Schedule II controlled substances.
- Amending section (d) to replace the term “possible causes” with “known causes”. Further, the section replaces the term “security improvements” with “action”, noting that security improvements may not always be made, but action would always be expected.

- Amending several sections to clarify that the inventory reconciliation report requirement applies to Schedule II controlled substances as designated by federal law, noting that because of some differences between the state and federal schedules of some substances, clarity on the board’s expectation was needed.
- Nonsubstantive changes were also identified and made as well. An example of a nonsubstantive change in the regulation is replacing “Inventory Reconciliation Report” with “inventory reconciliation report”

President Gutierrez noted that the committee will to continue to discuss the required reporting of drug losses at a future committee meeting (i.e. the federal requirement to report “significant” losses vs. the board’s requirement to report all losses).

Paige Talley, representing CCAP, asked if legislation would be required to define significant loss. President Gutierrez replied that further discussion would be required by the committee before that could be determined.

**Committee Recommendation (Motion):** Approve the proposed changed to Title 16, CCR section 1715.65, Inventory Reconciliation Report of Controlled Substances as provided below and release for a 15-day comment period.

#### **1715.65. Inventory Reconciliation Report of Controlled Substances**

- Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
- The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
- A pharmacy or clinic shall compile an ~~in~~ventory ~~re~~conciliation ~~re~~port of all federal Schedule II controlled substances at least every three months. This compilation shall require:
  - A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
  - A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last ~~in~~ventory ~~re~~conciliation ~~re~~port;
  - A comparison of (1) and (2) to determine if there are any variances; ~~and~~
  - All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and
  - Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.
- A pharmacy or clinic shall report in writing identified losses and known possible causes, ~~shall be identified in writing and reported to the board and, when~~

~~appropriate, to the Drug Enforcement Administration within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions security improvements necessary to prevent additional losses of controlled substances.~~

~~e) Likely Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.~~

~~e) The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director, (if a clinic), and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.~~

~~f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).~~

~~g) For inpatient hospital pharmacies, a separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.~~

~~h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:~~

- ~~1) All controlled substances added to an automated drug delivery system are accounted for;~~
- ~~2) Access to automated drug delivery systems is limited to authorized facility personnel;~~
- ~~3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~
- ~~4) Confirmed losses of controlled substances are reported to the board; and~~
- ~~5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, 4105.5, 4119.1, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

Support: 9      Oppose: 0      Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Gutierrez	X			
Law	X			
Lippe	X			
Munoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			

Wong	x			
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Ms. Freedman asked the board to make another motion to delegate authority to the executive officer to make any non-substantive changes or changes consistent with the board’s policy that are required to complete the rulemaking file.

**Motion:** Delegate authority to the executive officer to make any non-substantive changes and clarifying changes consistent with the board’s policy direction upon recommendations by control agencies.

**M/S:** Veale/Lippe

Support: 9      Oppose: 0      Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Dr. Wong asked that the board agendaize a discussion on the reporting of drug diversion and/or theft to the appropriate law enforcement agency.

f. Report on the March 11, 2017, Training Provided by the Board and DEA on CURES and Prescription Drug Abuse, and Possible Future Training

President Gutierrez reported that on March 11, 2017, the board, the Drug Enforcement Administration and UCSD provided a day-long conference on prescription drug abuse, corresponding responsibility and preventing drug losses from a pharmacy. There were nearly 200 attendees who earned six hours of continuing education credit for attending this training, and another 132 individuals who earned one additional hour of continuing education to secure the training needed to provide naloxone under California protocol. She added that evaluations of the training were positive.

Ms. Herold noted that an additional training session will be scheduled for other areas of California in the next fiscal year.

g. Summary of the Report Submitted to the Assembly Budget Committee Regarding the Board’s Prescription Drug Abuse Team

President Gutierrez explained that during the Legislature’s 2016-17 state budget negotiations, the board was asked to provide a report on the initial results of the formation of a specific team of investigators to proactively identify and initiate investigations involving controlled

drugs. This report was due in April 2017.

President Gutierrez summarized five questions covered in the report as provided below:

1. Narrative description of the preceding year's activities related to combatting prescription drug abuse.
2. Funding and expenses information, including the budgeted, allocated and expended money.
3. Number of positions and responsibilities.
4. Number of cases and disposition of cases referred to the Office of the Attorney General (AG) as a result of a case opened from a coroner report.
5. Number of hours spent combating prescription drug abuse, including separately identifying the total number of hours spent reviewing coroners' reports and submitting public records requests to obtain the reports.

President Gutierrez reported that during their meeting, the committee was advised that based on this review, key source data and analyses appear to be better indicators of when investigations may be warranted, including geospatial analysis and wholesaler data versus coroner's reports.

Ms. Sodergren noted that staff will continue to track the data used by the Prescription Drug Abuse Team.

**Note:** A copy of this report was provided in the board meeting materials

## **Part 2: Compounding Matters**

### a. Report on Statistics Regarding Outcomes of Board of Pharmacy Compounding Inspections

President Gutierrez reported that the committee heard a presentation on findings from sterile compounding inspections. The committee was advised of the outcome of 647 inspections that have been conducted on sterile compounding pharmacies, the majority of which were conducted as part of the renewal of a license versus issuance of a new license. Further, the committee was advised that of the 602 inspections conducted as part of a renewal, the board identified corrections at 311 of the locations and identified violations at 34 locations. Of the 45 inspections conducted for an initial license, the board identified corrections at 15 locations and violations at one location.

The committee was advised that the board has received 11 recall notices since July 1, 2016, and issued one cease and desist order.

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

Ms. Veale asked if the 11 recall notices were issued as a result of violations found during the inspections. Ms. Herold stated that she could not be too specific regarding the recalls, because there are disciplinary cases that will be coming before the board. However, she explained that recalls can be issued for problems such as incorrect expiration dates or lack of sterility.

### b. Discussion and Consideration of Waiver Requests for Compounding Construction Compliance

Delays Pursuant to Title 16, California Code of Regulations, Sections 1735.6(f) and 1751.4(l) and the Process for Review and Appeals of such Requests

President Gutierrez explained that Title 16 of the California Code of Regulations (CCR), section 1735.6 (f), states that where compliance with California’s compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver for a period of time to permit the required physical changes. She added that CCR section 1751.4 establishes similar provisions relating to sterile compounding.

President Gutierrez reported that toward the end of 2016, the board established a waiver process to permit construction needed to secure a pharmacy’s compliance with requirements for compounding with hazardous drugs.

President Gutierrez stated that at the October 2016 board meeting, the board delegated authority to the executive officer to process waiver requests with parameters from the board. The board further delegated authority for a committee assigned by the president (to include the president and Board Member Schaad) to hear waiver requests.

President Gutierrez reported that as of March 30, 2017, the board received 601 waiver requests, 509 of which had been reviewed. President Gutierrez briefly reviewed the table below:

*Source of Waiver*

Site Type	Received	Percentage
Hospital with LSC	213	42%
Pharmacy with LSC	242	48%
Pharmacy (nonsterile only)	98	19%

- HSP: 213/480 = 44.3% HSPs applied for a waiver
- PHY: 242/6586= 3.67% PHYs applied for a waiver
- NRP: 15/ 513= 2.92% of NRPs applied for a waiver

President Gutierrez commented that she is surprised at how few hospitals have submitted waiver requests. Ms. Herold responded that there are a number of rural hospitals that do not have sterile compounding facilities and noted that some hospitals may not need waivers if they are already in compliance with the regulation requirements.

President Gutierrez reviewed the table below:

*Waiver Outcomes*

Site Type	Number	Percentage
Approved	289	57%
Denied	47	9%
Withdrawn	45	9%
In Process	128	25%

President Gutierrez explained that many of the “withdrawn” waivers were withdrawn because the request was for something that did not require a waiver.



President Gutierrez reported that Victor Law and Allen Schaad are reviewing the waiver requests. Ms. Herold noted that since the committee meeting, board staff and counsel have worked to refine the waiver outcome communications as well as the appeal process. She also added that as part of the appeal process, appeals will be heard in public meetings overseen by Mr. Law and Mr. Schaad.

Ms. Herold reported that the California Society of Health System Pharmacists has asked board staff to provide written correspondence outlining estimates of how much it will cost to become compliant with USP 800. President Gutierrez asked how the board would know how much it will cost to become compliant. Ms. Herold responded that USP has a list of cost estimates.

President Gutierrez noted that the board has asked staff to ensure that applicants whose waivers were denied are informed that there is an appeal process. Ms. Freedman responded that staff and DCA legal have been working on a response that will be provided with all future waiver denials.

The board directed staff to contact all of the applicants that have been denied in the past to inform them of the appeal process available to them.

The board took a break at 12:15 p.m. and resumed at 1:16 p.m.

c. Update on the Board's Progress in Implementing California Business and Professions Code Sections 4129, et seq., Regarding Licensure and Regulation of Outsourcing Facilities

President Gutierrez reported that effective January 1, 2017, the board received the authority to license in-state and nonresident outsourcing facilities. This is an entirely new function and type of licensee from what the board has licensed in the past.

President Gutierrez explained that the board believes it will receive three new staff members (two inspectors, one supervising inspector) for this program beginning July 1.

President Gutierrez reported that the committee discussed how outsourcing facilities will be regulated, including compliance with cGMPs. The committee was advised that the board has received 28 applications for outsourcers. (Five of these are in California.) She noted that there are currently 68 outsourcing facilities listed on the FDA's website; however, not all registered facilities may seek licensure in California.

Ms. Herold reported that the board inspectors will be receiving specialized training on cGMPs through the FDA and the Department of Public Health. Dr. Gutierrez stated that Critical Point offers training. Ms. Herold responded that she has been in contact with Critical Point.

There were no comments from the public.

Note: Ms. Veale returned to the meeting at 1:20 p.m.

d. Discussion and Consideration of the United States Government Accountability Office's March 31, 2017, E-Supplement Report to Congressional Committees on *Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported*

## Challenges

President Gutierrez reported that at the last Enforcement and Compounding Committee meeting, the committee reviewed a GAO report on the FDA's implementation of compounding law, titled: *Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges* (GAO-17-64).

President Gutierrez explained that at the end of March 2017, the GAO released an e-supplement, which is a companion piece to the drug compounding report that was issued in November 2016. She added that the e-supplement is titled: *Drug Compounding: Survey of State Pharmacy Regulatory Bodies (GAO-17-363SP, March 2017), an E-supplement to GAO-17-64* and can be accessed at: <http://www.gao.gov/products/GAO-17-363SP>

Note: Ms. Butler returned to the meeting at 1:31 p.m.

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

e. Presentation by Road Runner Pharmacy Regarding Compounding for Veterinary Prescriber Office Use

President Gutierrez reported that Road Runner Pharmacy provided a presentation at the committee meeting regarding its concerns about the board's regulations related to the requirements for the establishment of beyond use dating (BUD) of products, including the need for method suitability tests, container closure integrity tests and stability studies. As part of the presentation, representatives highlighted some of the challenges for compounding medications for animals.

President Gutierrez reported that Road Runner questioned if the regulations in this area are appropriate for compounding products for animals. Presenters noted the costs to perform the tests needed to comply with the regulations and noted that such tests would raise the costs for pet owners.

President Gutierrez stated that after receiving numerous comments from the public, the committee decided that a special meeting to focus on several different aspects of the board's compounding regulations was needed.

President Gutierrez reported that an Enforcement and Compounding Committee meeting has been scheduled for June 2, 2017, in Orange County. She added that the meeting will focus on the board's current regulations and what, if any, changes need to be made to the regulations.

President Gutierrez asked if Road Runner Pharmacy had applied to become a 503B facility with the FDA. A representative from Road Runner Pharmacy responded that they are in the process of applying and they currently operate as a 503A facility. Mr. Wong asked if Road Runner Pharmacy does sterile compounding, and the representative confirmed that it does.

Mr. Weisser asked for an explanation of the difference between a 503A and 503B facility. President Gutierrez explained that 503A facilities do patient specific compounding, are regulated by the state and are licensed as a pharmacy. She explained that 503B facilities are in between a pharmacy and a manufacturer, are licensed by the FDA and must comply with

cGMPs.

The representative from Road Runner Pharmacy explained that their main concern with the BUD testing is that it is above and beyond what is required by the USP. He added that Road Runner Pharmacy is looking forward to the discussion at the June 2 meeting and stated that their staff will provide written comments to staff ahead of the meeting.

President Gutierrez stated that the purpose of the June 2 meeting is to consider if changes need to be made to the board's regulations to align them more closely with USP 795, USP 797 and USP 800.

Michael Blair, veterinary compounding pharmacist and Arizona Board of Pharmacy member, commented that the Drug Quality and Security Act only applies to compounding for human consumption, not veterinary compounding. Dr. Blair clarified that the comments he is making to the board are his own personal opinion and are not made on behalf of the Arizona Board of Pharmacy.

Dr. Blair stated that the current compounding regulations regarding BUDs have had a negative impact on patient access to compounded medications and are forcing many compounding pharmacies out of business. The board asked if Dr. Blair would be attending the June 2 meeting. Dr. Blair confirmed that someone from his pharmacy would be attending the meeting.

f. Discussion and Consideration of the Proposed Food and Drug Administration Rule, List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act and Proposed Lists

President Gutierrez explained that under section 503A of the Food, Drug and Cosmetic Act, a bulk drug substance that is not the subject of a USP or NF monograph or is not a component of an FDA-approved drug cannot be used in compounding unless it appears on a list promulgated by the FDA. She added that, until the substance has been evaluated and either included or not included on the bulks list, the FDA does not intend to take action if the product fits specific criteria (page 9 of the guidance document).

President Gutierrez reported that committee did not take action on this item but will make the information available on the board's website.

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

g. Discussion and Consideration of the Food and Drug Administration Rule Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act –Guidance for Industry and Proposed Lists

President Gutierrez explained that a bulk drug substance cannot be used in compounding unless it is used to compound a drug that appears on the FDA drug shortage list at the time of compounding, distributing and dispensing; or it appeared on the drug shortage list within 60 days of compounding.

President Gutierrez reported that committee did not take action on this item but will make the

information available on the board's website.

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

h. Discussion and Consideration of the Food and Drug Administration Rule Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances and Proposed Lists

President Gutierrez explained that regulations developed by the FDA for animal drugs specify that bulk drug substances cannot be used to compound animal drugs. However, the FDA also notes that because either no drug is approved for a specific animal species or a drug is available under extra label use provisions, an animal drug compounded from bulk drug substances may be an appropriate treatment option. However, President Gutierrez noted that the FDA also states that the "unrestricted compounding of animal drugs from bulk drug substances has the potential to compromise food safety, place animals or humans at undue risk from unsafe or ineffective treatment, and undermine the incentives to develop and submit new animal drug applications to FDA containing data and information to demonstrate that the product is safe, effective, properly manufactured, and accurately labeled."

President Gutierrez reported that the guidance provides that the FDA does not intend to take action if a state-licensed pharmacy, licensed veterinarian or outsourcer compounds animal drugs from bulk drug substances if operating under specified conditions. These include:

- If in a pharmacy, the animal drugs are compounded under the direct supervision of a pharmacist, after receipt of a prescription from a vet or based upon prescribed prior experience.
- If the compounded product is not used for food producing animals.
- If the bulk substance is part of an approved animal or human drug, there is a change from the approved drug that produces a clinical difference for the animal.
- And numerous other factors detailed in the guidance.

President Gutierrez explained that as part of its discussion, the committee discussed this guidance as part of the context of the Road Runner request. The committee heard concerns about the conflict between the board's compounding regulations that allow for compounding for prescriber office use versus the guidance issued by the FDA that is outside operating as a 503A (pharmacy versus compounding pharmacy).

Mr. Schaad asked if an FDA draft guidance document is something that the FDA uses for enforcement or if it is simply "guidance." Ms. Herold explained that the FDA does enforce to the guidance documents that they issue. She added that the board inspectors do not inspect to the guidance documents as they often differ from the board's regulations.

Mr. Schaad asked if staff could invite someone from the FDA to a future Enforcement Committee meeting.

**Part 3: General Committee Matters**

a. Enforcement Statistics

President Gutierrez noted that the Enforcement statistics were provided in the board meeting materials for review. She noted that the majority of the license revocations are for pharmacy technicians. President Gutierrez also noted that the “drug of choice” is now alcohol. Ms. Sodergren clarified that some licensees may have problems with more than one substance.

Dr. Wong asked how the board is notified about DUIs. Ms. Sodergren explained that all licensees must be fingerprinted prior to licensure. The board then receives subsequent arrest reports and investigates to determine if the arrest is substantially related to the practice of pharmacy.

Dr. Wong asked if pharmacists will get a warning for their first DUI. Ms. Sodergren explained that it depends on the findings and how egregious the crime is. She noted that the board’s disciplinary guidelines give the board different levels of discipline to consider depending on the findings.

Mr. Schaad expressed his concern that the board’s discipline is not clearly applied and stated that there should be more defined guidelines for discipline (example the first DUI always results in a citation) because people define egregious differently.

Deputy Attorney General Christina Jarvis explained that the problem with assigning a specific level of discipline to a type of crime is that the fact patterns for each case are always extremely different. She provided an example of one person getting a DUI with a .08 blood alcohol level vs. another person getting a DUI with a blood alcohol level of 0.3 and causing an accident. Ms. Jarvis stated that it is not possible to have a policy that would treat those to cases the same.

Ms. Freedman stated that this concern is often raised by boards within DCA. She explained that the board’s disciplinary guidelines are intended to provide the board with a range of possible discipline to apply depending on the fact pattern.

## **XI. Licensing Committee**

### **a. Summary of the Committee’s Pharmacy Technician Summit on April 4, 2017**

Chairperson Weisser explained that Business and Professions Code (BPC) section 4202 provides the general pathways to licensure as a pharmacy technician. In addition, California Code of Regulations (CCR) section 1793.5 further details the application requirements.

Chairperson Weisser stated that BPC section 4038 provides the definition of a pharmacy technician as an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties.

Chairperson Weisser reported that BPC section 4115 specifies that a pharmacy technician may perform packaging, manipulative, repetitive or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. He added that CCR section 1793.2 specifies duties that may be performed by a pharmacy technician.

Chairperson Weisser explained that the requirements for licensure as a pharmacy technician are fairly minimal and include:

- Application and fee.
- Fingerprint background check.
- Query from the National Practitioner Data Bank.
- Description on qualifications and supporting documents.

Chairperson Weisser stated that acceptable qualifications include any of the following:

- Completion of a technician training program.
- Certification from a specified program (currently either PTCB or ExCPT).
- Associate degree in pharmacy technology.

Chairperson Weisser added that the only requirement for renewal is currently a fee.

Chairperson Weisser explained that the board currently has a regulation pending to update the renewal requirements to also include self-reporting of criminal and disciplinary information. He stated that the board adopted this regulation, and it is currently undergoing review by the DCA.

Chairperson Weisser stated that the board is also in the process of updating the application form via regulation to update reference to certification programs as well as to modify Title 16, CCR section 1793.6, to strengthen the requirements of some pharmacy technician programs.

Chairperson Weisser reported that at the Pharmacy Technician Summit the committee discussed the current application and renewal requirements. The committee discussed if changes should be made to the renewal requirements to include completion of continuing education. He noted that the committee also sought clarification from those in attendance if requiring continuing education would become a barrier to continued licensure.

Chairperson Weisser stated that the committee discussed the various settings where pharmacy technicians may be focused on different types of responsibilities to support a pharmacist -- for example, a community pharmacy, hospital pharmacy, etc., -- and requested input from the public on each of the settings.

Chairperson Weisser explained that the committee expressed the need to review the current marketplace and anticipate future needs when assessing the issue while noting that any changes need to focus on how it will benefit consumers. Such benefits could include pharmacists being available to engage in more patient care activities.

Chairperson Weisser reported that the committee heard public comment about how the role of the technician is evolving in other states as well as recent studies in the area including tech-check-tech in the retail setting and a pilot program study in Iowa.

Chairperson Weisser explained that for its next discussion, the committee requested that staff prepare a comparison of the training requirements for some of the expanded duties currently being performed in other states.

Chairperson Weisser stated that during its next meeting, it is anticipated that the committee will review the comparison data provided and continue its assessment of application and renewal requirements as well as possible changes in duties. He explained that some of the large policy questions the committee will be considering are whether there should be creation of an advanced pharmacy technician license or similar model as well as if continuing education should

be a requirement for renewal of a pharmacy technician license.

Ms. Veale stated that while there is currently no action for the board to vote on from the committee, she found the meeting to be very insightful. She stated that the committee is considering how to raise the bar for new technicians and to create a grandfathering program for current technicians.

Mr. Weisser stated that the committee's goal is to study the evolving practice of pharmacy and determine if the role of the pharmacy technicians need to change in response. Ms. Veale added that they need to ensure that patients are receiving the best possible pharmacy care.

Ms. Veale stated that another area the committee will need to consider at future meetings is if the technician-to-pharmacist ratio needs to change. Mr. Weisser agreed and stated again that the committee is focused on making changes to the role of pharmacy technicians with the goal of giving patients better care by increasing the time the pharmacist can spend with the patient.

President Gutierrez stated that in Idaho pharmacy technicians are now allowed to provide immunizations. Ms. Butler added that in Idaho the pharmacy technician-to-pharmacist ratio is 6:1.

Ms. Butler stated that in light of SB 493 it is important for the board to review the duties of pharmacy technicians so that they can provide additional support to the advanced practice pharmacist.

The board heard comments from the public in support of the board's work in this area.

Chairperson Weisser stated that the committee is very invested in this topic and will continue to report back to the board on its progress.

## **b. Licensing Statistics**

Chairperson Weisser reviewed the licensing statistics as provided below.

### Licensing Statistics for July 1, 2016 – March 31, 2017

The board has received 12,673 license applications, including:

- 4,447 for pharmacy technician.
- 2,093 for intern pharmacist.
- 1,493 for pharmacist.
- 164 for advanced practice pharmacist.

As of March 31, 2017, the board has issued 9,326 licenses, renewed 48,286 licenses and has 139,286 active licenses, including:

- 44,905 pharmacists.
- 25 advanced practice pharmacists.
- 6,857 intern pharmacists.
- 72, 434 pharmacy technicians.
- 8,162 pharmacies.
- 516 hospitals and exempt hospitals.

Ms. Herold noted that the number of licensed advanced practice pharmacists has increased to 65 since the meeting materials were finalized.

President Gutierrez asked what license type has seen the biggest increase in applications. Ms. Herold stated that she believes it is the pharmacy technician applications.

The board took a break at 2:30 p.m. and resumed at 2:40 p.m.

### **XIII. Communication and Public Education Committee Meeting**

#### **a. Summary of Presentation and Proposal from Chapman University School of Pharmacy for Patient-Focused Labeling Changes to California Law**

Chairperson Law reported that at its March 23 meeting, the committee heard a presentation from Chapman University School of Pharmacy students regarding patient-focused labeling changes to California law. In the presentation led by pharmacy student Michael Phan, the students proposed the board mandate a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs.

Mr. Phan noted that oral chemotherapy medications in particular are growing in use. He said mandating a hazard symbol on prescription drug containers would help improve safe handling and proper disposal of hazardous drugs. The students asked that the symbol be required on the main prescription label, not as an auxiliary or supplemental label – but not necessarily within the patient-centered area of the label.

In response to questions from committee members and staff, the students said the FDA does not require a hazard symbol on medications and they were not aware of any states that require a hazard symbol on labels. However, they noted California requires that compounding drugs be identified as hazardous. The students said they spent a year researching the issue, and they are now working with other groups around the county to educate and promote the idea among pharmacies, drug manufacturers and other stakeholders.

#### **Committee Discussion**

Ms. Veale noted that adding a symbol to the main label might be too small to be noticed and suggested that an auxiliary label would allow a larger symbol to be used. The students said their research found that pharmacies often do not use auxiliary labels. They added that requiring the symbol to be located on the main label would allow for pharmacy software to automatically print out the symbol on the label and eliminate an extra step for pharmacists.

Ms. Veale asked if pharmacists currently could voluntarily put the symbol outside the patient-centered area, because the board's regulation specifies only what must be within the patient-centered area. Ms. Freedman said she believed a pharmacist could do that but added that she would research the issue. In response to a question from Mr. Brooks, Ms. Freedman said rulemaking would be required for the board to mandate the symbol on the label but would not be required for the symbol to be optional.

Committee members thanked the students for their presentation and expressed support for their efforts to educate stakeholders about the proposal as a first step before possibly seeking



regulations. Ms. Veale said the committee would be interested in seeing the results of the students' surveys of drug manufacturers about the issue. Ms. Herold invited the students to write an article about their proposal for *The Script*.

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

**b. Summary of Presentation by the Office for Civil Rights of U.S. Department of Health and Human Services on Final Rule Implementing Section 1557 of the Affordable Care Act Regarding Nondiscrimination in Health Programs and Activities**

The U.S. Department of Health and Human Services (HHS) issued a rule to implement Section 1557 of the Affordable Care Act (ACA) forbidding discrimination in health care on the basis of race, color, national origin, age, disability and sex. The rule took effect July 18, 2016.

The rule includes a requirement that health care providers that receive federal funding provide "meaningful access" to customers with limited English proficiency. The rule also requires providers to post taglines written in the top 15 languages spoken in the state by people with limited English proficiency. Taglines are defined as short statements advising the public that interpreter and translation services are available free of charge.

At previous board and committee meetings, members requested information about Section 1557 to determine whether the federal rule would have an impact on California laws and regulations, including requirements for prescription label translations. At the December 2016 board meeting, staff reported a possible conflict between the tagline requirements of Section 1557 and the "Point to your language" requirements in CCR section 1707.6(c). President Gutierrez suggested the board refer the matter to the Communication and Public Education Committee to get answers to ambiguities in the federal rule.

Update

The committee heard a presentation about Section 1557 from Eric Press, an investigator in the HHS Office for Civil Rights.

After giving a broad overview of Section 1557, Mr. Press discussed specific provisions for communicating with individuals with limited English proficiency (LEP). The provisions include a requirement that health care providers covered under the law must publish taglines in significant publications in the top 15 languages spoken by LEP individuals in the state. Covered entities also must post taglines in prominent locations and on their websites.

Mr. Press said covered entities also must post notices of nondiscrimination in physical locations where services are provided and in significant communications and publications. He said the notices must identify individuals' rights and the entity's obligations under Section 1557, and they must include taglines in the top 15 languages spoken by LEP individuals.

In addition, Mr. Press said a covered entity must post a nondiscrimination statement and two taglines in small-size communications and publications, such as postcards and brochures. To explain the difference between notices and statements, he said notices of nondiscrimination would be appropriate for posting in physical locations in stores and hospitals and would include taglines in 15 languages – while nondiscrimination statements would be appropriate only for posting in small-size printed materials and would have two taglines.

Mr. Press clarified the “Point to your language” tagline is different from the taglines in the federal rule, which are taglines printed on pamphlets, trifolds, postcards and anything that is mailed out to patients – not on a notice standing in front of a person in a pharmacy. He said it is not for face-to-face communication.

Mr. Press said he did not think the tagline requirement would apply for a prescription medication container, not for written material handed out with the container. He said the language assistance services would be provided at the pharmacy.

Ms. Freedman added that Section 1557 requires nondiscrimination statements for printed materials provided to patients – not for prescription labels.

Committee members and staff asked questions about whether taglines would be required for other types of printed materials given to patients, including printed package inserts and “black box” warnings provided by the manufacturer. Mr. Press said he could not answer specific questions about what documents would require taglines under Section 1557. He referred questions about Section 1557 to the Office for Civil Rights website, [www.hhs.gov/ocr](http://www.hhs.gov/ocr). Ms. Herold said the board may have specific questions later for OCR to ensure that California statutes and regulations comply with Section 1557.

In response to a question from Mr. Brooks about the potential viability of the federal rule, Mr. Press said repealing the ACA also would repeal Section 1557. He added that whatever legislation replaces the ACA probably would retain the less controversial provisions of Section 1557, including the LEP requirements.

There was no public comment.

**c. Update on NABP Request to Boards of Pharmacy Regarding Labeling Requirements for Emergency-Use Medications**

Background

The National Association of Boards of Pharmacy (NABP) sent a letter asking state boards of pharmacy to review their requirements regarding the labeling of epinephrine auto-injectors and other similar emergency-administration medications by dispensing pharmacies. NABP stated that EpiPens and similar emergency-use products represent a unique category of medications that must be given special consideration regarding their expiration dates.

NABP noted that many states require pharmacies to label dispensed prescription medications with a one-year expiration date or with the manufacturer-applied expiration date if less than one year from the date of dispensing. NABP requested that in situations where an EpiPen has not been removed from the original packaging, states allow a waiver for the EpiPen to be maintained and administered beyond the labeled one-year expiration date through the manufacturer-applied expiration date.

A copy of the NABP letter is in **Attachment 4**.

Ms. Veale and Ms. Herold noted that the board does not have a one-year expiration requirement that is mentioned by NABP. She pointed out the board has said pharmacists cannot

put an expiration date on compounding medications that is later than any of the ingredients in the compounded medication, or any date later than the date listed on a container by a manufacturer.

Ms. Herold said that as a matter of professional judgment, pharmacists know that if they have an EpiPen in a box that has never been opened, it can be used up to the manufacturer's date – even if it is outside one year. She said the issue of expiration dates could be covered in a brief article in *The Script*.

#### **d. Discussion and Consideration of Naloxone Matters**

##### **1. Update on Federal Legislation: US S. 524 – Comprehensive Addiction and Recovery Act of 2016 (CARA) – Provision Regarding Partial Fills for Schedule**

###### Background

At the September 2016 committee meeting, members discussed a potential conflict between Section 702 (f)(2)(A)(ii) of CARA and California law. At the October 2016 board meeting, staff provided the following clarification from legal counsel:

Pursuant to the Comprehensive Addiction and Recovery Act of 2016 (CARA), 21 USC §829(f) would be another situation where partial filling of a Schedule II controlled substance would be allowed provided the prescription is a valid prescription and the pharmacist exercises their corresponding responsibility when filling a controlled substance prescription:

(1) If requested by the patient or practitioner with no fill after 30 days from date written (21 USC §829[f]).

(2) For a terminally ill patient marked as “terminally ill,” tendered within 60 days from date issued and no more dispensing after 60 days from date of issuance (CCR 1745[a][2] and [c], H&SC11159.2, 21CFR1306.13[b]).

(3) For a Long Term Care Facility patient marked as “LTCF”, tendered within 60 days from date issued and no more dispensing after 60 days from date of issuance (CCR 1745[a][1] and [c], 21 CFR 1306.13[b]).

(4) When a pharmacy doesn't have enough, dispenses a partial with the balance within 72 hours (21 CFR 1306.13[a] and CCR 1745).

Staff reported that an article about this topic is planned for *The Script* scheduled for print in Summer 2017.

Ms. Herold also informed the committee that the California Pharmacists Association is putting amendments into AB 1048 this year to amend state law to partial filling for 30 days. She noted that HSC section 11159.2 exemption allows pharmacies special handling for hospice or terminally ill patients, and they do not have to use security forms.

There was no public comment.

##### **2. Summary of Availability of Naloxone at Pharmacies in Specific Communities, including Los**

## Angeles County

### Background

At the January 2017 board meeting, Dr. Rebecca Trotzky reported few pharmacies near Los Angeles County-USC Medical Center carry naloxone and most are not aware of laws allowing pharmacists to dispense naloxone without a prescription. She said that a survey by her medical students found that only 2 percent of independent pharmacies and about 30 percent of chain pharmacies carried naloxone in stock. She urged the board to provide more education and outreach to pharmacists about naloxone.

Because Dr. Trotzky spoke about a matter that was not on the board meeting agenda, President Gutierrez invited her to speak about this issue to the Communication and Public Education Committee.

### Update

Dr. Trotzky addressed the committee by telephone from Los Angeles.

Dr. Trotzky told the committee that when she prescribed naloxone to ER patients at LA County-USC Medical Center, many reported they could not get it from local pharmacies. She said when her students called to investigate, they learned pharmacies were telling patients that they could not give naloxone without a prescription, that they did not have naloxone in stock, that patients had to pay cash for it, and other responses that prevented patients from obtaining naloxone.

Dr. Trotzky said her students' survey was conducted in December 2016 and January 2017. She said she wanted to work with the board to increase awareness among pharmacists about naloxone and to increase the availability of naloxone to patients without a prescription.

Chairperson Law informed Dr. Trotzky of specific steps that board staff has taken to increase pharmacists' awareness of the naloxone since she spoke to the board in January, including:

- Emailing subscriber alerts reminding pharmacists about the protocol in March.
- Publishing an article about the protocol in a recent issue of *The Script* newsletter.
- Posting information for licensees about naloxone in the board's website.

He also noted that a training forum for pharmacists planned for March 11, 2017, included a session on naloxone.

Ms. Veale noted some pharmacists are not comfortable talking about naloxone with patients. Ms. Herold pointed out that the protocol includes specific questions for pharmacists to ask patients. She said CE providers could emphasize training for pharmacists on asking questions and communicating with patients about naloxone.

Chairperson Law said the board would take more steps to educate pharmacists about naloxone and to educate consumers about where they can find naloxone. Dr. Trotzky thanked the committee and said she might conduct another survey in a year to see if the situation improved.

Jonathan Bloomfield of Adapt Pharma, the manufacturer of Narcan nasal spray, told the committee pharmacists nationwide often are not proactive about furnishing naloxone because of the amount of time they are required to spend training patients or lack of reimbursement.

Mr. Weisser asked if Naloxone is covered by insurance. Ms. Veale stated that it is covered by most insurance companies, but it must be billed to the patient – it will not be covered for someone who is getting it for another person.

Dr. Wong asked if there are any legal problems for people who administer naloxone to someone else. Ms. Freedman responded that good Samaritan laws exist that generally protect people who are providing lifesaving treatment.

3. Committee Recommendation on a Request from Walgreens to Use In-House Fact Sheet for Patients Receiving Naloxone

Chairperson Law reviewed the meeting materials and advised the board that Walgreens sent a letter to the board requesting approval to use a Walgreens-specific naloxone fact sheet for patients receiving opioid antagonists. The fact sheet would be provided to Walgreens patients whose primary language is English. For patients, whose primary language is not English, Walgreens would provide materials printed in alternate languages that are on the board's website.

Chairperson Law stated CCR section 1746.3(c)(6) requires pharmacists to provide naloxone recipients with "a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English." Mr. Law advised the board that copies of the board's online fact sheet in English, the Walgreens letter, and the Walgreens fact sheet were included in the meeting materials.

Mr. Law advised the committee that Lori Walmsley of the pharmacy affairs department of Walgreens addressed the committee that Walgreens would like to use the Walgreens branded fact sheet that it uses in all other states to improve workflow. She said the Walgreens sheet contained all the same elements in the board's website fact sheet. She said the Walgreens sheet is automatically printed anytime an opioid antagonist is sold.

Mr. Law reported that Ms. Freedman informed the committee that section 1746.3(c)(6) requires a single fact sheet that is to be made available on the board's website. She said Walgreens could submit the fact sheet for board approval and posting on the website, but Walgreens would have to give copyright approval for its fact sheet to be posted and made available for use by other pharmacies. Alternatively, Ms. Freedman said, the board could modify section 1746.3(c)(6) to allow the board to approve alternate versions of the fact sheet.

Mr. Law reported that Ms. Walmsley told the committee that she would have to get corporate approval from Walgreens on the copyright issue. Ms. Veale noted that the board allows pharmacists to develop their own language for "Point to your language" notices or to produce their own videos for the Notice to Consumers. Ms. Herold pointed out that the

regulation specifically allows for alternative forms and for videos for the Notice to Consumers.

Mr. Law reported during the committee meeting, Ms. Herold asked if Walgreens would be open to using the current fact sheet on the board's website if CDPH gave approval for Walgreens to load the fact sheet in the company's software. Ms. Walmsley said Walgreens does not have the ability to automatically print different fact sheets for different states.

Mr. Law reported that Ms. Veale said she would prefer changing the section 1746.3(c)(6) to allow the board to approve alternative naloxone fact sheets rather than receiving individual requests from pharmacy chains to use their own fact sheets.

The committee discussed whether the Medical Board of California would have to review changes involving the naloxone fact sheet, because the Medical Board was involved in developing the protocol. After the committee meeting, Ms. Herold determined that the Medical Board would have to review any changes in the protocol but not in the public education materials.

Board member Schaad added as an agenda item or article in The Script to help refer people for rehab or safe area. Ms. Herold informed the board that there is a group in CDPH that is looking at the opioid epidemic and may have information in the future but at this point she was not aware of a point of reference to provide. Ms. Herold added frequently the treatment is not readily available and the consumer must wait 4-6 weeks as well as it is expensive. Mr. Schaad asked for this to be referred to the Communication and Public Education Committee.

Ms. Herold asked if the board will require in this instance Walgreens to have the fact sheet translated to the additional languages if approved. Mr. Weisser added that Walgreens was requesting to only use its fact sheet in English and continue to use the board's translated versions.

Lori Walmsley of the pharmacy affairs department of Walgreens addressed the board and clarified that Walgreens is currently printing its fact sheet in addition to going to the board's website to print the board provided fact sheet. Walgreens is looking to reduce duplicity. Ms. Veale clarified the committee's view was to make it as easy as possible to get the information available to the public about naloxone. Mr. Weisser agreed and acknowledged continuity is also important. Ms. Veale concurred and added this is the reason it must be approved by the executive officer. Ms. Veale confirmed the required elements would be there but the format would be different.

**Committee recommendation (Motion):** Change CCR section 1746.3(c)(6) to authorize the executive officer to approve substantially similar fact sheets for use so that individual pharmacies can use them.

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Gutierrez	X			

Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**e. Update on a Board-Developed Public Service Billboard Message and Related Communication Materials**

Background

At the September 2016 committee meeting, members reviewed proposed concepts for a bulletin board message developed by Mr. Brooks’ firm. The committee recommended the board proceed with a proposal featuring drawings of pills around the message “Unattended Drugs are the Leading Killer of Kids.”

At the October 2016 board meeting, members agreed with the committee recommendation and voted to sponsor the billboard message. The billboard is intended to encourage parents to talk to their children about prescription drug abuse.

Committee Discussion

Staff reached out to the Prescription Opioid Misuse and Overdose Prevention Workgroup, which is a joint effort among state agencies, is working to develop collaborative strategies to curb prescription drug overdose deaths and addiction in California. Staff is working to ensure that the board’s billboard project is consistent with communication strategies being developed by the workgroup’s Communication and Outreach Taskforce.

Ms. Herold asked if it might be more effective if the board participated in the outreach campaign being developed by the statewide task force rather than proceeding independently. Committee members expressed concern that process for the task force campaign process would take too long and recommended that the board’s billboard project continue independently.

Ms. Freedman asked if Mr. Brooks firm had any concerns about sharing its intellectual property with state agencies. Mr. Brooks said there were no concerns.

There was no public comment.

**f. Summary of Discussion of Efforts by Drug Manufacturers to Stop Illegal Sales of Non-FDA Approved Products**

Background

Representatives of Allergan met recently and discussed with board staff their concerns about the illegal importation of non-FDA approved products. They described Allergan’s efforts to shut down Amazon Medica, a foreign and unauthorized entity reported to be illegally selling Allergan Aesthetics products, including counterfeit products that are not FDA approved for use or distribution in the United States.

## Committee Discussion

Ms. Sodergren said the board is aware the problem also is happening with other manufacturers. She said the board would be considering legislation dealing with this problem.

There was no public comment.

### **g. Update on Communication Plan for Reaching Consumers and Licensees**

#### Background

At the September 2016 committee meeting, staff presented a draft communication plan that included aspects for both consumers and licensees. Staff developed the draft in accordance with the board's Strategic Plan. The committee approved the plan with continued modifications and updates.

#### Update

Staff presented an updated plan reflecting specific communication and public education activities in progress or planned by the board, including publication of *The Script*, website improvements, subscriber alerts and CE.

#### 1. Update on *The Script* Newsletter

Articles are undergoing legal review for publication, which is imminent.

#### 2. Update on Media Activity

Chairperson Law briefly reviewed media activity conducted by the board's executive officer as provided in the meeting materials.

#### 3. Update on Public Outreach Activities Conducted by the Board

Chairperson Law briefly reviewed the public outreach activities conducted by the board's executive officer and inspectors as provided in the meeting materials.

Ms. Herold provided an update on the March 11 forum at UC San Diego. She said 225 people attended the event, and the board offered seven CE units to participants. In addition, 132 participants received naloxone certification.

Ms. Herold said participants asked good questions and that the ratings were good. She said the event was videotaped and was being put online. In addition, she said organizers were asked to do the forum again, probably in Northern California.

Lori Hensic of Kaiser Permanente asked if the board could provide an event like the March 11 forum specifically for an employer or other organization. Ms. Herold said the board would want to open the event up. Ms. Sodergren added that any request to the board for an educational event must be made in writing.

Chairperson Law asked if the website has a master calendar listing outreach activities organized by professional groups that people can plan to attend. Ms. Herold said the board



often does not receive advance notice of events, and some are not open to the public. Ms. Sodergren said the board could create a calendar listing events sponsored by the board.

#### Update

Staff is the process of developing a mockup of a website calendar for the board's consideration. A copy of the mockup will be passed out as a handout at the board meeting.

### **XIII. Closed Session**

The board recessed to closed session at 3:35 p.m.

The board returned to open session at 4:47 p.m. and President Gutierrez adjourned the meeting for the day at 4:48 p.m.

#### **May 4, 2017**

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

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

Note: Valerie Munoz arrived at 9:09 a.m.

### **XIV. Presentation on the Board's Pharmacist Recovery Program**

Virginia Matthews, Maximus project manager, and Stephanie Trumm, Maximus clinical case manager, provided a very insightful presentation on substance use disorders and the board's Pharmacist Recovery Program (facilitated through Maximus).

The entire presentation is provided following these minutes and can be viewed on the board's website using the following link: [https://www.youtube.com/watch?v=gb\\_IBWskRLA&feature=youtu.be](https://www.youtube.com/watch?v=gb_IBWskRLA&feature=youtu.be)

Following the presentation, the members asked Ms. Matthews and Ms. Trumm questions, which have been summarized below.

Mr. Schaad asked if insurance covers the services offered by Maximus. Ms. Matthews explained that insurance typically covers the treatment facility; however, because Maximus is a case management service, it is not covered by insurance. Ms. Trumm added that often Maximus can help advocate for the patient to have the treatment covered through his or her insurance. Ms. Sodergren added that the Maximus administrative fees are subsidized by the board and the average cost to the participant is \$100. She noted that if someone cannot afford the \$100 he or she can submit an appeal to the board to lower the cost.

Ms. Butler and Ms. Veale expressed concern with the cost of drug testing. Ms. Sodergren explained that SB 4114 established uniform standards for health care practitioners with substance abuse problems and includes testing frequencies. She stated that if a licensee is not working, often the testing rate is lowered because they do not pose the same risk to the public as someone who is working in a pharmacy. Ms. Sodergren noted that she has never seen a pharmacist who had to drop out of the program because they could not afford the testing. She added that the board will look for ways to help achieve savings in other areas if the patient is struggling with the testing costs.

Mr. Weisser stated that often people who struggle with substance abuse also have financial difficulties, which are compounded by the difficulty they have finding work while in recovery. Ms. Matthews explained that if a participant is diagnosed with a mental illness or substance use disorder they are eligible for disability. She added that they can work in a non-medical setting to earn additional income. Ms. Trumm noted that Maximus will help patients find community resources while they work to stabilize their lives.

President Gutierrez asked what percentage of pharmacists successfully complete the recovery program. Ms. Matthews responded that the overall success rate for Maximus (which includes other health care boards) is approximately 60 percent.

President Gutierrez stated that the board sees cases where someone has received a DUI, but he or she is not on their way to/from work. She asked if DUIs are indicative of more problems that the licensee may need treatment for. Ms. Trumm responded that not everyone who gets one DUI has a full substance use disorder, but it is a red flag that the board should investigate further. She added that a pharmacist license is not just valid for the hours worked in a pharmacy, so any criminal act by a pharmacist is a violation of their professional code.

Dr. Wong asked what percentage of people that get a DUI actually have a substance abuse problem that will affect their work. Ms. Trumm responded that there is no statistic, it is on a case-by-case basis and must consider multiple factors. She added that statistics show that on average a person has driven impaired 200 times before he or she actually gets a DUI.

Ms. Veale stated that even if someone drinks or uses drugs outside of work hours, he or she may still be affected by the substance when they return for their next shift. Ms. Trumm agreed and stated that this is especially true if they return to work in less than 24-hours.

Ms. Herold stated that it is important to take into account the blood-alcohol level for DUI arrests. Mr. Trumm noted that a high blood-alcohol content is indicative of a tolerance that has been built up for alcohol.

Mr. Law asked if there is ever a point where someone is too far gone to successfully complete a recovery program. Ms. Trumm responded that as long as someone is breathing he or she has hope to recover and find a new way of living life.

Mr. Weisser asked if there is an average cost of for participation in the Maximus program. Ms. Sodergren stated that staff would gather the information and provide it to the board.

President Gutierrez asked if it would be appropriate for a pharmacist who is using suboxone to be allowed back to work. Ms. Tumm responded that if a patient is on suboxone Maximus will ask the patient's doctor to begin a scheduled taper until he or she is off suboxone. She added that Maximus does not consider someone to be sober until he or she tests completely negative for suboxone. Mr. Schaad asked if someone who is tapering off suboxone can work. Mr. Trumm responded that they cannot work until they are completely off of suboxone. Mr. Trumm added that no other California healing arts board allows licensees to return to work while on suboxone.

A pharmacist spoke in support of the Maximus program and stated that he has employed two pharmacists who successfully completed the program and achieved recovery.

**XVI. Legislation and Regulation Committee**

**Part 1: Legislation for Discussion and Consideration Report**

**a. Board Sponsored Legislation**

Chairperson Lippe reported that the bills listed below are sponsored by the board and are moving through the legislative process. He stated that details for each bill are provided in the board meeting materials for review.

Chairperson Lippe asked if there were any questions on any of the board sponsored legislation. There were no comments from the board or from the public.

- Omnibus Provisions: SB 800 (Hill) Professions and Vocations, Including Changes to Pharmacy Law
- SB 351 (Roth) Hospital Satellite Compounding Pharmacy: License: Requirements
- SB 443 (Hernandez) Pharmacy: Emergency Medical Services Automated Drug Delivery System
- SB 510 (Stone) Pharmacies: Compounding
- SB 752 (Stone) Pharmacy: Designated Representative-Reverse Distributors

**b. Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction with Recommended or Current Positions**

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

Chairperson Lippe explained that AB 12 would require each state agency to, on or before January 1, 2020, review regulations; identify any regulations that are duplicative, overlapping, inconsistent or out of date; revise those identified regulations, as provided; and report to the Legislature and governor, as specified. The bill would repeal these provisions on January 1, 2021.

Chairperson Lippe reported that as part of its discussion the committee noted the fiscal impact the measure would have to the board totaling \$478,000 (FY 2018/19) and \$454,000 (FY 2019/20). He noted that the committee was advised that possible amendments could be for staff to either to expand the time and/or synchronize efforts with Sunset review.

Chairperson Lippe stated that the committee took an Oppose Unless Amended position.

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

**Committee Recommendation (Motion):** Oppose Unless Amended.

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Gutierrez	X			

Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

2. AB 40 (Santiago) CURES Database: Health Information Technology System

**Chairperson Lippe explained that** AB 40 would require the Department of Justice to make the electronic history of controlled substances dispensed to an individual under a health care practitioner’s care, based on data contained in the CURES database, available to the practitioner through either an online internet web portal or an authorized health information technology system, as defined.

Ms. Herold stated that this bill will make access to CURES easier for practitioners.

Chairperson Lippe reported that as part of its discussion the committee noted the board’s long history of supporting the use of CURES. He stated that the committee took a support position on the bill.

There were no comments from the board or the public.

**Committee Recommendation (Motion):** Support AB 40.

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board discussed their desire to expand the CURES system so that the information can be shared with neighboring states. Ms. Sodergren stated that as part of its support letter staff will include details of the board’s policy desire to allow data to be shared with neighboring states.

3. AB 182 (Walderon) Heroin and Opioid Public Education (HOPE)

Chairperson Lippe explained that as amended SB 182 requires the Department of Health

Care Services (department) to develop and implement an education campaign (HOPE) to combat the growing heroin and opioid medication epidemic in California in consultation with stakeholders. The measure includes some of the information that must be used as part of the campaign as well as targeted audiences. He added that the department would also be required to submit a report on at least an annual basis summarizing its activities and assessment of the effectiveness of the program.

Chairperson Lippe reported that as part of its discussion, the committee noted the board’s Communication and Public Education Committee’s education campaign is under development.

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

**Committee Recommendation (Motion):** Support AB 182.

Support: 10      Oppose: 0      Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

4. AB 208 (Eggman) Deferred Entry of Judgment: Pretrial Diversion

Chairperson Lippe explained that AB 208 changes the deferred entry of judgment program to a pretrial program. AB 208 expands the conditions under which someone would be eligible for the program and reduces the conditions under which someone could be removed from the program. Chairperson Lippe added that AB 208 reduces the length of the program compliance to six-twelve months and prohibits information sharing once someone is in the program.

Chairperson Lippe reported that the committee discussed concerns with the measure, including the proposed expansion of the conditions under which someone would be eligible for the program, the reduction in the length of the program, and how the proposed measure would restrict the board’s ability to pursue a Penal Code 23 restriction. He added that the committee was advised on an analysis of administrative cases closed in the past three years that involved an arrest or conviction revealed that 119 of these cases would have been eligible for the pretrial program being proposed under this bill. In each of those cases the board would need to prove the arrest and underlying conduct.

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

**Committee Recommendation (Motion):** Oppose AB 208 Unless Amended.

Support: 10    Oppose: 0    Abstain: 0

<b>Board Member</b>	<b>Support</b>	<b>Oppose</b>	<b>Abstain</b>	<b>Not Present</b>
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

5. AB 315 (Wood): Pharmacy Benefits Management

Chairperson Lippe explained that AB 315 establishes regulatory framework for PBMs. As part of this framework, PBMs would be licensed by the board.

Chairperson Lippe stated that in March the board established a support position on a prior version of this bill measure.

Chairperson Lippe reported that in light of the full board’s discussion of the matter in late March 2017, the committee noted the board’s current support position and therefor did not make a recommendation. The committee heard public comment about a letter issued from the Federal Trade Commission (FTC) regarding the regulation of PBMs by the Mississippi Board of Pharmacy.

Chairperson Lippe explained that recently staff and counsel reviewed the letters from the FTC referred to during the committee meeting and noted a few items in response to the public comment (below).

1. The FTC letters offer opinion, not legal conclusions.
2. Although the FTC notes potential conflicts, the opinion offered is very general and appears unsupported. Additionally, staff questions how a pharmacy/pharmacist may enter into a contractual relationship with a PBM that is different from a contract with a drug wholesaler or manufacturer to purchase drugs where such a conflict has never been identified as problematic. Further, the FTC letter seems to imply the need to protect PBMs from regulation, rather than focusing on the anti-competitive effects of such regulation, which is under the jurisdiction of the FTC.
3. Provisions of the Mississippi law regulating PBMs identified by the FTC do not exist in SB 315 and as such are irrelevant.

Chairperson Lippe stated that during a Licensing Committee meeting the committee heard public comment that PBMs performed drug utilization reviews. He explained that such reviews are required under pharmacy law and must be completed by a pharmacist.

Mr. Weisser asked if the FTC could enforce based on the letters. Deputy Attorney General Joshua Room stated that the letters are not enforceable. He added that the FTC letters are not formal guidance documents.

Mr. Weisser stated that public comment made it seem like there could be legal action against the board in light of the North Carolina ruling. He asked if this was a realistic risk to the board. Mr. Room stated that the North Carolina case had a very specific set of facts, not all of which apply to the Board of Pharmacy. He explained that the North Carolina opinion said that the state actor immunity would not be afforded to state actors under certain circumstances. However, even if the immunity was removed, it would still have to be proven that there was anticompetitive conduct, that there was a market that was affected, etc. Mr. Room concluded that at this time he does not see that the board's involvement in regulating PBMs would constitute anticompetitive conduct.

Ms. Freedman stated that at face value, the Board of Pharmacy's ability to regulate PBMs does not seem constitute anticompetitive conduct.

Ms. Herold stated that there is a completely different set of facts in California, including the fact that the board members go through a different process to become appointed to the California Board of Pharmacy.

Mr. Schaad stated that he finds it immoral that PBM agreements prohibit pharmacists from providing certain information to patients.

Mr. Wong asked if the bill had been amended. Ms. Herold stated that the bill will be amended by the author; however, she does not know when it will be amended or what the amendments will contain.

Chairperson Lippe stated that the board currently has a support position on AB 315 and the committee did not make any changes to this position.

There were no comments from the public.

#### 6. AB 602 (Bonta) Pharmacy: Nonprescription Diabetes Devices

Chairperson Lippe explained that AB 602 would require pharmacies that dispense nonprescription diabetes test devices pursuant to a prescription to retain records, require the board to post the names of authorized distributors of such test strips, and make it unprofessional conduct for a licensee to seek reimbursement for such devices under specified conditions.

**Chairperson Lippe reported that as** part of its discussion the committee contemplated if the board should seek the ability to embargo such counterfeit products as well as if the provisions of unprofessional conduct should include purchasing such products from an authorized entity.

Chairperson Lippe stated that the committee took a support if amended position.

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

**Committee Recommendation (Motion):** Support AB 602 if amended.

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

7. AB 845 (Wood) Cannabidiol: Prescriptions in Accordance with Federal Law

Chairperson Lippe explained that AB 845 would, if consistent with federal law, authorize prescribing and dispensing a controlled substances prescription that contains cannabidiol.

Chairperson Lippe reported that as part of its discussion, the committee noted that in its current form, the measure would prevent a pharmacist from exercising professional judgment by stating in the statute that it shall be deemed for a legitimate medical purpose. At the committee meeting counsel explained the consequences for such an approach and how it runs contrary to the board's enforcement efforts, and staff noted the significant effort the board has taken to educate licensees about corresponding responsibility and that the measure is contrary to the board's policy in its current form. Chairperson Lippe reported that the committee noted that amendments could be offered that would allow for the policy goal of the author without undermining a pharmacist's corresponding responsibility.

Chairperson Lippe stated that the committee took an oppose unless amended position.

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

**Committee Recommendation (Motion):** Oppose Unless Amended

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			



Weisser	x			
Wong	x			

8. AB 912 (Obernolte) Small Business: California Small Business Regulatory Fairness Act

Chairperson Lippe explained that AB 912 would require a state agency to provide assistance to a small business in achieving compliance with laws and assist the business during an enforcement action. It would also require the state agency to establish a policy to waive civil penalties under specified conditions.

Chairperson Lippe reported that the committee noted the conflicts this measure creates, especially related to the dual role the board would be required to play during an enforcement action and how such a process may be a violation of the administrative procedures act. He stated that the committee indicated the need to seek amendments to remedy the conflict. Chairperson Lippe explained that the committee indicated that assisting small businesses with licensing requirements is appropriate but questioned the need for a mandate to provide such service.

Chairperson Lippe reported that the committee took and oppose unless amended position.

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

**Committee Recommendation:** Oppose AB 912 unless amended.

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

9. SB 17 (Hernandez) Prescription Drugs: Pricing: Notification

Chairperson Lippe explained that SB 17 is aimed at drug price transparency by establishing reporting requirements for prescription drugs cost and volume for health plans and reporting requirements for drug manufacturers regarding rate increases.

Chairperson Lippe reported that as part of its discussion the committee noted the need to reduce the costs of prescription medications and noted that a patient cannot receive the benefits of a prescription if he or she cannot afford it. The committee also noted that this measure may be a first step in helping to make prescriptions drugs more affordable.

Chairperson Lippe stated that the committee took a support position.

Mr. Weisser asked if there is any public reporting of drug prices. Ms. Sodergren explained that there is some public reporting of aggregated data. Ms. Sodergren added that in the measure it outlines all of the information that must be reported.

Ms. Veale asked how consumers will get better drug prices because of this bill. Ms. Sodergren explained that this bill will not help consumers find a pharmacy that has the drugs at the cheapest price. It is intended to create transparency in how the pricing of the drug is determined. President Gutierrez stated that the information is not the price the consumer pays, rather it is the acquisition drug cost.

There were no comments from the public.

**Committee Recommendation:** Support SB 17.

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

10. SB 27 (Morrell) Professions and Vocations: Licenses: Military Service

Chairperson Lippe explained that SB 27 would require every board within the Department of Consumer Affairs to grant a fee waiver for the application for and the issuance of an initial license to an applicant who supplies satisfactory evidence, as defined, to the board that the applicant has served as an active duty member of the California National Guard or the United States Armed Forces and was honorably discharged. He added that the bill would require that a veteran be granted only one fee waiver, except as specified.

Chairperson Lippe reported that the board had a support position on a similar measure last year and the committee took a support position on the bill at its meeting.

There were no comments from the board of the public.

**Committee Recommendation:** Support SB 27.

Support: 10    Oppose: 0    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

11. SB 641 (Lara) Controlled Substances Utilization Review and Evaluation System: Privacy

Chairperson Lippe explained that SB 641 would limit the conditions under which a law enforcement or regulatory board may access CURES and would establish a multidisciplinary advisory committee to assist, advise and make recommendations for the establishment of rules and regulations necessary to insure the proper administration and enforcement of the CURES database.

Chairperson Lippe reported that as part of the committee discussion, counsel expressed concern with some of the provisions in the measure, including challenges with law enforcement gaining access to the information needed. Staff also expressed concern with stakeholders developing policy recommendations on the appropriate administration and enforcement of the CURES database. Chairperson Lippe stated that at the meeting staff suggested that amendments could be offered to address the concerns by removing those provisions.

Chairperson Lippe stated that recently board staff has been advised that as written the measure may require the board to secure a warrant every time it requires information from the CURES system because of the way the measure is currently constructed. He explained that that, if true, this would create a significant barrier to board investigations and would further create a significant fiscal impact to the board.

Chairperson Lippe explained that the board does not use the information in CURES to investigate individual patients and questions the policy behind requiring the board to obtain a subpoena to access information in the CURES system that is reported by its licensees.

Chairperson Lippe stated that the committee took an oppose unless amended position.

Mr. Room reported that he attended a hearing with the California Supreme Court where the court is determining if the Medical Board should obtain warrants to obtain CURES data.

Ms. Veale stated that in light of the pending court case the board should consider taking an oppose position on the bill. Ms. Sodergren noted that sometimes an OUA is a stronger position than a straight oppose because it provided the opportunity to work with the author's office.

**Committee Recommendation (Motion):** Oppose SB 641 unless amended.

Support: 8    Oppose: 2    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Gutierrez	X			
Butler	X			
Law	X			
Lippe		X		
Munoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser		X		
Wong	X			

**12. SB 716 (Hernandez) California Board of Pharmacy: Pharmacy Technician Member**

Chairperson Lippe explained that originally SB 716 would have increased the number of board members to 14 by adding one pharmacy technician member who would be appointed by the Governor. He noted that the bill has since been amended to add one pharmacy technician member and one public member.

Ms. Sodergren explained that the bill is being sponsored by CSHP. She explained that because of how many pharmacy technicians the board licenses CDHP felt there should have a representative on the board.

Loriann DeMartini, representing CSHP, stated that they are pleased to be the sponsor of the bill. She explained that 10 other states have pharmacy technicians on the board. Ms. DeMartini explained that when the bill was heard, the Business and Professions Committee asked that the bill be amended to add an additional public member in response to the North Carolina decision.

Mr. Weisser asked why CSHP believes a pharmacy technician needs to be represented on the board. Ms. DeMartini responded that CSHP believes that as the role of pharmacists has evolved, the role of pharmacy technicians also needs to be updated and they feel it is important to have a technician involved in that process.

Ms. DeMartini noted that there is precedent to establish a separate board to regulate pharmacy technicians due to the high number of licensees. She referenced the Physician Assistant Board and Dental Hygienist Board as examples.

President Gutierrez asked if CPhA had a position on the bill. A representative from CPhA stated that they supported the original bill to add a pharmacy technician to the board. However, with the amendment to add the public member, they withdrew their support.

Paige Talley, representing CCAP, stated that they support the bill.

President Gutierrez stated that she supports pharmacy technician having a more active role in pharmacy; however, she does not feel that this bill will accomplish this. She stated that this would be accomplished through the work that the Licensing Committee is doing.

Mr. Schaad stated that he does not support adding additional members to the board as it will make establishing a quorum more difficult. He also stated that he does not believe that pharmacy technicians have experienced the level of sophistication that is necessary to serve on the board. Mr. Schaad stated that during his time on the board he has never had to ask a pharmacy technician for advice on an item that the board is considering. He added everything that a pharmacy technician does is under the complete supervision of the pharmacist. Mr. Schaad also noted that dental hygienists and physician assistants complete more extensive educational training and they make independent decisions while they are providing care.

Ms. Veale stated asked if a pharmacy technician could fill a public seat of the board. Ms. Freedman stated that there are specific criteria for public members and one of them is that they cannot be involved in a practice regulated by the board.

Ms. Munoz stated that a pharmacy technician would add a new and valuable perspective to the board in the same way that public members add different perspectives. She encouraged the board to take the initiative to broaden its view to provide better patient care and more consumer protection.

Mr. Schaad agreed that the different perspectives are valuable to the board's deliberations.

Ms. Veale stated that pharmacy technicians can always come before the board to testify on an agenda item.

Dr. Wong stated that he would like to keep pharmacists as the majority on the board.

Ms. Herold stated that the board's mandate is consumer protection and the board needs to discuss how adding a pharmacy technician member and a public member will affect consumer protection.

Chairperson Lippe called for a vote on the committee's recommended support position.

**Committee recommendation (Motion):** Support AB 716.

Support: 5    Oppose: 5    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez		x		
Law	x			

Lippe	x			
Munoz	x			
Sanchez	x			
Schaad		x		
Veale		x		
Weisser		x		
Wong		x		

Per parliamentary procedure the motion failed.

President Gutierrez asked if the board should consider an oppose unless amend to amend the bill to only add one pharmacy technician (as the bill was originally drafted).

Dr. Wong stated that he would not support adding a pharmacy technician member.

Ms. Butler stated that she would support adding a pharmacy technician to the board but would not support adding a public member.

Ms. DeMartini again stated that the Business and Professions Committee was very uncomfortable with having the professional members outnumber the public members. In order to move the bill, they requested that a public member also be added.

The board discussed the possibility of changing the requirements for the public member to allow the position to be filled by a pharmacy technician.

The board discussed the fact pattern of the of the composition of the board in the North Carolina case.

The board discussed the composition of the Medical Board (8 professional members and 7 public members).

Mr. Law stated that it is important to give pharmacy technicians a voice on the board.

**Motion:** Re-vote on the committee’s recommended support position.

**M/S:** Wong/ Weisser

Support: 9    Oppose: 1    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad		x		
Veale	x			

Weisser	x			
Wong	x			

**Re-vote of Committee Recommendation (Motion):** Support SB 716.

Support: 4    Oppose: 6    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler		x		
Gutierrez		x		
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad		x		
Veale		x		
Weisser		x		
Wong		x		

**Motion:** Oppose SB 716 unless amended to allow for one of the public positions to be filled by a pharmacy technician.

**M/S:** Butler/Wong

Support: 3    Oppose: 7    Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez		x		
Law		x		
Lippe		x		
Munoz		x		
Sanchez	x			
Schaad		x		
Veale		x		
Weisser		x		
Wong	x			

Ms. Butler and Dr. Wong made a motion to add one pharmacy technician and one pharmacist to the board. Mr. Law expressed concern with having so many professional members on the board.

After discussion, the board concluded that because the Business and Professions Committee was concerned with having public members outnumbered by professional members, they would not vote on the motion to add both a pharmacy technician and a pharmacist to the board.

**Motion:** Oppose SB 716 unless amended to appoint a pharmacy technician to the board (no

public member).

M/S: Wong/Butler

Support: 9 Oppose: 1 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad		x		
Veale	x			
Weisser	x			
Wong	x			

The board took a break at 12:20p.m. and resumed at 12:30 p.m.

**c. Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction, Measures without Recommendations or Current Positions**

**1. AB 401 (Aguiar-Curry) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy**

Chairperson Lippe explained that AB 401 establishes regulatory framework for telepharmacy.

Chairperson Lippe reported that the committee discussed this measure from both a policy perspective and an implementation perspective, noting that the provisions would allow a rural area access to a pharmacist that it may not otherwise have. He added that the committee expressed concerns with the proposed expansion of the supervisory duties of a pharmacist and questioned whether appropriate controls are in place to prevent consumer harm.

Chairperson Lippe stated that the committee did not take a position but directed staff to work with the author’s office to address some of the committee’s concerns.

Ms. Sodergren explained that this bill will help give patients in a medically underserved areas access to a pharmacist via telecommunication. She stated that the committee was concerned with the number of remote sites that a pharmacist would have to oversee as well as the number of pharmacy technicians they would oversee.

Ms. Sodergren explained the protections that are in place for controlled substances and the video cameras that would be used to monitor the location. She noted that the committee would like to extend the amount of time the video must be retained and available for review.



Mr. Weisser asked if the pharmacy technician ratios would be affected by the bill. Ms. Sodergren explained that the ratio would be changed *only* for these telepharmacy locations.

Ms. Butler expressed her significant concern with increasing the number of technicians that the pharmacist will have to oversee.

Ms. Veale asked if the board has been able to look at how other states have used this model. Ms. Sodergren responded that the author of the bill uses this model in other states and has drafted the bill for use in California.

Dr. Wong asked if the telepharmacy can continue to operate if another pharmacy enters the area (thus making it no longer medically underserved). Ms. Sodergren responded that this bill would allow the telepharmacy to continue to operate.

Dr. Wong motioned to oppose the bill unless it is amended to require the telepharmacy to close if the area is no longer medically underserved area.

Ms. Sodergren reported that for the purposes of this bill a medically underserved area means a location that does not have a pharmacy that serves the general public within 10 road miles of the remote dispensing site. President Gutierrez stated that there could be a lot of medically underserved areas as defined in the bill.

President Gutierrez asked if this bill would allow for automated drug delivery systems. Ms. Sodergren explained that this bill would not allow for the use of automated drug delivery systems.

Dr. Wong withdrew his motion to oppose unless amended.

Gary Caccitore from Cardinal Health (the sponsor of the bill) stated that this bill is intended to increase pharmacy access to medically underserved patients. He also stated that a consultation is required for every prescription and it is done using technology. He asked the board to support the bill to increase access to care for patients.

At the request of the board the Mr. Caccitore provided an overview of how the telepharmacy will operate and clarified that nothing can leave the pharmacy before it is reviewed by the pharmacist.

The board spoke in support of increasing access to quality pharmacy services for underserved patients.

Dr. Wong and Ms. Butler again expressed concern with how many technicians the pharmacist would have to supervise remotely.

A pharmacist from a rural area spoke in support of this bill as there is a need for pharmacist care in rural areas.

**Motion:** Support AB 401.

**M/S:** Weisser/Veale

Support: 6 Oppose: 3 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler		x		
Gutierrez	x			
Law		x		
Lippe	x			
Munoz			x	
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong		x		

2. SB 528 (Stone) Pharmacy: Automated Drug Dispensing Systems

Chairperson Lippe reported that SB 528 would allow a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B through the use of an automated drug dispensing system (ADDS) under specified conditions. As amended, the measure details the conditions that must be met to use the ADDS.

Chairperson Lippe stated that the committee did not make a recommendation and requested that staff continue to monitor the proposal.

Chairperson Lippe explained that since the committee meeting, the measure has been significantly amended to include greater detail to include controls that exist in other similar areas of pharmacy law.

Ms. Sodergren explained that the bill would require a health care professional to provide the medication and it requires either a password or biosensor. Ms. Sodergren noted that the bill does *not* require that someone who is authorized to administer medications to restock the machine.

Keven Rue, representing the sponsor of the bill, stated that the intent is for the stocking of the machine to be done by a member of the pharmacy staff. He also explained that the majority of their machines are used in rural, medically underserved areas.

President Gutierrez asked if the bill was for a specific company's machine. Ms. Sodergren responded that the bill is technology neutral.

Note: Valerie Munoz and Stanley Weisser left the meeting at 1:03 p.m.

President Gutierrez asked staff to work with the author's office to ensure the that restocking of the machine is done in accordance with current law.

Chairperson Lippe stated that while the committee does not have a position on the bill, the committee does think it is necessary to have their machines licensed by the board. The board agreed that a license should be required.

**Motion:** Support SB 528 if amended to require licensure.

**M/S:** Gutierrez/Veale

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Munoz				X
Sanchez	X			
Schaad	X			
Veale				
Weisser	X			X
Wong	X			

3. AB 1589 (Salas) Pharmacy: Pharmacist Supervision: Technicians

Ms. Sodergren explained that AB 1589 would require the board to hold meetings to review the pharmacist-to-pharmacy technician ratio on a biennial basis and would require the board to provide a report to the Legislature with recommendations if the board decides a change is necessary. She added that the bill would require the board to hire a part-time staff person.

Ms. Veale asked if the review could be done as part of a Licensing Committee meeting. Ms. Sodergren stated that it could be done as part of a committee meeting.

Chairperson Lippe stated that the board does not need legislation to require meetings to be held to review technician ratios.

Mr. Law asked if a change in technician ratios would require a statutory change. Ms. Freedman confirmed that a statutory change would be required.

Ms. Veale stated that the Licensing Committee is currently discussing technicians and will be discussing technician ratios in the future.

After discussion, the board decided that it does not need a mandate to review pharmacy technician ratios and did not take a position on the bill.

**Part 2: Regulations for Discussion and Consideration**

Ms. Sodergren stated that the proposed regulations to add Title 16 CCR section 1746.5

related to travel medications was resubmitted to the Office of Administrative Law (OAL) on April 21, 2017, and staff has asked for an immediate effective date upon approval.

Ms. Sodergren reported that the regulations to amend Title 16 CCR section 1760 related to the board's disciplinary guidelines was recently resubmitted to the Department for review.

Ms. Sodergren explained that the regulations to amend Title 16 CCR section 1707 related to offsite storage have recently been submitted to the Department for review.

Ms. Sodergren noted that board staff will continue to work with the Department and OAL to finalize the pending regulations.

The board adjourned to closed session at 1:16 p.m.

The board returned to open session at 2:02 p.m. President Gutierrez adjourned the meeting at 2:03 p.m.