



**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:** November 8-9, 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  
Victor Law, RPh, Vice President  
Allen Schaad, RPh, Treasurer  
Greg Lippe, Public Member  
Ricardo Sanchez, Public Member  
Deborah Veale, RPh  
Albert Wong, RPh  
Amjad Khan, Public Member

**BOARD MEMBERS  
NOT PRESENT:** Ryan Brooks, Public Member  
Valerie Muñoz, Public Member  
Lavanza Butler, RPh  
Stanley Weisser, RPh

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

**Call to Order**

**10:06 a.m.**

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

Vice President Victor Law called the meeting to order at 10:06 a.m. Board members present: Gregory Lippe, Albert Wong, Deborah Veale and Allen Schaad, Ricardo Sanchez and Victor Law.

Note: Amjad Khan arrived at 10:48 a.m. and President Gutierrez arrived at 1:00 p.m.

As a quorum of the board was not present Mr. Law explained that the board would take the agenda out of order to handle items that did not require action by the board.

## 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. Recognition and Celebration of Pharmacists Licensed by California for 50 Years

The board recognized Vito Fabrizio for 50 years of service as a pharmacist.

## IV. Legislation and Regulation Committee

Chairperson Lippe provided a summary of the committee meeting which had occurred immediately prior to the board meeting.

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

#### a. Board Sponsored Legislation

##### 1. Omnibus Provisions: SB 800 (Chapter 573, Statutes of 2017) Professions and Vocations, Including Changes to Pharmacy Law

Chairperson Lippe explained that SB 800 contains omnibus provisions for various programs within the Department of Consumer Affairs (DCA). Board specific provisions include:

- 013, Amend (d)(1) to add designated representative to the list of individuals who need to join the email subscriber list. 4
- 316, Clarify the board's authority to issue a cease-and-desist for unlicensed activity and that the issuing of the order will be delegated to the executive officer. 4

He added that the measure also repeals 4001.5, which established a requirement for the Joint Committee to review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage. Chairperson Lippe noted that the repeal was not board sponsored but rather was included by the Senate Business, Professions, and Economic Development Committee.

There were no comments from the board or the public.

##### 2. SB 351 (Chapter 623, Statutes of 2017) Hospital Satellite Compounding Pharmacy: License: Requirements

Chairperson Lippe reported that SB 351 creates options for hospitals that wish to obtain additional licenses from the board for purposes of providing pharmaceutical care. Specifically, the board can now issue hospital satellite compounding pharmacy licenses that will not need to be located in the acute care hospital building. He added that this measure also allows the board to issue a hospital pharmacy license that can be located outside of the general acute care hospital but in another physical plant regulated under the California Department of Public Health's hospital license.

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

3. SB 443 (Chapter 647, Statutes of 2017) Pharmacy: Emergency Medical Services Automated Drug Delivery System

Chairperson Lippe stated that SB 443 creates an option for county emergency medical services to restock ambulances through use of an emergency medical services automated drug delivery system (EMADDS) that is located within a county operated fire department. He added that as part of the measure, the board can issue a license for the use of the EMADDS as well as a license to a designated paramedic.

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

4. SB 510 (Chapter 649, Statutes of 2017) Pharmacies: Compounding

Chairperson Lippe explained that SB 510 repeals an outdated statutory requirement specifying the environments in which a pharmacy must compound sterile products.

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

5. SB 752 (Chapter 598, Statutes of 2017) Pharmacy: Designated Representative-Reverse Distributors

Chairperson Lippe reported that SB 752 establishes the creation of a designated representative-reverse distributor license and shortens the waiting period an applicant must wait to retake the pharmacist licensure examination to 45 days.

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

**b. Chaptered Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction with Board Established Positions**

1. AB 40 (Chapter 607, Statutes of 2017) CURES Database: Health Information Technology System

Chairperson Lippe explained that AB 40 requires the Department of Justice to make CURES available to a practitioner through either an online internet web portal or an authorized health information technology system, as defined. He noted that this measure included an urgency provision and took effect immediately upon signature of the governor.

2. AB 208 (Chapter 778, Statutes of 2017)) Deferred Entry of Judgment: Pretrial Diversion

Chairperson Lippe stated that AB 208 changes the deferred entry of judgment program to a pretrial program. It also expands the conditions under which someone is eligible for the program and reduces the conditions under which someone could be removed from the program. Chairperson Lippe stated that AB 208 reduces the length of the program compliance to six to 12 months and prohibits information sharing once someone is in the program.

Chairperson Lippe explained that the board's proposed amendments were secured that ensured that the board will have access to relevant information relating to the arrest and participation in the program.

There were no comments from the board or the public.

3. AB 401 (Chapter 548, Statutes of 2017) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy: Shared Clinics

Chairperson Lippe reported that AB 401 establishes regulatory framework for telepharmacy and establishes mandatory reporting by wholesalers of suspicious drug orders.

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

4. AB 602 (Chapter 139, Statutes of 2017) Pharmacy: Nonprescription Diabetes Devices

Chairperson Lippe stated that AB 602 requires pharmacies that dispense nonprescription diabetes test devices pursuant to a prescription to retain records; requires the board to post the names of authorized distributors of such test strips; and makes it unprofessional conduct for a licensee to seek reimbursement for such devices under specified conditions. He noted that this measure contained an urgency provision and took effect upon signature of the governor.

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

5. SB 17 (Chapter 603, Statutes of 2017) Prescription Drugs Costs

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.

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

6. SB 547 (Chapter 429, Statutes of 2017) Professions and Vocations

Chairperson Lippe reported that SB 547 allow the board to hire its own legal counsel.

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

The board's executive officer, Virginia Herold, thanked the authors of the board's bills and the legislative staff for working with the boards on amendments.

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

### **c. Board Adopted - Approved by the Office of Administrative Law Regulations to Amend and/or Add Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5, Related to Renewal Requirements**

Chairperson Lippe reported that effective January 1, 2018, these regulations will establish standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives. Additionally, sections 1702.1 and 1702.2 require pharmacy technicians and designated representatives to be fingerprinted as a condition of renewal if the Department of Justice does not have an electronic fingerprint record on file. He noted that section 1702.5 requires nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal.

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

**d. Board Adopted - Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law**

Anne Sodergren, the board's assistant executive officer, reported that the following regulations are pending review by either the department or OAL.

- Proposed Regulations to Amend Title 16 CCR Sections 1760, Related to the Board's Disciplinary Guidelines
- Proposed Regulations to Amend Title 16 CCR Sections 1749, Related to the Board's Fees
- Proposed Regulations to Add Title 16 CCR Sections 1715.65, Related to the Inventory Reconciliation Report of Controlled Substances

Board member Allen Schaad asked why the Disciplinary Guidelines regulation is still under review by the department. Ms. Sodergren agreed that this regulation has taken longer than usual partly due to OAL's disapproval. She provided a brief timeline for the regulation as provided below.

*Timeline*

- Approved by Board: July 29, 2015
- Rulemaking Initiated: September 4, 2015
- Adopted by Board: April 27, 2016
- Submitted to DCA: August 4, 2016
- Submitted to OAL: November 30, 2016
- Disapproved by OAL: January 13, 2017
- Modified Text Approved by Board: February 17, 2017
- Resubmitted to DCA: April 27, 2017

**e. Board Approved to Initiate Rulemaking - Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency, or Returned to Board Staff for Revisions Pursuant to Such Review:**

**1. Proposed Emergency Regulations to Amend Title 16 CCR Section 1735.2, Related to Compounding Beyond Use Dates**

Chairperson Lippe explained that this emergency regulation amends the board's regulation regarding the establishment of compounding beyond use dates as it relates to sterile and nonsterile compounding drug preparations.

Ms. Sodergren reported that the emergency rulemaking package was approved by the board on July 25, 2017, and was submitted to the department on August 15, 2017. She added that at this time it is still undergoing pre-notice review by the department.

Board member Debora Veale asked if this is an acceptable amount of time for a regulation to undergo pre-notice review. Ms. Herold responded that board staff does not find the department's timeline acceptable and the process is taking too long.

Ms. Veale asked if there is anything the board can do expedite the department's review. Ms. Herold stated that a meeting to discuss the issue has been scheduled with the Director of the department next week.

Mr. Lippe asked if the department is short staffed causing the delay in review. Ms. Herold responded that she is not aware of their staffing levels.

Daniel Martinez representing the California Pharmacists Association reported that the association has submitted a letter to the department explaining the urgency of the emergency regulation and asking the department to expedite the review of the emergency regulation. Ms. Herold thanked CPhA and agreed that the long review time undermines the board's determination that an emergency regulation is necessary for public protection.

2. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors

Chairperson Lippe explained that this regulation establishes the regulatory framework for third-party logistics providers.

Ms. Sodergren reported that the regulation package was returned by the department with recommended changes. She explained that staff is reviewing the proposed changes to determine the next course of action for this regulation package.

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

3. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Chairperson Lippe stated that this regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians. He added that it has been resubmitted to the department on August 23, 2017, for pre-notice review.

It was noted that the Licensing Committee is continuing to discuss pharmacy technician requirements and duties.

There were no comments from the public.

4. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

Chairperson Lippe stated that this regulation amends the board's regulations regarding the waiver requirements for offsite storage of records to allow those cited for a records violation to receive a waiver to store records off-site. He noted that the package was submitted to the department on April 27, 2017, for pre-notice review.

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

5. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Chairperson Lippe explained that this regulation amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride. He reported that the rulemaking package was submitted to the department on May 31, 2017, for pre-notice review.

6. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

Chairperson Lippe explained that this regulation amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

Ms. Sodergren noted that this rulemaking package has been returned by the department with proposed changes. She noted that board staff is reviewing the proposed changes to determine the next course of action for this regulation package.

**f. Board Approved to Initiate Rulemaking – Board Staff Drafting Rulemaking Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency**

1. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

Chairperson Lippe stated that this regulation establishes regulatory requirements for automated refill programs. He reported that board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

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

2. Proposed Regulations to Amend Title 16 CCR Sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, Related to Compounding

Chairperson Lippe explained that this regulation formally amends the board's regulations regarding the establishment of compounding beyond use dates as it relates to sterile and non-sterile compounded drug preparations. Additionally, this regulation allows for the use of a double filtration system. He noted that board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

**Part 3: General Committee Matters**

Chairperson Lippe reported the following committee meeting dates for 2018.

- January 17, 2018
- April 24, 2018
- July 10, 2018
- October 20, 2018

It was noted that October 20, 2018 is a Saturday, so a new date would need to be selected. Chairperson Lippe asked board staff to work with the committee members to find a new date.

## V. Executive Officer's Report

### a. **Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacist Licensure Examination (NAPLEX)**

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 CPJE statistical report for April 2017 through September 2017 reflects that the overall pass rate for the CPJE is 78.8 percent. The pass rate for graduates from the California schools of pharmacy is 91.0 percent. The overall pass rate for the NAPLEX is 93.3 percent.

### b. **Response to FDA's Guidance for Industry Titled "Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy"**

At the July Board Meeting, the board directed that a letter be sent in response to the FDA's new policy to delay for one year implementation of the product identifier requirements to implement the track and trace requirements for medications (from November 27, 2017 until November 17, 2018). The letter is being reviewed by Board President Gutierrez.

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

### c. **Update on the Executive Officer's Engagement at the Federal Level**

Ms. Herold reported that since the July Board Meeting, she has represented the board at the following meetings with national scope:

- *FDA 50-State Meeting on Compounding*: This was a two-day meeting in Washington DC where the FDA brought in the states to discuss compounding and outsourcing issues. I was asked to speak on how California regulates sterile compounding pharmacies and outsourcing facilities. I highlighted the fact that outsourcing facilities are not regulated as pharmacies by CA, how we deal with compounding for future furnishing and other related topics, and the EO's ability to issue cease and desist orders. I also met with the FDA staff that is implementing FDA's track and trace requirements.



- *National Association of Boards of Pharmacy Interactive Forum for Executive Officers:* This was a two-day meeting in Chicago to discuss national issues affecting pharmacy boards. I spoke as part of a panel on regulatory oversight following the North Carolina/FTC decision.
- *National Association of Boards of Pharmacy .Pharmacy (“dot pharmacy”) Executive Committee Meeting:* I serve as the regulatory board representative on this committee, which exists to establish use of a verified top-level domain to identify legitimate web sites for purchasing drugs from the 97 percent that are not legitimate. This was the only in-person meeting of this committee during the year.
- *Department of Public Health/CDC Meeting on Opioids:* CDPH Director Karen Smith invited me to attend this day long meeting in Sacramento with three CDC staff to discuss California’s approach and activities to address the opioid epidemic. It included grants provided by the CDC to CDPH for naloxone distribution, principally to northern CA counties.
- *American Society of Pharmacy Law:* Immediately before the board meeting I will attend this meeting, which addresses emerging pharmacy law issues.

The board thanked Ms. Herold for representing the board.

**d. Update on Opioid Training Provided to the Board’s Inspectors and Other Healing Arts Investigators**

Ms. Herold reported that in mid-October, board inspectors attended a two-day training session in Sacramento. Part of this training included a session on appropriate opioid prescribing presented by Scott Fishman, MD, a published pain management physician from UC Davis.

Ms. Herold reported that investigators from other Department of Consumer Affairs healing arts boards were invited, and a number of these investigators attended. Dr. Fishman provided an overview of the philosophy of pain management over the last decade and the philosophy today about prescribing these medications, including prescribing guidelines from the California Medical Board and the CDC.

The board asked that Dr. Fishman would write an article for *The Script*. Ms. Herold stated that she would ask Dr. Fishman.

**e. Update on the Joint DEA and Board of Pharmacy Training Events**

Ms. Herold reported that the board continues to offer its popular six-hour CE programs on prescription drug abuse. During these six-hour seminars, the following topics are discussed: common drugs of abuse, corresponding responsibility, preventing pharmacy thefts, drug take back programs, preparing for a board or DEA inspection and compliance with the Combat Methamphetamine Act. She added that pharmacists who are interested may stay for an additional hour to gain the certification necessary to provide naloxone.

Below are statistics on the events.

Date	Location	Attendance: 6 Hour Program	Attendance: Naloxone Training
8/26/17	Northstate University School of Pharmacy	160	125
10/21/17	KGI School of Pharmacy	128	116

Ms. Herold reported that the evening of November 7, 2017, the board offered a three-hour presentation in conjunction with a two-day prescription drug abuse conference convened by the California Opioid Policy Summit that includes several sponsors, including the DEA and the Department of Public Health. She noted that 175 licensees attended the event and 150 of them stayed for the Naloxone training.

Ms. Herold stated that board staff will be hosting seven-hour event in San Francisco at UCSF on January 27, 2018. She added that details are being finalized as this packet is being prepared, and an alert will be released announcing the training after the board meeting.

#### **f. Federal Re-evaluation of the Distribution of Controlled Substances**

Ms. Herold explained that in recent weeks, there have been a number of announcements involving the regulation of controlled substances over the last years.

*From the New York Times:*

On October 16, 2017, President Trump directed the Department of Health and Human Services to declare the [opioid crisis](#) a public health emergency, an action to address a rapidly escalating epidemic of drug use. However, he did not declare “a national emergency” on opioids, which would have prompted the rapid allocation of federal funding to address the issue.

*Among the President’s statements:*

“No part of our society — not young or old, rich or poor, urban or rural — has been spared this plague of drug addiction and this horrible, horrible situation that’s taken place with opioids”

“This epidemic is a national health emergency.”

Ms. Herold explained that according to media reports, the result of this declaration is that this will allow for some grant many to combat opioid abuse, permit the hiring of specialists to tackle the crisis, and expand the use of telemedicine services to treat people in rural areas where doctors are in short supply. Additional federal plans linked to the announcement include a policy to develop nonaddictive painkillers and efforts to stop shipments of fentanyl. However, the declaration does not link substantial increases in federal funding that some had hoped for, nor seek out government pressure to make naloxone available at lower prices.

Ms. Herold stated that meanwhile, some in Congress are reconsidering repeal of a 2016 law that made it substantially more difficult for the DEA to issue what amounts to suspension orders to

drug wholesalers when excessive/suspicious opioid sales to pharmacies are detected. The issues involving enactment of this law were highlighted in a recent Washington Post series and 60 Minutes segment that were based on the report of former head of DEA's Office of Diversion Control Joe Rannazzisi.

Ms. Herold explained that the new law limited the ability of the DEA to issue suspension orders to freeze drug shipments where the agency determined the shipments posed an imminent danger. Instead the standard was converted to "a substantial likelihood of an immediate threat," a much higher standard. She noted that the debate over the law and enactment occurred during a time when deaths due to opioid overdoses were escalating.

**Note:** The Washington Post article may be found using the following link:  
[https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm\\_term=.d8ac603c2b6c](https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.d8ac603c2b6c)

The board asked what action is taken when a pharmacy is suspected of dispensing too many controlled substances. Ms. Herold explained that an investigation would be conducted and if appropriate an accusation would be filed with the attorney general and disciplinary action would be taken.

**Note:** Board member Amjad Khan arrived at 10:48 a.m.

#### **g. Board's Response to the State of Emergency Declared by Governor Brown Due to Multiple Wildfires**

Ms. Herold reported that in early October, California was burning from a number of wildfires scattered throughout the state. Thousands of people were relocated to emergency shelters, in some cases in the middle of the night.

Ms. Herold explained that as the Governor issued state of emergency declarations, the board issued two subscriber alerts (October 9 and 16) to remind pharmacies and pharmacists how they could assist patients who sought emergency supplies of medications they could no longer access.

Ms. Herold reported that the board also issued three temporary licenses to pharmacies that were affected by the fires. She noted that the board was not advised of any destroyed pharmacies.

The board asked the Communication and Public Education Committee to look at additional ways by which the board can provide emergency information to licensees.

#### **h. Personnel Update**

Ms. Herold provided a brief personnel update as proved below.

##### *Recent Hires/Transfers/Promotions*

- Taydene Dalrymple was promoted to a SSM I over the Complaint Unit.
- Debi Mitchell was promoted to a SSM II over the Licensing and Administration.
- MaryJo Tobola was hired as the SSM II over the Enforcement, Complaint, and Criminal

Conviction units.

- Sheri Ross-Hustana joined the board as an Inspector on SI Hunt’s Compliance team.
- Louisa Tsoi joined the board as an Inspector on the Prescription Drug Abuse team.
- Lyle Matthews joined the board as an Inspector on the Compliance team.
- Sidney Truong joined the board as an Inspector on the Outsourcing team.
- Kevin Dong joined the board as an Inspector on the Compounding team.

*Departures*

- Veronica Wogec, SSM II, left the board in July.
- Trish Rodriguez, SSM II, left the board in September.

*Recruitments Underway*

- One SSM I for Licensing.
- One AGPA for Enforcement.
- One AGPA for Sterile Compounding in Licensing.
- One AGPA for the Prescription Drug Abuse Prevention Team in the Complaint Unit.
- One Office Technician in Enforcement.

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

**VI. Approval of the July 25-26, 2017 Board Meeting Minutes**

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

**Motion:** Approve the July 25-26, 2017, board meeting minutes.

**M/S:** Lippe/Schaad

Support: 6      Oppose: 0      Abstain: 1

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

**VII. Approval of the September 19, 2017 Teleconference Board Meeting Minutes**

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

**Motion:** Approve the September 19, 2017, board meeting minutes.

**M/S:** Lippe/Veale

Support: 7      Oppose: 0      Abstain: 0

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

**VIII. Approval of the September 28, 2017 Board Meeting Minutes**

Ms. Veale noted that she needs to be listed as being present on the first page of the minutes. There were no comments from the public.

**Motion:** Approve the September 28, 2017, board meeting minutes with the correction to the first page of the agenda adding Ms. Veale to the list of board members present at the meeting.

**M/S:** Lippe/Veale

Support: 7      Oppose: 0      Abstain: 0

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

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

Director Dean Grafilo reported that former Deputy Director of Board and Bureau Relations, Christine Lally, has taken a position at the California Medical Board.

Mr. Grafilo introduced the following new executive staff.

- Christopher Shultz, Chief Deputy Director
- Christopher Castrillo, Deputy Director, Board and Bureau Services
- Natalie Daniel, Deputy Director, Administrative Services

Mr. Grafilo reported that he will be holding annual meetings with all of the DCA Board Presidents in addition to the quarterly Director Meetings.

Christopher Castrillo stated that he is looking forward to working with the board on providing excellent customer service and consumer protection. He reported funding has been reallocated to add additional staff to Board and Bureau Relations Office to expand the services offered to the boards and bureaus.

Board member Schaad expressed frustration with the amount of time regulations take to be approved by the department. Mr. Castrillo responded that they would be reviewing the processes to find ways to streamline the process. The board thanked Mr. Castrillo for looking into the issue and asked that he work with board staff and the board president as needed.

**X. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR Section 1735.2 Related to the Compounding Self-Assessment Form 17M-39 and Proposed Regulations to Amend Title 16 CCR Sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26**

Ms. Sodergren explained that the purpose of a self-assessment is to promote compliance of businesses regulated by the board through self-examination and education. Because the self-assessment forms are compilations of Pharmacy Law, modification must be made on an annual basis to incorporate changes in the law. She further noted that because of the mandate for licensees to complete the forms no later than July 1 of each odd-numbered year, it is necessary to update the forms and complete the rulemaking process within a very narrow time period.

Ms. Sodergren reported that because the timeframe to promulgate a regulation is generally at least 12 months, the current versions of the forms were not promulgated in sufficient time to ensure changes to Pharmacy Law are captured.

Ms. Sodergren stated that to address this issue, board staff and DCA legal staff worked to develop a new streamlined process for updating the self-assessment forms.

Ms. Sodergren explained that currently the self-assessment form is incorporated by reference. The form itself contains the essential elements inherent within the regulation (e.g. name, signature, certification under penalty of perjury, etc.). She explained that this means that *any* change to the self-assessment form must be done through the rulemaking process.

Ms. Sodergren stated that staff is proposing an alternative that will instead detail all the essential elements of the form in the regulation itself. She explained that this new format will allow the annual updates in pharmacy law to be done through the streamlined Section 100 change process.

Ms. Sodergren noted that the language for the proposed regulation was provided in the board meeting materials.

Board member Veale asked if the board would have to go through the full rulemaking process to update the regulation language as provided in the meeting materials. Ms. Sodergren explained that the first time the board would have to go through the entire regular rulemaking process in order to incorporate the essential elements of the form (i.e. name, signature, certification under penalty of perjury, etc.) into the regulation. Subsequent changes to the self-assessment forms would then be done through the streamlined Section 100 process.

Ms. Freedman stated that under the existing regulation the board has incorporated the self-assessment form by reference. She explained that every time you update a form that is incorporated by reference you have to go through the entire rulemaking process. She noted that the proposal being brought before the board will incorporate the substantive requirements of the self-assessment form into the regulation text.

Ms. Veale spoke in support of the concept and asked if the same process could be used for other forms such as the pharmacy technician application. Ms. Freedman responded that board staff will continue to look for other areas that this same process can be utilized. She noted that the board used this process for the drug-take-back forms.

**Motion:** Initiate the formal rulemaking process to amend the text of Title 16 CCR Sections 1715, 1735.2 and 1784 relating to self-assessment form requirements as proposed and authorize the Executive Officer to make any clarifying changes consistent with the board’s policy to the rulemaking package, and provide a 45-day public comment period.

**M/S:** Veale/Lippe

Support: 7      Oppose: 0      Abstain: 0

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

The board recessed for a break at 12:30 p.m. and resumed at 1:35 p.m.

**Note:** President Gutierrez arrived at 1:00 p.m.

## **XI. Licensing Committee**

President Gutierrez provided a summary of the committee's efforts at the August 22, 2017, and October 27, 2017, meetings in Chairperson Weisser's absence.

### **a. Discussion and Consideration of Licensing Requirements of an Advanced Pharmacy Technician (APT)**

President Gutierrez reported that the Licensing Committee is offering recommendations to the board to establish an advanced pharmacy technician license. This recommendation comes after two meetings where the committee discussed the concept as well as the framework. As part of the development of the proposal, the committee focused on how such a framework would benefit consumers. President Gutierrez explained that the committee believes that the primary benefit in creating this new category of licensure would be to allow a pharmacist to be redirected to provide more direct patient care activities, including increasing pharmacist interaction with consumers while an advanced pharmacy technician is redirected to perform specific duties.

President Gutierrez explained that in general, the provisions create a definition of an advanced pharmacy technician to include "an individual licensed by the board who is authorized to perform technician pharmacy tasks as authorized in BPC Section 4115.6..." She added that an APT is also authorized to perform any of the duties of a pharmacy technician.

President Gutierrez reported that in addition to the proposed definition, the committee considered the appropriate minimum requirements for licensure. She stated that after discussion and consideration at two meetings, the committee is recommending the following general criteria for licensure:

1. Hold an active pharmacy technician license; and
2. Possess certification by a pharmacy technician certifying program (e.g. PTCB or ExCPT); and
3. Obtain a minimum of an AA degree in pharmacy technology, or a bachelor's degree, or completion of a training program approved by the board; and
4. Have 3,000 hours of pharmacy technician experience.

**OR**

5. Graduate from a school of pharmacy.

President Gutierrez stated that the committee is also offering a recommendation to establish the renewal requirements including:

1. Twenty hours of continuing education, including two hours of education in medication error prevention and two hours of board sponsored law and ethics education.
2. Maintain certification by a pharmacy technician certifying program.

President Gutierrez reported that as part of its discussion the committee considered the current marketplace but also anticipated progression in the pharmacy profession, including the expanded roles pharmacists have in providing direct patient care. The committee noted the



importance of identifying duties that can be performed by other pharmacy personnel that possess appropriate training and education. President Gutierrez noted that based on articles and position statements, it is clear that nationally there is recognition that pharmacy operations need to change to allow for this direct patient care by pharmacist.

President Gutierrez explained that the committee's recommendation takes a similar approach to the advanced practice pharmacist legislation enacted through Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013). Such an approach allows for more a more robust reassignment of duties that do not require professional judgment and addresses liability concerns expressed by the committee. She added that this approach is flexible and will allow for an easy response to a dynamic marketplace, will allow for appropriate tools for the board to meet its consumer protection mandate, will allow PICs to decide if they will use the proposed authorized duties for ATPs, and will allow pharmacy technicians to continue functioning in their current capacity if they so choose.

President Gutierrez explained that the committee is providing recommendations that would facilitate the creation of an advanced pharmacy technician licensing category. As part of the recommendation, the committee is offering several motions. She noted that the committee is seeking policy guidance from the board on the item below:

- Does the board believe it is appropriate to create two separate licensure categories for the advanced pharmacy technician, one focused on the community/ambulatory care pharmacy and a second focused on the inpatient pharmacy?

The board agreed that having two separate licensure categories for APTs is appropriate.

President Gutierrez reviewed the three committee recommendations (motions) as provided below.

Committee Recommendation (Motion): Pursue statutory change to add the definition of an advanced pharmacy technician.

Committee Recommendation (Motion): Pursue statutory change to add the licensing requirements for an advanced pharmacy technician.

Committee Recommendation (Motion): Pursue statutory change to establish the renewal requirements for an advanced pharmacy technician.

Board member Law suggested that the board create a standardized exam that APT applicants must pass prior to licensure to ensure that there is a common knowledge base for APTs. Board member Lippe and President Gutierrez agreed with this recommendation.

Board member Veale stated that requiring applicants to pass the PTCB and maintain their certification is a way of ensuring standardized knowledge.

President Gutierrez expressed concern that pharmacy technicians can pass the PTCB without actually having any experience in pharmacy. She explained that this makes her wonder how difficult the PTCB exam is.

Board member Schaad stated that he likes the idea of the exam. However, he is concerned that logistically it will be difficult for the board to accomplish.

Ms. Veale stated that she is concerned that an additional exam will create a barrier to entry for APTs. Mr. Lippe stated that consumer protection is the board’s mandate.

President Gutierrez asked if the board agreed with the committee’s recommendation to pursue statutory changes to add the definition of an APT. The board agreed with the committee recommendation.

There were no comments from the public.

**Committee Recommendation (Motion):** Pursue statutory change to add the definition of an advanced pharmacy technician (as provided below).

*Proposed BPC 4038.5 (Definition)*

“Advanced Pharmacy Technician” means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.6. Such an individual may also perform nondiscretionary tasks as specified in Section 4115.

Support: 8    Oppose: 0    Abstain: 0

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

President Gutierrez next asked the board to consider the committee’s recommendation outlining the requirements for APTs as provided below.

1. Hold an active pharmacy technician license; and
2. Possess certification by a pharmacy technician certifying program (e.g. PTCB or ExCPT); and
3. Obtain a minimum of an AA degree in pharmacy technology, or a bachelor’s degree, or completion of a training program approved by the board; and
4. Have 3,000 hours of pharmacy technician experience.

**OR**

5. Graduate from a school of pharmacy.

Mr. Law asked the board to add the requirement to pass a comprehensive board exam prior to licensure.

Angie Manetti representing the California Retailer Association (CRA) spoke in support of the requirements developed by the licensing committee. She asked to change the 3,000 hours of experience to 1,500 hours. Board members did not support reducing the experience hours as they feel that 3,000 hours is an appropriate amount of experience for an ATP in order to protect consumers.

Ms. Manetti stated that CRA would not support a board exam as it would create a barrier to licensure.

Ms. Veale asked if a board exam would really be appropriate as the ATP applicants would have already completed a training course or earned a college degree. She suggested only requiring the exam for applicants who earned a college degree in an area not related to pharmacy (i.e. business degree).

Pharmacist Robert Stein spoke in support of the board exam and 3,000 experience hours.

President Gutierrez expressed concern that the creation of the APT license will not actually lead to more direct pharmacist patient care. She stated that she is concerned that the APT will simply be used to increase the pharmacy's bottom line profit.

Mark Johnson, representing CVS Health, stated that creating a psychometrically sound exam is very expensive.

Ms. Veale asked Mark Johnson if in Idaho they have to pass a board test. He responded that they do not take board exam; they just have to pass the PTCB prior to licensure.

Ms. Veale asked Mr. Johnson if Idaho requires any experience. He explained that Idaho originally required 2,000 hours but they have since eliminated that requirement. President Gutierrez asked if a technician in Idaho could pass the PTCB and be licensed without having any experience in a pharmacy. Mr. Johnson confirmed.

A pharmacy technician stated she wouldn't feel comfortable performing the duties of an ATP after just passing the PTCB. She stated that there should be a requirement to prove an applicant is capable of actually performing the duties required.

Daniel Martinez representing CPHA spoke in support of lowering the number of experience hours to 1,500. Mr. Martinez stated that studies have shown that when a pharmacist has extra time they do more consultations and direct patient care.

Mr. Lippe suggested changing the requirement to 1,500 general pharmacy experience hours and 500 experience hours in the APT duties.

A representative from Walgreens explained that in Idaho if a technician is going to be doing advanced duties such as immunizations, he or she must complete specific training in that area.

Dennis McAllister noted that in military hospitals pharmacy technicians already do these advanced duties successfully.

Mr. McAllister speaking as an Arizona Board of Pharmacy Member stated that in Arizona they use “technology assisted product validation” to validate everything that a technician does. He added that Texas and Wisconsin will also begin using this technology to free pharmacist time to provide more direct patient care.

Mr. Sanchez left the room at 2:24 p.m.

**Committee Recommendation (Motion):** Pursue statutory change to add the licensing requirements for an advanced pharmacy technician (as provided below).

*Proposed BCP 4211 (Licensing Requirement)*

(a) The board may issue an advanced pharmacy technician license to an individual who meets all the following requirements:

- (1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing,
- (2) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
- (3) Has obtained a minimum of an associate’s degree in pharmacy technology, obtained a bachelor’s degree, or higher or completed a board approved training program.  
Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a pharmacy.

(b) As an alternative to the requirements in subdivision (a), has graduated from a school of pharmacy recognized by the board.

(c) A license issued pursuant to this section shall be valid for two years.

Support: 0    Oppose: 7    Abstain: 0

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

The board discussed the need to add a standardized board exam as a requirement for licensure.

Mr. Lippe asked if the board should change the requirement to require that a certain number of experience hours are earned doing “advanced” duties. Ms. Herold responded that from an enforcement perspective that would be difficult to verify and monitor.

Board member Wong suggested changing the requirements to allow the applicant to choose between completing a certification program *or* earning a college degree.

Ms. Veale again stated that she does not feel an additional board exam is necessary as the applicant would have already had to complete examinations as part of a certification program or college degree.

A professor from Cerritos Community College spoke in support of requiring a college degree for APT licensure. She also stated any student that earned a degree from an ASHP accredited school would have completed a final comprehensive examination prior to obtaining their degree.

**Note:** Board member Sanchez returned at 2:43 p.m.

A pharmacy technician spoke in support of completing an AA degree and a board exam that covers the specific duties of an APT.

Angie Manetti from CRA stated that the association would oppose adding a board exam.

Daniel Martinez representing CPHA also spoke in opposition to adding an exam.

Mark Johnson, representing CVS Health, again stated that creating a psychometrically sound exam is very expensive. Ms. Herold noted that the board staff would determine if there are ways to create a valid exam at a lower cost. She also added that an APT exam would be far less complex than the pharmacist licensure exam.

Megan Paige with the California Society of Health System Pharmacists stated that their association does not have a position on the board's proposal, however they are supportive of the board creating requirements that ensure that quality applicants are licensed as APTs.

The professor from Cerritos Community College suggested that the board exam be designed to test specifically for APT duties.

**Motion:** Pursue statutory change to add the licensing requirements for an advanced pharmacy technician with the addition of a standardized board exam (as provided below).

Proposed BCP 4211 (Licensing Requirement)

(a) The board may issue an advanced pharmacy technician license to an individual who meets all the following requirements:

- (1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing,
- (2) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).
- (3) Has obtained a minimum of an associate's degree in pharmacy technology, obtained a bachelor's degree, or higher or completed a board approved training program.
- (4) Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a pharmacy.
- (5) Has passed an advanced pharmacy technician examination.

(b) As an alternative to the requirements in subdivision (a), has graduated from a school of pharmacy recognized by the board.

(c) A license issued pursuant to this section shall be valid for two years.

**M/S:** Law/ Gutierrez

Support: 6    Oppose: 2    Abstain: 0

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

Mr. Schaad stated that the board should create separate license types for APTs working in community pharmacies and hospital pharmacies as the duties in each setting are very different.

Daniel Martinez representing CPhA stated that the only concern with creating two license types would be creating a possible barrier to entry and noted that the board would need to ensure the licensure requirements are equal.

**Motion:** Create separate license types for community pharmacy advanced pharmacy technicians and hospital advanced pharmacy technicians.

**M/S:** Schaad/Lippe

Support: 8    Oppose: 0    Abstain: 0

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

The board took a break at 3:00 p.m. and resumed at 3:18 p.m.

**b. Discussion and Consideration of the Duties an APT May Perform in a Traditional Community Pharmacy Setting and Proposed Pharmacy Requirements for Patient Care Services**

President Gutierrez reported that as part of the development of the APT provisions, the committee discussed the scope of practice of an individual granted licensure as an APT. The committee discussed the duties currently authorized by law for all pharmacy technicians to perform and noted that all such nondiscretionary duties must be completed under the direct supervision and control of a pharmacist.

President Gutierrez stated that the committee reviewed a proposal to establish the scope of practice for an APT in the community/ambulatory care pharmacy setting. She added that the committee considered various articles related to the topic, including one regarding accepting verbal prescriptions and prescription transfers as well as the outcomes of a Drake University study regarding a “Tech-Check-Tech” program in community pharmacies.

President Gutierrez explained that after discussion and hearing public comments, the committee voted to pursue a statutory change to establish duties that an APT may perform in a community/ambulatory care pharmacy:

1. Verify the accuracy of a typed prescription label and ensure the label accurately reflects the container’s contents for a drug order.
2. Accept new orders and seek clarification on prescriptions from a prescriber’s office, as specified, including inquiring about the intended purpose or indication for a prescribed medication.
3. Inquire about the intended purpose or indication of the medication from the prescriber’s office.
4. Transfer prescriptions.
5. Receive a transferred prescription.
6. Perform the technical task of vaccine administration.
7. Compile patient medication lists.

Mr. Law asked stated that he would not want an APT to accept new orders from a prescriber’s office.

President Gutierrez stated that “seeking clarification on a prescription” seems vague. Ms. Sodergren explained that the actual proposed language states that the APT can “seek clarification about a prescription from a prescriber’s office unless the prescription requires the professional judgment of a pharmacist.”

Ms. Veale stated that she is comfortable with the APT accepting new orders because the pharmacist still must verify the medication is correct. Ms. Herold added that the APT will also inquire about the purpose of the medication so that the pharmacist can use the information to verify that the medication is correct.

Dr. Wong stated that he would not want an APT taking a new controlled substance prescription over the phone because it will lead to more diversion. Ms. Herold agreed that this is a risk that the board should consider. He added that as a pharmacist he would not be comfortable using an APT because it may put his license at risk. Ms. Veale noted that the APT will also be held responsible for his or her actions.

Dr. Wong stated that a pharmacist may want to record the calls so that the pharmacist can review the call if he or she thinks an APT made an error.

Mr. Lippe stated that if the board removes the duty of taking new prescriptions over the phone there will not be many benefits to having an APT license. Dr. Gutierrez agreed and stated that part of the reason the board will be creating an exam is to ensure that they can perform these duties.

A pharmacy technician stated that if she got a phone call for a new prescription and she was not given the purpose of the medication or was not familiar with the medication, she would seek clarification from the pharmacist, especially if her license was going to be held responsible.

Robert Stein, pharmacist, stated that federal law prohibits anyone other than a pharmacist from taking a controlled substance prescription or transferring a controlled substance to another pharmacy. The board's legal counsel stated that they believe Mr. Stein is correct but would research the issue and provide staff with the information to use while refining the language.

Mark Johnson representing CVS stated that 19 other states allow technicians to take new prescriptions over the phone without any problems.

Mr. Law clarified that in order to administer a vaccination the APT must complete the required training. Mr. Johnson stated that in Idaho they created a pharmacy technician specific immunization training.

President Gutierrez stated that the board should require that the immunization should only be given by an APT under the supervision of pharmacist who has been trained in immunization.

Mary Staples from NACDS asked the board to add an additional duty for APTs. She asked that APTs be allowed to perform other technical tasks such as taking a patient's blood pressure or temperature. The board agreed with this recommendation.

**Motion:** Pursue statutory change to add the duties of an advanced pharmacy technician as provided below. Delegate authority to staff to further refine the language as needed based on the board's discussion and legal review.

*Proposed 4115.6*

- (a) In a pharmacy as defined in Business and Professions Code Section 4037, a licensed advanced pharmacy technician may perform these technical tasks:
- (1) Verify the accuracy of the typed prescription label and verify the filling of a prescription container by confirming that the medication and quantity reflected on the label accurately reflects the container's contents for drug orders that previously have been reviewed and approved by a pharmacist. A pharmacist is responsible for performing all reviews and verification requiring professional judgement including drug utilization review.
  - (2) Except for controlled substances, accept new or seek clarification about a prescription from a prescriber's office unless the prescription requires the professional judgment of a pharmacist.



- (3) Inquire about the intended purpose or indication for prescribed medication on verbal orders received from a prescriber's office.
- (4) Except for controlled substances, transfer a prescription to another pharmacy.
- (5) Receive the transfer of a prescription from another pharmacy.
- (6) Provide the technical task of administration of an immunization under the supervision of a pharmacist trained in immunizations.
- (7) Compile a medication list by interviewing patient.
- (8) Perform other technical tasks including taking patient's blood pressure or temperature.

M/S: Veale/Gutierrez

Support: 8    Oppose: 0    Abstain: 0

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

President Gutierrez reported that the committee also discussed how the proposed new duties would impact pharmacy services and the conditions that must be satisfied for an APT to perform such duties. As part of its discussion, the committee discussed how the proposal would benefit consumers and requirements that a community/ambulatory care pharmacy must fulfill to allow for the use of the APT, with the ultimate goal of increased patient access to pharmacists and clinical services.

President Gutierrez explained that after discussion and consideration, the committee voted to recommend a statutory change to include that a community/ambulatory care pharmacy using an APT must ensure:

- (b) A pharmacy as used in subdivision (a) may use the services of an advanced pharmacy technician if all the following conditions are met:
  - (1) The duties authorized in subdivision (a) are performed under the supervision of a pharmacist and are specified in the pharmacy's policies and procedures.
  - (2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).
  - (3) A pharmacist shall personally provide all new prescription medications directly to the patient or patient's agent, and must provide patient information consistent with the provisions of Section 4052 (a) (8) or other clinical services.
  - (4) A pharmacist shall provide other clinical services
  - (5) A record is created identifying the personnel responsible for the preparing and dispensing of the prescription medication.

Mr. Law stated that he would like to see pharmacists hand the patient *all* prescriptions, not just new prescriptions.

Ms. Veale stated that nothing prohibits the pharmacist from handing out all prescriptions, but she would not like to make it a requirement that they do so. Mr. Johnson from CVS stated that he would not support requiring the pharmacist to physically hand patients *all* prescriptions.

President Gutierrez asked what “other clinical services” would be. Ms. Sodergren explained that this was added to try to capture the fact that the use of the APT is intended to free up a pharmacist’s time so that the pharmacist can provide direct patient care. President Gutierrez recommended changing the language to read as follows. The board agreed with President Gutierrez’s recommendation.

(6) A pharmacist shall provide other clinical services beyond required consultation.

**Motion:** Pursue statutory change to establish the conditions that must be met for a community/ambulatory care pharmacy to use an APT as provided below. Delegate authority to staff to further refine the language as needed based on the board’s discussion.

(b) A pharmacy as used in subdivision (a) may use the services of an advanced pharmacy technician if all the following conditions are met:

- (1) The duties authorized in subdivision (a) are performed under the supervision of a pharmacist and are specified in the pharmacy’s policies and procedures.
- (2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).
- (3) A pharmacist shall personally provide all new prescription medications directly to the patient or patient’s agent, and must provide patient information consistent with the provisions of Section 4052 (a) (8) or other clinical services.
- (4) A pharmacist shall provide other clinical services beyond required consultation.
- (5) A record is created identifying the personnel responsible for the preparing and dispensing of the prescription medication.

**M/S:** Veale/Lippe

Support: 8    Oppose: 0    Abstain: 0

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

**c. Discussion and Consideration of the Employment of APTs in a Closed-Door Pharmacy Which Provides Pharmacy Services for Patients of Skilled Nursing and Long-Term Care Facilities and Proposed Pharmacy Requirement for Patient Care Following Discharge**

President Gutierrez reported that during prior committee meeting discussion, the committee considered the possible role an APT could play in a closed-door pharmacy and how consumers would benefit from such changes. The committee discussed what constitutes a closed-door pharmacy and noted that in a closed-door pharmacy, there is different patient interaction. President Gutierrez noted that the committee discussed an example of a patient being discharged from a hospital to a skilled nursing facility, where a pharmacy is providing medications but does not provide patient consultation.

President Gutierrez explained that the committee noted that patients might benefit from patient consultation upon discharge from a skilled nursing facility and has asked that the Communication and Public Education look at patient consultation in closed door pharmacies.

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

**d. Discussion and Consideration of the Employment of APTs in Inpatient Hospital Pharmacies**

President Gutierrez stated that the committee briefly considered the role an APT could play in an inpatient hospital and the resulting benefits to consumers.

President Gutierrez explained that the committee deferred much of its discussion to action on a recommendation related to APTs in an inpatient hospital and will await guidance from the board on the possible creation of an APT for the inpatient hospital. In addition, the committee requested information from stakeholders of possible duties an APT could perform in the setting.

President Gutierrez stated that the committee will resume its discussion during the next committee meeting.

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

**e. Discussion and Consideration of Application and Renewal Requirements for Pharmacy Technicians**

President Gutierrez stated that in prior meetings, the committee has considered the current renewal requirements for all pharmacy technicians. During its April 2017 meeting, the committee questioned if continuing education should be required as a condition of renewal.

President Gutierrez explained that as part of its discussion, the committee contemplated if such a requirement would become a hurdle to renewal. She stated that the committee was advised by the public that given the availability of courses, many of which can be done online or at no cost, such a requirement would not be a hurdle.

President Gutierrez stated that the committee briefly considered if inclusion of a continuing education requirement as a condition of renewal for a pharmacy technician license was necessary and they decided such a requirement was not necessary.

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

#### **f. Licensing Statistics**

President Gutierrez briefly reviewed the statistics as proved below. There were no comments from the board or from the public.

##### Licensing Statistics for July 1, 2017 – September 30, 2017

During this time the board has received 4,712 applications, including:

- 1,267 intern pharmacists.
- 539 pharmacist exam applications.
- 67 advanced practice pharmacists.
- 1,299 pharmacy technicians.
- 3 nonresident outsourcing facilities.
- 106 temp licenses for various business licenses.

As of September 30, 2017, the board has issued 4074 licenses, renewed 15,944 licenses and has 140,066 active licenses, including:

- 6,778 intern pharmacists.
- 45,677 pharmacists.
- 173 advanced practice pharmacists.
- 72,413 pharmacy technicians.
- 6,583 pharmacies.
- 477 hospitals and exempt hospitals.
- 6 nonresident outsourcing facilities.

#### **g. Future Committee Meeting Dates**

President Gutierrez announced the future Licensing Committee meeting dates below.

- January 16, 2018
- April 19, 2018
- June 26, 2018
- September 26, 2018

## **XII. Organizational Development Committee**

### **a. Discussion and Consideration of Proposal to Amend BPC Section 4400 to Require Collection of Application and Renewal Fees for Government-Owned Facilities**

President Gutierrez reported that during the last legislative session, the board sponsored legislation that established new licensure programs for the restocking of emergency medications on ambulances. There were fees established for the new programs and included in the fees as an exemption for government-owned automated drug delivery systems. She explained that the Department of Finance asked why the board was exempting fees for government-owned drug delivery systems. In efforts to remove the opposition of the Department of Finance, the board removed the government exemption for licensure fees from SB 443. Board staff also committed to seek the removal of all exemptions for government

owned facilities in our act. President Gutierrez noted that other agencies, such as the Department of Public Health do not exempt government-owned facilities from licensure fees.

President Gutierrez explained that approximately 600 government owned site licenses will be affected by the repeal of the fee exemption for government-owned facilities, which will increase board revenue by \$390,00 annually.

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

**Motion:** Remove the fee exemption for government-owned site licenses.

**M/S:** Lippe/Law

Support: 7 Oppose: 0 Abstain: 0

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

**b. Budget Update/Report**

1. Final Budget Report for Fiscal Year 2016/2017

President Gutierrez stated that Fiscal year 2016/2017 ended on June 30, 2017. However, the final FY 2016/2017 numbers were not available at the July Board Meeting, therefore the information is being provided at this meeting. The final budget information for FY 2016/2017 is summarized below.

President Gutierrez explained that the board received \$20,323,700 in revenue originating from the following:

Revenue Sources		
Source	Amount	Percentage
Licensing	\$16,930,200	83%
Citation Fines	\$2,094,300	10%
Cost Recovery	\$1,204,300	6%
Interest	\$94,900	1%

President Gutierrez reported that the board expended \$21,643,938, which is approximately 97% of its authorized budget. The largest expenditure categories are detailed below.

Expenditures		
Source	Amount	Percentage
Personnel	\$13,556,431	63%
Enforcement	\$3,711,060	17%
Prorata	\$2,529,354	12%

## 2. Budget Report for Fiscal Year 2017/18

President Gutierrez reported that the new fiscal year started July 1, 2017. The board's authorized expenditures for the year are \$22,317,000.

President Gutierrez stated that in July 2017, the Department transitioned to a new statewide Accounting and Budgeting system known as Fi\$Cal. The Department went "live" in the Fi\$Cal system on July 10, 2017.

President Gutierrez explained that as with any type of significant change or transition to a new system, there have been unexpected challenges and hurdles to overcome during implementation. As a result, expenditure and revenue reports have proved difficult to extract from the system and has caused a delay in the Department being able to provide this information to boards and bureaus. According to the Department it is expected that the issues will be resolved in early November and the revenue and expenditure reports for the first three months of Fiscal Year 2017/2018 will be provided to the board at that time.

Board staff stated that they will review the budget reports to verify that the new Fi\$Cal system is accurately capturing the board's revenue and expenditures. The budget information for Fiscal Year 2017/2018 will be provided at the next board meeting.

## 3. Fund Condition Report

President Gutierrez stated that the information below was prepared by the department's budget office and reflects the estimated fund condition as of October 24, 2017.

Fund Condition: With Fee Increase Effective July 1, 2017		
Fiscal Year	Fund Balance	Months in Reserve
2016/2017	\$8,084,000	4.1
2017/2017	\$9,838,000	4.9
2018/2019	\$11,258,000	5.5
2019/2020	\$12,226,000	5.9

President Gutierrez explained that the proposed FY 2018/2019 Governor's Budget will be released in January 2018. The Governor's Budget will include incremental changes to the board's authorized expenditures for items such as employee compensation, approved budget change proposals, etc. She noted that board staff will provide an updated fund

condition reflecting the changes in the 2018/2019 Governor’s Budget at the next board meeting.

**c. Board Member Reimbursement Information**

President Gutierrez stated that board members may seek reimbursement for travel 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 also stated that these figures only represent hours and travel expenses where reimbursement was sought. It is not uncommon for board members to waive their per diem payments or only request partial reimbursement of travel expenses. President Gutierrez noted that the reimbursements figures are available for review in the board meeting materials.

**d. Board Member Attendance Information**

President Gutierrez stated that board member attendance statistics were provided in the board meeting materials for review.

**e. Future Meeting Dates**

President Gutierrez reported that following futures board meeting dates. It was noted that board staff is currently working on a location for the next petitioner board meeting and that the location would be picked based on where the majority of the petitioners live.

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

The board adjourned to closed session at 4:14 p.m.

**Thursday, November 9, 2017**

**XIII. Reconvene Open Session**

President Gutierrez called the meeting to order at 8:35 a.m. and the board recessed to closed session at 8:37a.m.

President Gutierrez reconvened open session at 9:56 a.m.

Board members present: Amy Gutierrez, Greg Lippe, Albert Wong, Victor Law, Allen Schaad, Ricardo Sanchez, Amjad Khan and Deborah Veale.

The board honored Anne Sodergren for her 25 years of dedicated state service.

#### **XIV. Enforcement and Compounding Committee**

Chairperson Allen Schaad provided a summary of the September 15, 2017, committee meeting as follows.

##### **a. Discussion and Consideration of the Discrepancies Between the State and Federal Controlled Substance Schedules and its Impact on Healthcare Services and Potential Changes to Impact Laws and Regulations**

Chairperson Schaad explained that medications with the potential to be the most highly abused or lead to addiction are classified under separate federal and state laws into five lists of “scheduled” drugs. Both federal and California law number these schedules by Roman numerals -- I, II, III, IV and V. The lower the number, the higher the potential for abuse.

Chairperson Schaad stated that the California controlled substances schedules are codified in the California Health and Safety Code. This is statutory law, and no single agency is responsible for ensuring the lists are current with respect to drugs of abuse and addiction. He added that the federal controlled substances schedules are promulgated federally principally by the DEA and are found in the Code of Federal Regulations.

Chairperson Schaad reported that Schedule I drugs are generally not intended for medicinal use, except under tightly controlled research studies and are considered “illegal” or “street” drugs. He noted that marijuana is Schedule I drug federally, LSD is a Schedule I drug in both federal and state schedules.

Chairperson Schaad explained that Schedule II drugs have medicinal value and are prescribed under tightly controlled conditions but also have high abuse/addiction potential. Examples are morphine, oxycodone, hydromorphone, Adderall. In California, these medications must be prescribed on a California security form or e-prescribed according to specific federal requirements, and cannot generally be ordered via telephone or refilled even one time. An original new prescription is needed for each dispensing unless the original prescription has been partially filled, and then there are time limits to fully fill the prescription.

Chairperson Schaad stated that Schedule III and IV drugs have lesser addictive and abuse potential but are still more tightly regulated than prescription medication generally. For example, in California they are subject to more restrictive prescribing requirements – including the use of a security form if written, limits on refilling a prescription to six months, and limits on quantity for the aggregate of all refills, and a limit on the number of refills. He noted that unlike Schedule II drugs, these medications can be orally ordered for a patient by a prescriber (as well as e-prescribed under federal requirements).

Chairperson Schaad reported that in California prescriptions written for scheduled drugs must be prescribed by prescribers using specialized prescription forms ordered from a CA Department of Justice licensed printer. There are specific security features for these forms (e.g., thermochromic ink, water marks). Scheduled drugs may be prescribed electronically under e-prescribing systems that meet federal requirements, but faxing a prescription (where a written prescription is faxed to a pharmacy) is not authorized because of original signature requirements. Chairperson Schaad added that Schedule III -V medications can be orally ordered in CA.



Chairperson Schaad explained that generally, there is a high degree of similarity in how medications are classified under the federal and state schedules. However, there are some differences between the federal and state schedules. For example, federal law classifies hydrocodone as a Schedule II drug, but under California law, hydrocodone is a Schedule III drug. Chairperson Schaad also stated that federal law today classifies tramadol as a Schedule IV drug, but it is not a scheduled drug under California law.

Chairperson Schaad stated that the lack of agreement in how a given drug is classified between the federal and state schedules makes for interesting results: While a prescription for hydrocodone is a Schedule II drug federally, because it is a Schedule III drug in California, there is a question about whether hydrocodone could be dispensed by refills (which are allowed for a C-III drug but not for a C-II drug).

Chairperson Schaad explained that in addition to hydrocodone being classified in a different federal schedule than California, several additional drugs of abuse are federally scheduled but not scheduled at all in California – specifically tramadol and soma.

Chairperson Schaad provided the examples below of products exempt under federal law but not exempt in CA (meaning they are scheduled drugs in this state):

- Fioricet (CA - CIII), HSC 11056(c)(3) butalbital product with barbaturic acid or any salt thereof.
- Donnatal (CA – CIV), HSC 11057(d)(26),
- Phenobarbital Librax (CA-CIV) HSC 11057(d)(5),
- Clordiazapoxide

Chairperson Schaad stated that if it's a combination product that has ingredients (such as clordiazepoxide, phenobarbital, butalbital, pentobarbital, meprobamate, etc.) on the federal exempt list, these medication products remain controlled drugs in California.

Chairperson Schaad reported that the Enforcement and Compounding Committee discussed this issue and directed staff to evaluate systems that could mesh the federal and state schedules in a manner that preserves the requirements of each but ensures that the more highly classified structure of a drug in either schedule would take precedence in California.

Chairperson Schaad noted that the board's attorneys are working on a legislative solution that will be provided to the committee and to the board for evaluation.

Ms. Veale spoke in support of the committee's recommendation.

There were no comments from the public.

**Committee Recommendation (Motion):** Direct staff to evaluate the differences in the two schedules to determine a way to mesh the federal and state schedules in a manner that preserves the requirements of each but ensures that the more highly classified placement takes precedence and bring it back to the Enforcement Committee for review.

Support: 8 Oppose: 0 Abstain: 0

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

**b. Discussion and Consideration of Proposed 2018 Board Sponsored Legislation Regarding CURES**

Chairperson Schaad reported that at the January 2017 Board Meeting, the board identified multiple items for future changes it would like to see made to the CURES program. The board also directed staff to pursue implementation strategies for these proposals. Specifically, the board proposed the following changes:

- a. Add “days’ supply” of a medication into the viewing screen of a patient when pharmacists access the system.
- b. Make modifications to permit prescribers to view the patients and prescriptions in CURES where they are identified as the prescriber.
- c. Require dispensers to report data into CURES within 48 hours of dispensing (currently this time frame is no longer than 7 days).
- d. Add the reporting of Schedule V medications dispensed to the CURES system (currently federal Schedule II – IV medications are required to be entered).

Chairperson Schaad reported that item (a) was activated by the Department of Justice soon after they participated in a discussion with the board. For months, pharmacists have been able to view the days’ supply of medication for each medication entered into a patient’s profile.

Chairperson Schaad explained that the remaining three items have not been incorporated into CURES. He noted that item (b) may need to be made statutorily; items (c) and (d) will require legislation.

Chairperson Schaad reported that at the July 2017 Board Meeting, staff from the Department of Justice made a presentation to the board on the CURES 2.0 implementation. During part of that presentation, the DOJ staff indicated a willingness to work with the board on possible statutory modifications to the CURES system in the coming year.

Chairperson Schaad reported that the committee discussed the above items. Additional discussion included that California is one of seven states that is not sharing its prescription drug monitoring program across state lines.

Chairperson Schaad explained that following its discussion the committee made the following recommendation.

**Committee Recommendation:** Sponsor the following provisions in 2018 legislation:

1. Make modifications to permit prescribers to view the patients and prescriptions in CURES where they are identified as the prescriber.
2. Require dispensers to report data into CURES within 48 hours of dispensing. (Currently this time frame is no longer than 7 days.)
3. Add the reporting of Schedule V medications dispensed to the CURES system. (Currently federal Schedule II – IV medications are required to be entered.)
4. Secure interstate data exchange of PDMP information.

**Note:** The text of the proposed legislative changes was provided in the board meeting materials.

Mr. Law asked if the DOJ can make it easier to reset your CURES password. Ms. Herold stated that she would discuss this with the DOJ at her next meeting.

Ms. Herold reported that following the committee meeting she conducted additional research on the reported time frame used in other states. Based on her research Ms. Herold recommended modifying the committee’s recommendation to require dispensers to report data into CURES by the next business day. The board agreed with this recommendation.

Ms. Herold also requested that the board modify the committee recommendation to add the reporting of “additional drugs of concern.” She explained that this would allow the board to require the reporting of an additional drug if they see that a specific drug is becoming widely abused in California. The board agreed with this recommendation.

Robert Stein stated that a patient report in CURES could contain errors that would be unknown to the patient. He explained that this could result in the patient receiving incorrect medications or being denied access to necessary controlled substances. He added that patients are allowed to be given a copy of their patient report by a health care practitioner. He requested that the board modify its motion to clarify that as a health care practitioner, a pharmacist can provide patient access reports when requested. The board agreed with this recommendation.

**Motion:** Sponsor the following provisions in 2018 legislation:

1. Make modifications to permit prescribers to view the patients and prescriptions in CURES where they are identified as the prescriber.
2. Require dispensers to report data into CURES by the next business day.
3. Add the reporting of Schedule V medications dispensed to the CURES system as well as “additional drugs of concern.”
4. Secure interstate data exchange of PDMP information.
5. Clarify that pharmacists are permitted to provide patient reports when requested.

**M/S:** Lippe/Law

Support: 8 Oppose: 0 Abstain: 0

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

Ms. Herold stated that she would like the board to sponsor legislation to require e-prescribing for controlled drugs. She noted that the board is seeing an increase in fraudulent prescription pads being used to obtain controlled substances. She added that other states are beginning to use e-prescribing to combat drug abuse. The board agreed to agendaize this for discussion at a future meeting.

Mr. Room asked a clarifying question regarding the board’s motion on meshing the federal and state Schedules. Mr. Room asked if the board intends to create legislation that will impact other health care practitioners, e.g. physicians. President Gutierrez stated that consistency is important and that other health care providers should need to follow the same Schedule.

**c. Discussion and Consideration of Board Policy to Conduct Inspections of All Pharmacies Every Four Years**

Chairperson Schaad reported that last year during the board’s sunset review, a proposal was made to require that the board perform inspections of all pharmacies once every four years. The goal was to ensure that all pharmacies would have a compliance inspection during this time. The focus of these inspections would be aimed at compliance and education, and not specifically due to performance of a sterile compounding inspection, nor due to the need for an investigation of a complaint or possible violation of pharmacy law.

Chairperson Schaad explained that at the time the board concluded that a statutory requirement to perform compliance inspections every four years was not necessary and instead developed a policy that the board’s inspectors would inspect all pharmacies once every four years.

**Note:** Below is inspection data for the prior four years.

**Total Inspections: FY 13-14 thru FY 16-17 by Visit Type**

<b>Inspection Type</b>	<b>FY 13-14</b>	<b>FY 14-15</b>	<b>FY 15-16</b>	<b>FY 16-17</b>	<b>Total</b>
Routine	287	342	235	300	1164
Investigation	875	926	1065	757	3623
Probation/PRP	139	227	208	311	885
Sterile Compounding	996	1067	1123	976	4162
Other	32	26	9	9	76
<b>Grand Total</b>	<b>2329</b>	<b>2588</b>	<b>2640</b>	<b>2353</b>	<b>9910</b>

Chairperson Schaad reminded that board that the education of licensees is an important part of the board's operations. He added that the board educates licensees in various ways as described below.

- **The Script:** The board's primary means of education for licensees is its newsletter, which is published once per quarter and is available on the board's website. <http://www.pharmacy.ca.gov/publications/script.shtml>
- **Presentations:** The board provides presentations at various events such as association meetings and schools of pharmacy. The presentations usually include updates to pharmacy law or board priorities. Often CE units are provided for attendees.
- **Subscriber alert system:** The board utilizes an electronic subscriber alert system to provide information directly to licensees about new laws or regulations as they take effect, and then provides links to the board website where licensees can learn more about a new requirement.
- **Self-assessment forms:** Completing the self-assessment forms allows licensees to identify key laws that impact their practice to ensure compliance.
- **"Ask an inspector:"** The board has reinstated the "ask an inspector" program to give licensees the opportunity to speak with a board inspector regarding questions of pharmacy law.

Chairperson Schaad stated that additionally, the board now requires every pharmacist to take at least two CE units of education provided directly by the board as a condition of license renewal.

Chairperson Schaad explained that a periodic inspection by a board inspector where compliance is the focus would further benefit the public through improved education of board licensees. It would also allow identification of violations before they come to the board's attention in other ways as well.

Chairperson Schaad reported that the Enforcement Committee discussed the statistics and directed staff to establish a means to ensure that all pharmacies will be inspected every four years. The committee emphasized that these inspections needed to be accomplished with

existing resources.

Chairperson Schaad stated that the board's staff will provide periodic reports to the committee and board on its progress to achieve the compliance inspections. Among the reports requested will be graphs to compare the activities of inspectors by number of inspections, investigations and other work. He added that staff will also research requirements in other states for inspections and their frequency.

Dr. Wong asked if an inspection done as part of a complaint investigation will count as a compliance inspection. Ms. Herold responded that this is a possibility, but ideally there will be two separate inspections.

**d. Discussion and Consideration of Possible Statutory or Regulatory Changes to Expand the Use of Automated Drug Delivery Systems (ADDS)**

Chairperson Schaad explained that there is increasing interest and demand for expanded use of ADDS in pharmacies, clinics and other environments to provide medications to patients. Generally, there are two major forms of these machines:

1. Storage of medication until a specific dose is needed for a patient (e.g., Pyxis machines in hospitals and skilled nursing facilities) where the medication is obtained by a health care provider after it has been ordered for a patient.
2. Storage of a full dosing regimen for a specific patient awaiting patient pick up (e.g., Asteres machine currently under study by UCSD, ADDS that comply with requirements established by California Code of Regulation section 1713 for refills that patients opt in to use from a machine adjacent to a pharmacy counter, use of ADDS via remote technology as authorized in clinics licensed by Business and Professions Code section 4186).

Chairperson Schaad reported that at a technology summit held by the board earlier this year, various forms of technology were demonstrated.

Chairperson Schaad stated that in 2017 there were two legislative proposals introduced in the California Legislature to allow for additional uses of the machines:

- A machine that can store medication in fire departments and EMSA offices to replenish ambulance supplies when convenient for the ambulance (sponsored by the board and enacted).
- A machine installed in clinics, operated by a pharmacy, to dispense 240B drugs to qualified patients (stalled in the Legislature).

Chairperson Schaad reported that during the year, board staff has been working to resolve various issues relating to the existing law we have in this area (see below):

- Under Health and Safety Code section 1261.6 (where medication can be stored for unit dose administration to patients by health care personnel after the medication is delivered to a skilled nursing facility by a pharmacy):
  - Who can refill the machines?
  - Who can deliver the medication to the facility? Should storage in vehicles be

- prohibited? What type of security during transportation is required?
- Can the medications be stored at the facility before loaded into the machine? If so, where?
- How will expired medication be removed from an ADDS?
- Under Business and Professions Code sections 4105.5, 4186 and California Code of Regulations section 1713 (where patients will be dispensed their medication):
  - Is patient consent required to use the ADDS? How often does it need to be reviewed/reaffirmed?
  - Is patient consultation required? When, only on initial fills?
  - Is a phone connection adequate, or is a video camera also needed?
  - How can language interpretations be secured via ADDS?
  - Should ADDS be placed in non-pharmacy areas? If so, how should security of the medication and patient confidentiality be provided?
  - How long may a refill be provided?
  - Should all medication be available via an ADDS dispensing?
  - Should patients be reminded about the need for some drug therapy to be monitored periodically via testing? If so, how should this be meshed into patient care?
- General questions:
  - Who can own/operate an ADDS (A licensed pharmacy, a pharmacist, anyone)?
  - If a pharmacy must own the ADDS, can it do so from an out of state location?
  - Where can (or even if) drug stock that will be placed in the machine may be temporarily stored outside the machine (in locked areas, in transport vehicles, etc.)
  - Should the board inspect the machines?
  - Authentication systems to ensure the appropriate patient gains access to the stored medication.

Chairperson Schaad reported that the committee directed staff to work with him on developing a framework for future regulation of ADDS and bring this to the next Enforcement and Compounding Committee.

Ms. Veale spoke in support of the use of ADDS.

There were no comments from the public.

**e. Discussion and Consideration of the University of California San Diego’s Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)**

Chairperson Schaad reported that at the July 2017 Board Meeting, the board heard and discussed the results of the UCSD experimental study involving the use of ADDS technology to dispense new and refill medications to outpatients in an area nonadjacent to a pharmacy counter. This study involves a waiver of California Code of Regulations Title 16, section 1713, in that it allows first-time fills to be dispensed via an ADDS machine, and the ADDS is not adjacent to a pharmacy counter but is installed in a hospital location.

Chairperson Schaad stated that during the July Board Meeting, the board heard the final report of this study and supported a request from UCSD to extend the study for one year to provide

additional data regarding the study and time for the board to consider a regulation modification involving ADDS to provide medication to patients.

Chairperson Schaad reported that following the discussion, the board approved the following motion: Extend the UC San Diego study for another 12 months (July 26, 2017 -July 25, 2018). Additionally, request that the data provided to the board include a distinction between new prescriptions (as defined by law) and previously dispensed prescriptions.

Chairperson Schaad reported that during the September Enforcement and Compounding Committee meeting, the committee again heard presentations from Asteres and UC San Diego. He added that during the presentation Dr. Hirsch requested that that following changes be made to the data collection parameters for the study moving forward.

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

Chairperson Schaad explained that the committee discussed whether the study should be extended longer than one year to build in time to gather more data and if appropriate to secure statutory or regulation changes. Staff counsel also requested that the amended IRB be provided to the board at its next meeting.

Chairperson Schaad noted that after consideration, the committee made the following motions.

**Committee Recommendation:** Approve the changes to the study as provided below and direct staff to work with UCSD to ensure that the changes made to the IRB are consistent with the committee's discussion.

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

**Committee Recommendation:** Direct UCSD to provide study updates to the Enforcement Committee every six months.

Ms. Herold stated that staff is requesting that the board consider amending the study time frame from one year to two years (July 2019) to allow UC San Diego to gather more patient data and to allow adequate time should the board decide to amend 1713. She explained that the Enforcement Committee discussed extending the study beyond one year; however, the committee did not vote to approve the extension.



The board agreed with the staff recommendation.

There were no comments from the public.

**Motion:** Extend the study to July 2019 to allow adequate time to gather more patient data and for the board to consider possible amendments to 1713. Approve the changes to the study as provided below and direct staff to work with UCSD to ensure that the changes made to the IRB are consistent with the board’s discussion.

- Return to Stock: continue to collect data
- Pick-Up Time: continue to collect data
- Kiosk Patient Survey Data: continue to collect data
- Counseling Logs: continue to complete the logs through the end of 2017 (note: all counseling will continue to occur; the log is the only part that stop)
- Truly New Prescriptions: add this manual data collection to the study
- Therapeutic Class: remove from study

**M/S:** Gutierrez/Lippe

Support: 7    Oppose: 0    Abstain: 0

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

**Motion:** Direct UCSD to provide study updates to the Enforcement Committee every six months.

**M/S:** Gutierrez/Lippe

Support: 7    Oppose: 0    Abstain: 0

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

**f. Status Report on Waivers Issued for Compounding Construction Compliance Delays Pursuant to California Code of Regulations, Title 16, Sections 1735.6 and 1751.4**

Chairperson Schaad explained that Title 16 of 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. He added that there is a related provision in CCR section 1751.4 that provides the same allowances for sterile compounding facilities.

Chairperson Schaad stated that an application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board is able to grant the waiver for a specified period when, in its discretion, good cause is demonstrated for the waiver.

Chairperson Schaad reported that initial review of the waiver is performed by staff led by the executive officer, who approves or denies the waiver request. Approval or denial of a waiver is provided to facilities in writing. He explained that if a waiver is denied by the executive officer, there is an appeal process which will be reviewed by two board members, currently Board Members Schaad and Law.

Chairperson Schaad stated that the goal of the construction waiver process is to secure full compliance at the earliest possible time.

Chairperson Schaad reported that facilities that have been denied a waiver have been made aware that there is an appeal process. There have been no additional appeals made since July 1, 2017.

Chairperson Schaad noted that most request waiver sections are 1735.6(e) and 1751.4(g) for the

external venting requirement for compounding hazardous drugs.

Chairperson Schaad explained that until mid-October, the implementation date of USP <800> was July 1, 2018. The board had been using this date as the final end date for any waiver it issued. However, this time frame was recently extended until December 1, 2019, when modifications to USP <797> are also expected.

Chairperson Schaad stated that the board needs to explore how it will handle waiver requests for compliance that will occur beyond July 2018. He added that the board continues to receive requests for waivers well beyond even the December 2019 date, sometimes as long as 2022.

President Gutierrez recommended extending the final end date for any waiver to December 1, 2019, to match the new USP <797> date. The board agreed with this recommendation.

Chairperson Schaad reviewed the following statistics.

**Status of Waiver Requests Received as of 6/27/17:**

- Total Waivers Received: 609
- Total Waivers Processed: 607
  - Denied: 40 - 6.5%
  - Withdrawn: 100 - 16.5%
  - Approved: 380 - 62.6%
  - Non-responsive letters sent: 21 - 3.5%
  - In process: 66 - 10.8%
- Total Waivers Pending Review: 2
- Total Waiver Extensions Granted: 60

Since November 1, the 401 waivers have been approved.

Of these:

- 164 are hospital pharmacies (41%)
- 24 are nonresident pharmacies (6%)
- 213 are community/outpatient pharmacies (53%)

Of the 401 approved waiver are for facilities holding the following license

- 253 hold sterile compounding licenses (63%)
- 8 hold nonresident sterile compounding licenses (2%)
- 140 pharmacies with waivers do not have sterile compounding licenses

There were no comments from the public.

**Motion:** Authorize the Executive Officer to allow the extension of waivers to December 1, 2019 when necessary.

**M/S:** Gutierrez/Law

Support: 7 Oppose: 0 Abstain: 0

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

Ms. Herold noted that inspectors will continue to write corrections in their reports when a facility has an approved waiver. This will allow the board to ensure that the facility is continuing to move towards compliance by December 1, 2019. Mr. Room clarified that these corrections are not discipline; they are simply a note in the inspection report.

**g. Enforcement Statistics**

Chairperson Schaad stated that the enforcement committee statistics were provided in the meeting materials for review.

Ms. Herold noted that board staff is working on providing summaries of disciplinary actions that are reported in *The Script*.

**h. Future Committee Meeting Dates**

Chairperson Schaad announced that the next Enforcement Committee Meeting would be held on December 11, 2017. A member of the public requested that the committee meeting be webcast.

Chairperson Schaad announced the 2018 Enforcement Committee meeting dates as provided below.

- March 28, 2018
- June 7, 2018
- September 5, 2018
- December 13, 2018

President Gutierrez recessed the meeting to closed session at 10:51 a.m.

The board returned to open session at 10:55 a.m. and adjourned the meeting at 10:56 a.m.