



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

**DATE:** Oct. 26-27, 2016

**LOCATION:** Holiday Inn San Jose – Silicon Valley  
1350 N. First St.  
San Jose, CA 95122

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

**BOARD MEMBERS  
NOT PRESENT:** Ricardo Sanchez, Public Member

**STAFF  
PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Laura Freedman, DCA Staff Counsel  
Juliet Cox, Administrative Law Judge  
Joshua Room, Deputy Attorney General  
Kristina Jarvis, Deputy Attorney General  
Christine Acosta, Supervising Inspector  
Debbie Damoth, Staff Manager  
Lori Martinez, Staff Manager  
Sue Robinson, Staff Analyst

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

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



Visit our website at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

**Wednesday, Oct. 27, 2016**

Call to Order

9:35 a.m.

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

President Gutierrez called the meeting to order at 9:35 a.m. Board members present: Greg Lippe, Lavanza Butler, Victor Law, Stan Weisser, Debbie Veale, Amy Gutierrez, Allen Schaad and Albert Wong.

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

President Gutierrez asked if there were any comments from the public. There were no comments from the public.

**Approval of the July 12, 2016; July 27-28, 2016; Aug. 31, 2016; and Sept. 22, 2016 Board Meeting Minutes**

There were no changes to the July 12 minutes.

**Motion:** Approve the July 12, 2016, board meeting minutes.

M/S: Lippe/Law

Support: 7      Oppose: 0      Abstain: 1

<b>Name</b>	<b>Support</b>	<b>Oppose</b>	<b>Abstain</b>	<b>Not Present</b>
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz				X
Sanchez				X
Schaad	X			
Veale	X			
Weisser			X	
Wong	X			

Ms. Veale requested changes to the July 27-28 meeting minutes: On page 74, second paragraph, change “Chairperson Lippe” to “Chairperson Veale.”

**Motion:** Approve the July 27-28, 2016, meeting minutes with changes.

M/S: Lippe/Weisser

Support: 8      Oppose: 0      Abstain: 0

<b>Name</b>	<b>Support</b>	<b>Oppose</b>	<b>Abstain</b>	<b>Not Present</b>
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz				X
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

There were no changes to the Aug. 31 minutes.

Motion: Approve the Aug. 31, 2016, meeting minutes.

M/S: Lippe/Butler

Support: 8      Oppose: 0      Abstain: 0

<b>Name</b>	<b>Support</b>	<b>Oppose</b>	<b>Abstain</b>	<b>Not Present</b>
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz				X
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

Ms. Veale requested changes to the Sept. 22 meeting minutes: On page 4, change the motion made by Ms. Veale and Ms. Butler to reflect that the forum regarding section 1557 of the Affordable Care Act could be a board hearing or a committee meeting in case not enough board members can attend to qualify as a board meeting.

**Motion:** Approve the Sept. 22, 2016, meeting minutes with changes.

M/S: Weisser/Law

Support: 8                  Oppose: 0          Abstain: 0

<b>Name</b>	<b>Support</b>	<b>Oppose</b>	<b>Abstain</b>	<b>Not Present</b>
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz				X
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

**Recognition and Celebration of Pharmacists Licensed in California for 50 Years**

The board recognized Bruce Bettencourt, Dan Bryant, George Lee and Sara Goldberg Conrad for 50 years of service as pharmacists.

**Update from the Department of Consumer Affairs**

Shelly Jones from the Executive Office of the Department of Consumer Affairs thanked the board for the opportunity to share what is happening at DCA. She noted that DCA Director Awet Kidane and the DCA Executive Team met with executive officers and board presidents on Sept. 7.

Ms. Jones advised the board of the following changes in the DCA Executive Team:

Tracy Rhine, DCA chief deputy director, accepted a job with the Rural County Representatives of California. The governor appointed Jeff Mason, formerly chief deputy commissioner for the Bureau of Real Estate, as chief deputy director.

Melinda McClain, DCA deputy director for legislation and regulatory review, accepted a position in the Governor’s Office. The governor appointed Adam Quiñonez, formerly assistant deputy director for legislation, as the legislative deputy.

Tamara Colson, DCA assistant chief counsel, was appointed assistant chief counsel of the Bureau of Medical Cannabis Regulation. The governor appointed Ryan Marcroft, formerly deputy attorney general at the California Department of Justice, as DCA assistant chief counsel.

Ms. Jones also advised the board of the governor's regulatory review program. She stated that review and approval of a fiscal impact statement is required for all proposed regulations prior to submission of a notice of proposed action to the Office of Administrative Law (OAL). Since 2009, the Business, Consumer Services and Housing Agency has waived this requirement for DCA Boards. Given an increase in the number of rulemaking packages disapproved by OAL due to issues of clarity and necessity, however, Agency has rescinded this waiver effective Sept. 7, 2016.

Ms. Jones said that, therefore, before noticing any approved regulatory packages at OAL, all boards must first submit them to the Department and Agency for review and approval. She said that rulemaking packages should be submitted to the Department's Division of Legislative & Regulatory Review. She added that the Department is committed to ensuring this is a timely process that affects the boards as minimally as possible.

In response to questions from board members, Ms. Herold explained that this review would occur up front, before the board releases a rulemaking package for a 45-day notice. She said that the administration is aware of the need to have the review done quickly and stated that the idea is that upfront review will help reduce the number of rulemaking files rejected by OAL. She said the upfront review would occur after the board has finalized rulemaking language but before the rulemaking is release for a 45-day notice. She also advised the board that the upfront review could add at least 90 days to the rulemaking process, because it would occur between board meetings.

Ms. Freedman advised that it might be possible for the board to delegate a certain amount of authority to the executive officer to amend language before issuing the notice to address any concerns related to clarity of language. She added that the upfront review would apply to any new rulemaking that is not already under way and advised the board that, for any new rulemaking, she would offer additional language at the time a motion is made allowing the board to delegate authority to the executive officer to make clarifying changes consistent with the policy directed by the board.

Regarding other DCA matters, Ms. Jones told the board:

DCA will host its annual Distributed Costs Review and Open House for Executive Officers, Bureau Chiefs and Board Presidents on Oct. 27.

The department is working with Sen. Hill on legislation to address anti-trust issues raised by the U.S. Supreme Court decision in *North Carolina Board of Dental Examiners v. Federal Trade Commission* in February 2015.

The Director has issued a memo providing a copy of the Little Hoover Commission report *Jobs for Californians: Strategies to Ease Occupational Licensing Barriers* and requesting feedback from executive officers and bureau chiefs on the report and proposed recommendations.

The department has implemented a process to assist boards with onboarding new executive officers.

Board members must complete orientation training within one year of appointment and reappointment. In addition, board members must complete ethics, sexual harassment prevention and defensive driver training.

The Governor's Executive Order limiting in-state and out-of-state travel for "mission critical" purposes remains in effect.

The department's Office of Information Services (OIS) is working with the California Department of Technology to migrate email services to an Office 365 model.

The department's Future Leadership Development Program is working to help develop the next generation of bureau chiefs and executive officers. In addition, SOLID launched the Employee Career Empowerment and Mentorship pilot program in July.

The department is developing a new strategic plan for 2017-2019. The process includes a survey of stakeholders, including board members, in a few weeks.

Mr. Law asked if any orientation classes are planned in Southern California. Ms. Herold said classes would be held in Sacramento and that dates would be known after the next board meeting Dec. 16. She said staff would advise board members of training sessions needed for completion.

### **Executive Officer's Report**

Assembly Health Committee Informational Hearing "Understanding the Pharmaceutical Supply Chain: What is Driving Up the Cost of Drugs?"

Ms. Herold said the board has been invited to speak before the Assembly Health Committee on Oct. 31 at an informational hearing on understanding the pharmaceutical supply chain and what is driving up the cost of drugs. She noted that although the board does not regulate the price of drugs, the board has taken action in the past against a company that charged so much for drugs that it was viewed as moral turpitude.

Ms. Herold announced the agenda items:

Opening Remarks from the Assembly Health Committee

Historical Perspective on Drug Pricing

The Economics of Pharmaceuticals

Drug Pricing in Other Countries

Drug Pricing in the Pharmaceutical Supply Chain

Ms. Herold said NABP would give an overview of the supply chain at the hearing, and then she would speak about how the board regulates the supply chain. She said stakeholders, an economist and a consumers' advocate also are scheduled to speak. Note: A copy of the agenda is attached to these minutes.

Note: Mr. Brooks arrived at 10:14 a.m.

Public comment: Steve Gray of Kaiser Permanente asked if health care service plans would be speaking and if the hearing is open to the public. Ms. Herold said PBMs would be speaking and the hearing is open to the public. Steve Rosati, a pharmacist from Hollister, provided the board with a written statement about drug pricing and expressed concerns about multi-tier pricing.

#### Discussion and Consideration of the Timeline for Reporting Immunizations into California's Department of Public Health CAIRS Data Base Pursuant to 16 CCR Section 1746.4

Ms. Herold noted that the board's new immunization regulation requires pharmacists to report all immunizations to the immunization registry within 14 days. To do so, pharmacies must be registered with the California Immunization Registry (CAIR). Ms. Herold explained that CAIR receives reports from pharmacies in 10 California regions. Pharmacies may submit the information electronically or manually.

Ms. Herold said the California Department of Public Health is converting CAIR to a more automated system called CAIR2. She reported that CAIR2 currently is operating in four regions: Northern California, Greater Sacramento, Central Coast and Inland Empire. CAIR2 will be rolled out Dec. 5 for pharmacies in the Bay Area and Central Valley. The final roll-out is expected by March 5 for pharmacies in Los Angeles and Orange counties.

Ms. Herold said that CDPH has requested that the board use discretion in enforcing the 14-day reporting requirement for affected pharmacies in those counties that do not yet have CAIR2. The delay affects only pharmacies that report data manually. Pharmacies can continue to submit data electronically, and most large chains already do so.

Ms. Herold recommended that the board use enforcement discretion for another six months to allow all pharmacies to be able to comply without having to use the old CAIR system while also learning to use CAIR2. Mr. Schaad and President Gutierrez expressed support for the recommendation. Ms. Freedman said the temporary delay is reasonable.

#### Update from the Medical Board of California on Issues Affecting Both Boards

Ms. Herold informed the board that she would be discussing key matters in meetings with the executive director of the Medical Board in the coming weeks – including the issue of compounding in prescribers' offices, pain management guidelines, collaborative practice agreements, and prescribers operating drug dispensing machines. She said that she and the Medical Board director will report on their meetings to their respective boards, and she invited board members to recommend topics for discussion.

## NAPLEX and CPJE Examination Statistics

Ms. Herold informed the board that the CPJE pass rate has gone down over the past couple of years and that there has been a decrease in the NAPLEX pass rate. She presented statistics showing that the CPJE pass rate for tests taken between April and September dropped from 83.4 percent in 2014 to 70 percent in 2016. She reported a decrease for the NABP exam as well, from 96 percent in 2014 to 91 percent in 2016.

Ms. Herold said the overall CPJE pass rate for California schools is 82 percent, and the NAPLEX rate is 92 percent.

Mr. Weisser asked if the CPJE exam has changed to focus more on California law rather than general pharmacy expertise. Ms. Herold said that as the NAPLEX has become more clinical in its focus, the CPJE has more questions focused on the law than previously. She said the change in focus might explain the CPJE scores. Mr. Schaad noted the CPJE questions deal mostly with applied law, which is more demanding for test takers. He said the competency committee has gone to great lengths to ensure the exam is valid.

Ms. Herold noted that shift in pass rates is reflected at the national level with the MPJE as well. Board members also discussed the possible impact of a declining pool of student applicants to pharmacy schools. Mr. Room noted that pass rates for the California Bar Exam and other professional exams are much lower than for pharmacy.

Public comment: Mr. Gray noted that most schools teach pharmacy law in the first quarter or semester, so a refresher course offered to graduating pharmacy students who are about to take the exam could be helpful.

The board recessed for a break at 11:01 a.m. and reconvened at about 11:15 a.m.

### **Discussion and Consideration of Proposed Regulations to Amend and Add Title 16 CCR sections 1702, 1702.1, 1702.2 and 1702.5 related to Renewal Requirements**

President Gutierrez stated that at the July 2013 board meeting, the board approved proposed text to amend and/or add Title 16 CCR sections 1702, 1702.1, 1702.2 and 1702.5 related to standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as require nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal. The 45-day comment period began on Aug. 12, 2016, and ended Sept. 26, 2016. The board received a few comments.

President Gutierrez asked the board to discuss the future of the regulation and determine what course of action it wishes to pursue. She said options include:



1. Adopt the regulation as noticed for comment on Aug. 12, 2016.
2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Board members noted that the comments mostly focused on the \$500 fine threshold for reporting traffic infractions. Mr. Room reminded the board that an infraction does not count as a conviction. He said the board's only concern about infractions is if the conduct involved would be a basis for disciplinary denial, i.e., driving under the influence. He said the board could get at the conduct by requiring reporting of "traffic infractions not involving drugs or alcohol" without specifying a fine of any amount. Board members noted that removing the \$500 language would require another 15-day comment period.

Mr. Lippe noted that dates mentioned in sections 1702.1 and 1702.2 need to be changed from 2014 to 2017. President Gutierrez noted that the date already was crossed out in section 1702; Ms. Sodergren explained it was because that requirement already existed for pharmacists, but the effective date must be specified for pharmacy technicians and designated representatives in sections 1701.1 and 1702.2 respectively.

Dr. Wong noted that the board actively disciplines licensees for DUIs. He asked that the board consider DUIs at a future meeting and said that board should not discipline them because it is very easy to get a DUI ticket with one or two glasses of wine. He said that as long as licensees are not doing it on the job, the board should not penalize them so heavily for DUIs.

President Gutierrez summarized the changes suggested by board members: Remove "under \$500" in sections 1702.1(b) and 1702.2(b) and change dates of July 1, 2014, in sections 1702.1 and 1702.2 to July 1, 2017.

Ms. Freedman informed the board that most DCA agencies do include a threshold limit for traffic infractions. She suggested the board first check with an enforcement staff member to determine what reported information would not be collected if the fine amount were removed. In response to a question from President Gutierrez, she added this rulemaking would not have to be pre-reviewed by the Agency.

Ms. Freedman noted that even if information is reported, it does not necessarily result in disciplinary action. She said that removing the fine limit might be appropriate but suggested that the board first check with staff before taking action. She said the language included a \$300 figure when it was first promulgated by the department, and some boards have since raised the amount to \$1,000.

Ms. Veale asked if a reckless driving citation is something the board would want to know. Mr. Room said most reckless driving offenses are "wobblers" that can be charged as either an infraction or misdemeanor. He said that if the offense is entered as an infraction, the board

would not be able to take action on the conviction itself because it is not a “conviction” for the board’s purposes – but the board could look at the underlying conduct. He said the board would not learn about that reckless driving if it were an infraction.

Ms. Veale asked about other types of infractions that the board would not learn about if the fine threshold were removed from the regulation. Mr. Room said that driving with a suspended license or driving without a license sometimes is treated as an infraction instead of a misdemeanor. Ms. Sodergren added that sometimes the board is notified of a citation for driving with a suspended license and then further investigation reveals a previous issue – such as a DUI – that the board did not know. Mr. Brooks said that driving without a safety belt or driving around a school bus could be infractions.

Mr. Room suggested an alternative approach requiring licensees to simply report all convictions without any exceptions. Mr. Lippe suggested specifying an exception for infractions. Mr. Room pointed out that would exclude infractions involving alcohol or drugs. Ms. Veale recommended leaving in the reporting language with a specific exception for traffic infractions not involving alcohol, dangerous drugs or controlled substances but removing the \$500 amount.

In response to a question from Mr. Weisser about keeping the \$500 threshold, Ms. Freedman noted that it allows the board to collect information that it otherwise would not receive. She noted that simply reporting an infraction would not necessarily result in discipline by the board.

Ms. Sodergren informed that board that staff does receive a number of reports on renewals and opens cases only where the infractions involve using drugs or alcohol. She said that removing the dollar value or increasing the amount would decrease the amount of associated workload for enforcement staff. She added that enforcement staff indicated that the average infraction amounts they see are between \$500 and \$1,000.

Board members said they supported removing the dollar amounts and changing the effective dates to 2017 for pharmacy technicians and designated representatives.

There was no public comment.

**Motion:** Adopt the regulatory language as noticed on Aug. 12, 2016, with the changes made by the board and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

## **1702. Pharmacist Renewal Requirements**

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee’s fingerprints does not exist in the Department of Justice’s criminal offender record identification database shall successfully complete a state and federal level criminal offender record

information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010.~~

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. ~~omitting~~ ~~†~~ ~~Traffic~~ infractions ~~under \$300~~ ~~\$500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproof.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

### **1702.1 Pharmacy Technician Renewal Requirements**

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal

offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2017~~4~~.

(1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions ~~under \$500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

## **1702. 2 Designated Representative Renewal Requirements**

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of

Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 20174.

(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions ~~under \$500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproof.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority : Sections 4001.1 and 4005, Business and Professions Code.

Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.**

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any

government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, “disciplinary action” means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproof.

Authority: Section 4005, Business and Professions Code.

Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code

M/S: Weisser/Lippe

Support: 9                      Oppose:0                      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**Discussion and Consideration of Proposed Regulations to Add Title 16 CCR sections 1776 et seq. related to Prescription Drug Take-Back**

President Gutierrez stated that at the January 2016 board meeting, the board approved proposed text to add sections 1776 *et seq.* of Title 16 CCR related to Prescription Drug Take-Back Programs. The 45-day comment period began on Feb. 12, 2016, and ended March 28, 2016. Two regulation hearings were held on April 13, 2016 (one in Northern California and one in Southern California).

President Gutierrez stated that at the April 2016 board meeting, the board approved a modified text to address concerns expressed during the 45-day comment period and at the regulation hearing. A 15-day comment period began May 3, 2016, and ended May 18, 2016.

President Gutierrez said that at the June 2016 board meeting, the board reviewed the comments received during the 15-day comment period. The board made policy decisions based on the comments and instructed staff to make the recommended changes to the language and present the modified language at the July 2016 board meeting.

President Gutierrez said that at the July 2016 board meeting, the board reviewed and approved the modified language as recommended by staff. A second 15-day comment period began Aug. 4, 2016, and ended Aug. 19, 2016.

President Gutierrez stated that at the September 2016 board meeting, the board approved a modified text to address concerns expressed during the second 15-day comment period. A third 15-day comment period began Sept. 29, 2016, and ended Oct. 14, 2016.

President Gutierrez asked the board to discuss the future of the regulation and determine what course of action to pursue. She advised the board of a staff recommendation: Adopt the regulatory language as approved on Sept. 22, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

President Gutierrez said board members had read the comments and agreed that most would be rejected per staff recommendations. Ms. Veale said the comments were issues that the board had previously addressed.

Public comment: Andria Ventura of Clean Water Action said the regulations will impose barriers for existing local take-back programs. She said that allowing a pharmacist to use professional judgment in determining whether to have a take-back program will enable the pharmacist to not comply with local ordinances that require take-back programs. She said the regulations will get in the way of DEA rules and local ordinances. She said the board is sending a message that pharmacists do not have to provide these programs. She also said that EpiPens should be allowed to be collected if they are in original packaging.

Board members expressed disagreement with Ms. Ventura's characterization of the intent of the regulations. President Gutierrez said the regulations will educate pharmacists on how to comply with DEA regulations on take-back programs while ensuring the safety of consumers and patients. Ms. Herold said staff could develop guidance and FAQ documents to help educate pharmacists on implementing the regulations.

An employee of the city and county of San Francisco spoke about the exclusion of sharps in take-back programs. She requested an exception to allow unused, pre-loaded, self-injector devices still in original packaging to be collected. She noted that the Business and Professions Code section cited by staff deals with hypodermic needles and syringes, which she distinguished from auto-injectors.

In response to a question from President Gutierrez, Ms. Freedman read B&PC section 4146 states, "A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container, as defined in Section 117750 of the Health and Safety Code." She said that an EpiPen is a needle and added that a take-back receptacle liner would have to be a sharps container in order to accept EpiPens.

Mr. Brooks asked about EpiPens that are expired but have never been used and are in original packaging. Mr. Room said the law speaks of needles and syringes, and since EpiPens have needles, they can only be returned in sharps containers. But he said the policy underlying the law refers to used needles and syringes because they are a biohazard, and the law does not make a clear distinction between used needles and unused needles in original packaging.

Ms. Herold advised the board that to make an exception for EpiPens would still require the board to change the receptacle liner. She also said that an EpiPen container would not fit into the slot for a receptacle. She suggested that a separate solution for EpiPens is needed. Mr. Room suggested that the board move forward with the existing regulation and agree to address the EpiPen issue with an amendment to the regulation or a separate regulation.

Another speaker told that board that regardless of the regulations, the public will put whatever they want to put in the bins. Dr. Wong said that EpiPens are safe for bins because they arrive at the pharmacy in packaging that is not safe from puncture.

An employee of the Santa Rosa Water Department asked if the intent of section 1777.1(l) is to prohibit pharmacists or pharmacies on probation from distributing mail-back envelopes or packages. Board members said yes. Regarding section 1776.3(b), he asked for a definition of "near emergency area" in a small pharmacy, where anywhere in the pharmacy would count as being "near" the door and that could be an emergency door. President Gutierrez said the regulation referred to a DEA definition regarding anywhere that emergency care is provided and added that the question could be addressed with guidance. Regarding section 1776.4(a), he asked for clarification regarding a pharmacy requiring skilled nursing facility employees to keep records of mail-back drugs.

Angie Manetti of the California Retailers Association and Brian Warren of the California Pharmacists Association thanked the board for its work on the regulations and expressed support for the staff recommendation and board motion. Mr. Warren added that he had not heard of any questions or confusion among pharmacists about the regulations.

**Motion:** Adopt the regulatory language as approved on Sept. 22, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.



**Proposal to add** new Article 9.1 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

### **Article 9.1. Prescription Drug Take-Back ~~Programs~~ Services**

**Proposal to add** § 1776 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

#### **Section 1776 Prescription Drug Take-Back ~~Programs~~ Services: Authorization**

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board ~~and licensed skilled nursing facilities~~ may offer, under the requirements in this article, specified prescription drug take-back services through collection receptacles and/or mail back envelopes or packages to the public to provide options for the public to ~~destroy~~ discard unwanted, unused or outdated prescription drugs. Each ~~of these entities~~ entity must comply with regulations of the federal Drug Enforcement Administration (DEA) and ~~the Board of Pharmacy regulations contained in~~ this article.

~~All board licensed authorized collectors should be vigilant to prevent the public patients or their agents from disposing of prohibited items through drug take back collection methods. Federal, state and other laws prohibit the deposit in drug take back receptacles of the following in pharmaceutical take back receptacles: medical sharps and needles (e.g., insulin syringes), iodine containing medications, mercury containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), illicit drugs, and compressed cylinders or aerosols (e.g., asthma inhalers).~~

Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug distributors (licensed wholesalers and third-party logistics providers) who are registered with the Drug Enforcement Administration (DEA) as collectors and licensed in good standing with the board ~~and are also registered with the Drug Enforcement Administration as collectors~~ may host a pharmaceutical take-back receptacle as participate in drug take back programs authorized under this article.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, 4026.5, and 4301, Business and Professions Code and Section 1317.40, Title 21 Code of Federal Regulations.

**Proposal to add** § 1776.1 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

#### **Section 1776.1 Pharmacies**

Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.

~~(b) (a) Pharmacies may provide take-back services to the public patients as provided in sections 1776—1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish-maintain collection receptacles in their facilities. Pharmacies may operate collection receptacles offer drug take-back services as specified-in in section 1776.4 in skilled nursing facilities licensed under California-Health and Safety Code section 1250(c).~~

~~(c) (b) There are multiple federal, and state and local requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.~~

~~(d) (c) For purposes of this article, prescription drugs means dangerous drugs as defined by California-Business and Professions Code section 4022, which includes including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages-or envelopes or packages with other dangerous drugs.~~

~~(d) Once drugs are deposited into a collection receptacle or mail back envelopes or packages by a consumer patient, they are not to be removed, counted, sorted or otherwise individually handled-separated by pharmacy staff or others.~~

~~(e) (d) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's prescription drug take-back collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage informing the public that medical sharps and needles (e.g., insulin syringes) are of the items prohibited from being deposited shall be placed posted on collection receptacles as referenced in section 1776.3.~~

~~The collection receptacle shall contain signage that includes:~~

~~The name and phone number of the responsible pharmacy;~~

~~Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and~~

~~Consumers may deposit prescription drugs including Schedule II-V controlled substances.~~

~~(f) (e) Prescription drugs that are eligible for collection in as part of drug take-back programs operated-services maintained by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a patient or patient's agent-consumer. Dangerous drugs that have not been dispensed to patients consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in as part of a pharmacy's drug take-back service programs.~~

~~(g) As part of its drug take-back services, a Pharmacy shall not:~~

~~Pharmacy staff shall not r-Review, accept, count, sort, or otherwise individually handle any prescription drugs returned-from the-public-consumers.~~

~~A-pharmacy shall not-a-Accept or possess prescription drugs returned to the pharmacy by-from skilled nursing homes-facilities, residential care homes, -other-facilities, health care practitioners~~

or any other ~~entity-entities in a collection receptacle~~.

~~A pharmacy shall not d~~ Dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock ~~in a drug take-back collection receptacle~~. Instead the pharmacy must return these items to a reverse distributor.

~~(g)(f)(h)~~ A pharmacy must be registered with the federal ~~Drug Enforcement Administration~~ DEA as a collector for purposes of ~~operating~~ maintaining a prescription drug take-back ~~collection receptacle program~~. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.

~~(h)(g)(i)~~ Any pharmacy that ~~operates~~ maintains a drug take-back collection receptacle program as authorized in this article shall notify the board in writing on a form designated by the board within 30 days of establishing the collection program.

Additionally:

Any pharmacy that ceases to ~~operate~~ maintain a drug take-back collection receptacle program shall notify the board in writing within 30 days ~~on a form designated by the board~~. If the pharmacy later ~~ceased to operate the collection receptacle~~, the pharmacy must notify the board within 30 days.

Any pharmacy ~~operating a mail-back program or maintaining~~ a collection receptacle~~s~~ shall disclose identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.

Any tampering with a storage collection receptacle or theft of deposited drugs shall be reported to the board in writing within 14 days.

Any tampering, damage or theft of a removed liner shall be reported to the board in writing within 14 days.

~~(i)(h)(j)~~ If the pharmacy later ceases to ~~operate~~ maintain the a registered collection receptacle, the pharmacy must notify the DEA Drug Enforcement Administration within 30 days.

~~(j)(k)~~ A pharmacy shall not provide take-back services to consumers, ~~as provided in sections 1776-1776.4~~, if, in the professional judgment of the pharmacist ~~in charge~~, the pharmacy cannot comply with the provisions of this article or the DEA Drug Enforcement Administration rules.

~~(j)(l)~~ A pharmacy shall not provide take-back services to consumers, ~~as provided in sections 1776-1776.4~~ if the pharmacy or the pharmacist ~~in charge~~ is on probation with the B-board, and, if the pharmacy had previously provided take-back services, the pharmacist ~~in charge~~ shall notify the B-board and the DEA Drug Enforcement Administration as required in subsections (h) and (i), above.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005 and 4022, Business and Professions Code and Sections 1301.71, 1317.30, 1317.40, Title 21 Code of Federal Regulations.

**Proposal to add** § 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

## **1776.2 ~~Pharmacies Offering Mail Back Envelope or Package Services~~ ~~Mail Back Package and Envelope Services from Pharmacies~~**

(a) Pharmacies that provide prescription drug take-back services may do so by ~~establishing providing~~ ~~mail back services~~, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages ~~s containers~~ to allow a consumer to for returning prescription drugs to an authorized ~~DEA Drug Enforcement Administration~~ destruction location.

(b) All envelopes and packages must be preaddressed to a location registered with the ~~DEA Drug Enforcement Administration~~ as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed ~~to be delivered for delivery~~ to facilities that comply with this section.

(c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.

(d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and ~~contain~~ instructions for users that indicate the process to mail back drugs.

(e) ~~The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.~~

(f) ~~Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.~~

(g) (e) Once filled with unwanted prescription drugs, the A pharmacy shall not accept any mail back packages or envelopes that contain drugs unless they are registered as a collector and have an onsite method of destruction that complies with the DEA requirements. Instead, C consumers shall be directed to mail the envelopes or packages ~~or deposit them into a pharmaceutical take back receptacle~~. shall be mailed and not accepted by the pharmacy for return, processing or holding.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code and Sections 1317.70 and 1317.70, Title 21 Code of Federal Regulations.

**Proposal to add** § 1776.3 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

### **1776.3 Collection Receptacles in Pharmacies**

A pharmacy ~~Pharmacies~~ may that provide prescription drug take-back services to the public may do so by ~~establishing~~ maintain a collection receptacle ~~in the pharmacy~~ whereby for the public to may deposit their unwanted prescription drugs for destruction. The pharmacy is responsible for the management and maintenance of the receptacle.

The receptacle shall be ~~securely locked and~~ substantially constructed, with a permanent outer container and a removable inner liner. The collection receptacle shall be locked at all times to prevent access to the inner liner. ~~In During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block the public patients from access to the collection receptacle by some means.~~

~~A~~The pharmacy operating maintaining ~~the a~~ collection receptacle must securely install fasten the receptacle to a permanent structure so it cannot be ~~moved or~~ removed. The receptacle shall be installed in an inside location ~~within the pharmacy premise, where,~~ Except as provided in subsection (c), the receptacle is visible to pharmacy or DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter.

In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the supervising responsible pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. ~~When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from public patient access by some means.~~

The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. ~~During hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit~~ opening slot on the collection receptacle.

~~The pharmacy is responsible for the management and maintenance of the receptacle. A pharmacy shall direct consumers to directly deposit drugs into the collection receptacle. A Pharmacy staff shall not accept, count, sort or otherwise handle prescription drugs returned from the public consumers, but instead direct the public to deposit the drugs into the collection receptacle themselves.~~

A liner as used in this article shall be made of material that is certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

(1) The liner shall be waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's

manufacturer or distributor.

The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, ~~or~~ counted, sorted or otherwise individually handled.

If the liner is not already itself rigid or already inside of a rigid container when as it is removed from the collection receptacle, the liner must be immediately, without interruption, placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair. ~~Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed and be kept clean and in good repair.~~

The liner may be removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner, these pharmacy employees who shall be immediately, without interruption, sealed and the pharmacy employees shall record ~~seal the liner and record~~, in a written log, their participation in the removal of each liner from a collection receptacle. ~~If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container.~~ Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.

Liners and their rigid containers that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than three 14 days.

The pharmacy shall make and keep the records specified in 1776.6. ~~maintain a written log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:~~

- ~~(1) The unique identification numbers of all unused liners in possession of the pharmacy;~~
- ~~(2) The unique identification number and dates a liner is placed in the collection receptacle;~~
- ~~(3) The date the liner is removed from the collection receptacle;~~
- ~~(4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle; and~~
- ~~(5) The date the liner was provided to a licensed DEA registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to~~

~~the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.~~

The pharmacy shall ensure the sealed inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.

~~The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not permissible to deposit any Schedule I drugs into the collection receptacle. Labeling The signage shall also identify informing the public that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.~~

The collection receptacle shall contain signage that includes:

The name and phone number of the responsible pharmacy;

Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

Consumers may deposit prescription drugs including Schedule II-V controlled substances.

~~The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process.~~

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Section 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.60, 1317.75, and 1317.80 Title 21 Code of Federal Regulations.

**Proposal to add** § 1776.4 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:

#### **1776.4 ~~Collection-Drug Take-Back Services~~ in Skilled Nursing Facilities**

A P-pharmacy may offer drug take-back services in S-skilled nursing facilities licensed under Health and Safety Code section 1250(c) ~~may participate in drug take-back programs~~ as authorized by this article.

(a) Skilled nursing facility ~~personnel~~ employees or person lawfully entitled to dispose of the resident decedent's property may dispose of a current resident's unwanted or unused prescription drugs by using mail back ~~packages or envelopes~~ and/or packages based upon a request by the resident patient. ~~Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. The pharmacy may allow skilled nursing facility employees to distribute mail back envelopes or packages to consumers.~~ The pharmacy shall require ~~Records shall be kept by the~~ skilled nursing facility employees to keep records noting the specific quantity of each prescription drug

mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.

(b) Only ~~retail~~ pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs. A pharmacy and hospital/clinic with an onsite pharmacy maintaining a collection receptacle in a skilled nursing facility shall:

~~(1) Any pharmacy and hospital/clinic with an onsite pharmacy operating maintaining collection receptacles in skilled nursing facilities shall b~~ (1) Be registered and maintain registration with the DEA as a collectors.

~~(2) Any pharmacy or hospital/clinic with an onsite pharmacy that operates maintains a collection receptacle at a skilled nursing facility shall n~~ (2) Notify the board in writing within 30 days of establishing a collection receptacle ~~on a form designated by the board.~~

~~(3) Any pharmacy or hospital/clinic with an onsite pharmacy~~ (3) Notify the board in writing within 30 days when they that ceases to operate maintain a the collection site receptacle ~~at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.~~

~~(4) Notify the board in writing within 14 days of any tampering of the collection receptacle or theft of deposited drugs.~~

~~(5) Notify the board in writing within 14 days of any tampering, damage or theft of a removed liner.~~

~~(6) Any pharmacy operating a collection receptacle site at a skilled nursing facility shall~~ (6) List all collection receptacles it ~~operates~~ maintains annually at the time of renewal of the pharmacy license.

~~(c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.~~

~~Every pharmacy and hospital/clinic pharmacy that operates maintains a collection site receptacle at any skilled nursing facility shall notify the board within 14 days of any loss or theft from the collection receptacle or secured storage location for the storage of removed liners.~~

(d) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.

(e) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.

(f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be ~~moved or~~ removed. The collection receptacle shall have a small opening



that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.

(g) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.

(1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be ~~viewed,~~ removed, sorted, counted, or otherwise individually handled ~~counted.~~

(2) If the liner is not already itself rigid or already inside of a rigid container as when it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have sealable tight-fitting covers, and be kept clean and in good repair. Rigid containers ~~may be of any color.~~ All rigid containers must meet standards of the United States Department of Transportation ~~for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.~~

(h) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

(1) The liner shall be waterproof, tamper evident and tear resistant.

(2) The liner shall be opaque to prevent viewing ~~or~~ and discourage removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number ~~established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.~~

~~(i) The collection receptacle shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.~~

The collection receptacle shall contain signage that includes:

The name and phone number of the responsible pharmacy;

Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and

Consumers may deposit prescription drugs including Schedule II-V controlled substances.

(j) Once deposited, the prescription drugs shall not be ~~handled,~~ counted, ~~inventoried~~ sorted or otherwise individually handled.

(k) The installation, removal, transfer and storage of inner liners shall be performed only by:

(1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or

(2) By or under the supervision of two employees of the authorized collector pharmacy.

(l) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.

(m) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction ~~by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or~~ by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

(n) ~~A pharmacy maintaining a collection receptacle in a skilled nursing facility shall make and keep the records as specified in 1776.6. Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.~~

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, Business and Professions Code and Sections 1304.22, 1317.05, 1317.40, 1317.60, 1317.75, 1317.80, and 1317.95, Title 21 Code of Federal Regulations

**Proposal to add § 1776.5 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:**

### **1776.5 Reverse Distributors**

A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered with the DEA ~~as a collector~~ may accept the sealed inner liners of collection receptacles at the reverse distributor's registered location by common or contract carrier pick-up, or by reverse distributor pick-up at the collector's authorized collection location. Once received, the reverse distributor shall establish records required by this section.

A licensed reverse distributor may not open, or survey, or otherwise analyze ~~count, inventory or otherwise sort or x-ray~~ the contents of inner liners. All liners shall be incinerated ~~destroyed~~ by an appropriately licensed and registered DEA reverse distributor in a manner that makes the drugs irretrievable.

If a reverse distributor picks up the sealed inner liners from the collector's

authorized location, at least ~~T~~two employees of the reverse distributor shall be present, pick up or accept the receipt of inner liners from DEA registrants. If the sealed inner liners are delivered to the reverse distributor via common or contract carrier, at least one employee of the reverse distributor shall accept the receipt of the inner liners at the reverse distributor's registered location.

A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

~~Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.~~

~~(f)~~(e) For each sealed liner or mail back envelopes or packages received from collectors or law enforcement pursuant to federal Title 21 CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes ~~/~~or packages, including the:

Date of acquisition;

Number and the size (e.g., five 10-gallon liners, etc.);

~~Inventory~~ Unique Identification number of each liner or envelope/package;

The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner;

The date, place and method of destruction;

Number of packages and inner liners received;

Number of packages and inner liners destroyed;

The ~~number~~ name and signature of the two employees of the registrant that witnessed the destruction.

For liners only, the information specified in subsection (e)(1)-(8) above shall be created at the time of receipt and at the time of destruction.

Note: Authority cited: Section 4005, Business and Professions Code.

Reference: Sections 4005, Business and Professions Code and Section 1301.71, 1304.21, 1304.22, 1317.15, and 1317.55 Title 21 Code of Federal Regulations.

**Proposal to add § 1776.6 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations as follows:**

### **1776.6 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services**

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the ~~following~~ records required by this article for three years.

When obtaining unused mail-back packages and envelopes for future distribution:

The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.

For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.

For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.

For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,

For sealed mail-back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.

(a) For pharmacies ~~using~~ maintaining collection receptacles, the pharmacy shall maintain make and keep the following records for each liner:

Date each unused liner is acquired, its unique identification number and size (e.g., ~~five~~ 5 gallon, ~~10~~ 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.

Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., ~~five~~ 5 gallon, ~~10~~ 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.

Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed ~~each~~ the removal and sealing.

Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., ~~5~~ 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.

Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was

transferred, the unique Identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading) and the signature of the driver.

~~(b) For each reverse distributor (wholesaler or third-party logistics provider) accepting sealed mail-back packages: the date of receipt and the unique identification of the individual package or envelope.~~

~~(c) For each reverse distributor that will destroy the mail-back packages: the number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.~~

~~(d) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, the following records must be maintained, with recording taking place immediately upon receipt of a liner:~~

~~The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier or pick-up by reverse distributor).~~

~~For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, Business and Professions Code and Section ~~1317.22~~ 1304.22, Title 21 Code of Federal Regulations

M/S: Weisser/Lippe

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz				X
Sanchez				X
Schaad	X			
Veale	X			

Weisser	x			
Wong	x			

Ms. Herold indicated that the board has to continue working on a solution for EpiPens and other sharps. She said it would be put on the agenda for the next Enforcement Committee meeting.

**Communication and Public Education Committee**

Chairperson Law noted that the board meeting packet includes a copy of the minutes from the committee’s Sept. 8, 2016, meeting in Attachment 10. He added that the committee meeting minutes include discussion of the final rule implementing Section 1557 of the Affordable Care Act. He said the item is scheduled for a committee meeting on Dec. 14 in Glendale.

Update and Discussion on the Development of a Revised Patient Consultation Survey Questionnaire

Chairperson Law said that at the October 2015 board meeting, President Gutierrez asked the committee to develop a survey for licensees about patient consultation. At the May 2016 Communication and Public Education Committee Meeting, Division of Program & Policy Review Chief Tracy Montez, Ph.D., of the Department of Consumer Affairs addressed the committee and her office’s ability to develop the patient consultation survey for the board’s licensees.

Chairperson Law stated that at the September 2016 Communication and Public Education Committee meeting, the committee discussed the advantages of the board funding an additional survey. Board staff provided rough estimates from the DCA of approximately \$15,000-\$20,000 plus an additional \$1/per pharmacist surveyed. The DCA recommended surveying 10,000-20,000 pharmacists.

Chairperson Law said committee members discussed the importance of ensuring patient consultation is provided to patients; however, they expressed hesitation in a survey being the most effective instrument used to increasing patient consultation. The committee discussed various means to ensure patient consultation, including licensing and enforcement measures.

Chairperson Law said the committee recommended that the board redirect the subject of patient consultation to the Licensing Committee; recommended that the Licensing Committee focus on regulations that could be streamlined to increase pharmacist availability for consultations; recommended that no survey be conducted; and recommended canceling the pharmacist survey by the DCA.

Ms. Butler expressed support for the recommendation. She said the board does not need a survey, because the board already has heard pharmacists say that they are too busy and do not

have time to provide patient consultations. Mr. Brooks agreed and said the committee felt that a different committee should look at what regulations might help ease the burden on pharmacists so that they could have time for consultations. President Gutierrez and Ms. Veale also expressed support for the recommendation.

There was no public comment.

**Committee Recommendation:** Recommend that the board re-direct the subject of patient consultation to the Licensing Committee; recommend that the Licensing Committee focus on regulations that could be streamlined to increase pharmacist availability for consultations; and recommend that no survey be conducted.

Support: 9                      Oppose: 0                      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**Committee Recommendation:** Recommend canceling the pharmacist survey by the Department of Consumer Affairs.

Support: 9                      Oppose: 0                      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			

Wong	x			
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Update and Discussion on Development of FAQs Received from [ask.inspector@dca.ca.gov](mailto:ask.inspector@dca.ca.gov)

Chairperson Law informed the board that licensees continue to be able to call and ask general questions of pharmacy inspectors. Inspectors answer calls on Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email inquiry to an inspector at [ask.inspector@dca.ca.gov](mailto:ask.inspector@dca.ca.gov). Board staff in concert with legal counsel developed a series of FAQs, including the most frequent questions and issues posed to the inspector during this time. A copy of the FAQs posted on the board’s website is in Attachment 1.

Chairperson Law said that the FAQs are not intended as, nor should they be construed to be, legal advice. He said the information is intended to provide guidance to the reader on relevant legal sections that should be considered when using professional judgment to determine an appropriate course of action. He added that should a licensee require legal advice or detailed research, the licensee is encouraged to contact an attorney or other source.

Mr. Schaad said some pharmacists have complained that it takes too long to get an adequate answer to their questions. Chairperson Law said he was connected to an inspector within a minute and a half of calling the phone line. Ms. Brooks also said that she has had no problems getting answers on the phone line and that she has received positive feedback from pharmacists about the service.

Ms. Herold said there might be a delay for a question that requires research to answer. Ms. Veale said pharmacists have told her that they received quick responses to emailed questions. She said one complained that the inspector would not give legal advice and instead directed the caller to an attorney.

Dr. Wong asked about caller statistics and whether staffing or hours should be increased to meet demand. Ms. Herold said she was not aware of any staffing problems and said that adding staff to phone lines would decrease inspection times.

#### Discussion and Consideration of Naloxone Related Matters

##### Communication to the California Healing Arts Boards Regarding Naloxone

Chairperson Law informed the board that at previous committee meetings, committee members have expressed interest in reaching out to California healing arts boards regarding naloxone access and the regulation and protocol.



Chairperson Law said that staff recently developed an article about pharmacists and naloxone to be shared with the other California healing arts boards, including the Medical Board of California, Board of Registered Nursing, Dental Board of California, Dental Hygiene Committee of California, California State Board of Optometry, Osteopathic Medical Board of California, Physician Assistant Board, California Board of Podiatric Medicine, Veterinary Medical Board, and Board of Vocational Nursing and Psychiatric Technicians. He said that a copy of the article and transmittal letter is included in Attachment 2.

#### Naloxone FAQs

Chairperson Law said that at previous committee meetings, committee members have expressed the need for a naloxone FAQ. Board staff drafted naloxone FAQs in concert with legal counsel. The naloxone FAQs are posted on the board's website. A copy of the FAQs is included in Attachment 2.

Mr. Lippe asked if a pharmacist is protected by legislation from liability in a case where naloxone produces a negative result or fails to work as intended. Mr. Room said the statute does not include liability protection for the board.

There was no public comment.

#### SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016)

Chairperson Law said the committee discussed SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016), which requires the California Department of Public Health to award funding to local health departments, local government agencies, or on a competitive basis to community-based organizations, regional opioid prevention coalitions, or both, to support or establish programs that provide naloxone to first responders and to at-risk opioid users through programs that serve at-risk drug users, including syringe exchange and disposal programs, homeless programs, and substance use disorder treatment providers. There is approximately \$3 million available from this law. The board is not eligible to apply for the funding.

Chairperson Law said pharmacies that want to provide naloxone should contact to the Department of Public Health for this funding. He said the board would disseminate information via subscriber alerts when the information is available on how to apply for the funding. Ms. Herold advised the board that the \$3 million is one-time funding.

There was no public comment.

#### Discussion on Federal Legislation: US S. 524 – Comprehensive Addiction and Recovery Act of 2016

Chairperson Law said that on July 22, 2016, President Obama signed into law US S. 524 – known as the Comprehensive Addiction and Recovery Act (CARA) of 2016 – in an effort to combat the national epidemic of prescription opioid abuse and heroin use. A copy of the enacted law is included in Attachment 2.

#### Lali's Law

Chairman Law informed the board that Lali's Law was passed by the House by a vote of 415-4 on May 12, 2016, and the bill was signed into law as part of the Comprehensive Addiction and Recovery Act of 2016 on July 22, 2016. Lali's Law increases access to naloxone throughout the United States. The bill is named in memory of Alex Laliberte, an Illinois resident who passed away seven years ago from a drug overdose.

Chairperson Law said the committee discussed how Lali's Law creates a competitive grant program that will help states increase access to naloxone. The primary purpose of the grant is to fund state programs that allow pharmacists to distribute naloxone without a prescription. Many states use these programs to allow local law enforcement officers to carry and use naloxone.

Chairperson Law said the law authorizes the CDC to award grants to states to encourage pharmacies to dispense medications that reverse opioid overdoses. He said staff contacted the Congressman Dold's legislative assistant, who responded the Department of Health and Human Assistance will implement the Lali's Law grant programs, but the assistant was unaware which sub-agency or department would actually carry it out. She also indicated she would advise board staff when additional information is available. A copy of the press release announcing Lali's law is included in Attachment 2.

Dr. Wong asked if any of the money would be available to pay for recovery programs. Mr. Law said the money is only for naloxone. Dr. Wong said that many pharmacists do not know where they can refer addicts seeking treatment. Mr. Lippe asked if users are being educated on how to use naloxone properly. Ms. Herold said the board's regulations require pharmacists to give naloxone consultation and that patients are not allowed to waive the consultation.

There was no public comment.

#### Provisions Regarding Partial Fill for Schedule II

Chairperson Law said the committee discussed potential conflict between Section 702 (f)(2)(A)(ii) of CARA and California law. He presented the board with the following clarification provided by legal counsel to board staff:

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

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

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

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

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

Chairperson Law also informed the board that the committee said this issue should be brought to the attention of pharmacists by the board such as in an article in The Script for the winter 2016/17 edition. He said board staff will work on developing an article for the winter edition of The Script.

There was no public comment.

#### Discussion on the Development of FAQs for SB 493 Related Items

Chairperson Law stated that at the April 2016 board meeting, the board requested that the Communication and Public Education Committee coordinate the development of a Frequently Asked Questions (FAQs) for SB 493 related items. At the September 2016 Communication and Public Education Committee, board staff reported the draft was under legal review and would be posted on the board’s website as soon as possible.

Ms. Sodergren informed the board that the FAQs were pulled back from legal review for updates. She said the FAQs would be sent back to legal review by the end of the week.

There was no public comment.

#### Discussion on CE Courses Available for Naloxone, Self-Administered Hormonal Contraception and Nicotine Replacement Therapy under Protocols

Chairperson Law informed the board that the committee members reviewed a chart summarizing options for CE that are available specific to naloxone, self-administered hormonal

contraception and nicotine replacement therapy under protocols. The committee concurred the chart should be updated to reflect the training required prior to initiation of the protocol and show any continuing education required, if applicable.

Chairperson Law said staff has updated the chart and will seek legal approval and post to the board's website. He said that as part of the update, staff included the vaccination protocol. A copy of the updated chart is included in Attachment 3.

There was no public comment.

#### Update and Discussion on Resources Available on the Board's Website

Chairperson Law stated that at prior meetings, the committee reviewed multiple items for posting on the board's website as resources for consumers and licensees. At the May 2016 meeting, the committee directed staff to develop and bring to the committee a draft policy for posting resources on the board's website.

Chairperson Law said staff consulted with other boards within DCA and state agencies and drafted the California State Board of Pharmacy's Website Guidelines. He said the need for the policy statement arose because the board received general requests to post items on the board's website. He said committee members agreed that the draft policy is a good place for the board to start and make changes as necessary.

Chairperson Law reported the committee directed staff to move forward and post the policy on the board's website. He said that a copy of the policy has been added to the board's website and can be found in Attachment 4.

There was no public comment.

#### Discussion of a Board-Developed Billboard Message and Related Communication Materials

Chairperson Law stated that through the efforts and actions of Board Member Ryan Brooks, the committee reviewed the concept for a roadside billboard message and related communication materials. Chairperson Law said the billboard is intended to encourage parents to talk to their children about prescription drug abuse. The draft concepts were developed by staff at Mr. Brooks' firm. The first draft included drawings of pills around the message "Unattended Drugs are the Leading Killer of Kids." The second draft featured "Kid KILLER" with capital letters superimposed on a prescription drug pill.

At the board meeting, several members said that they liked the first draft concept. Chairperson Law informed the board that the billboard also would inform viewers that the message is sponsored by the California State Board of Pharmacy. Board members thanked Mr. Brooks for

his work and contribution to the project. Mr. Brooks said his firm would work with the executive officer to finalize the billboard message, identify locations and perhaps generate additional media exposure and public speaking opportunities. Ms. Veale said the board should write a letter thanking Mr. Brooks’ firm.

Ms. Herold said the billboard fits with a public campaign being developed by a number of state agencies working with the Department of Public Health. She said the billboard also would be linked to the board’s website for more information about preventing prescription drug abuse.

There was no public comment.

**Committee Recommendation:** Sponsor the billboard message and move the concept with the full board’s consent.

Support: 9                      Oppose: 0                      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Communication Plan for Consumers and Licensees

Chairperson Law informed the board that in accordance with the board’s strategic plan, staff provided committee members with copies of a draft communication plan that included aspects for both consumers and licensees. He said that a copy of the draft plan is included in Attachment 6.

There was no public comment.

Update and Discussion on the Forty-Fifth Annual Report of the Research Advisory Panel of California for 2015 Regarding Controlled Drugs Research

Chairperson Law stated that pursuant to Health & Safety Code Sections §11480 & §11481, California law requires that proposed research projects using certain opioid, stimulant and

hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances as their main study drug(s) be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office.

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

Chairperson Law reported to the board that the panel reviewed 45 research study submissions in 2015, including 43 that were approved. Among the approved studies, 14 studies were academic research studies; two studies were substance abuse treatment research protocols; and 27 studies were multi-clinical drug trial research studies. Chairperson Law reported that at the end of 2015, the panel was monitoring 121 research projects. He said a copy of the panel's report is included in Attachment 7.

There was no public comment.

Board Publications – Review and Recommendations for Changes

Counterfeit Prescription Drugs: Protect Yourself, Your Family and Your Pets  
Buying Prescription Medications Online: Are the Drugs You Buy Fake or Real?

Chairperson Law reported that the committee assessed the two board produced publications to determine if the pamphlets should be updated or removed from publication. A copy of both documents is included in Attachment 8.

Chairperson Law said the committee feels the pamphlets contained good information but perhaps they were not hitting the proper target audience. He said the committee suggested asking retailers associations to distribute the pamphlets to customers when they fill their prescriptions. He said copies also should be made available at board meetings and speaking presentations.

In addition, Chairperson Law said the committee asked that the pamphlets be translated into the top five languages and that pharmacies be notified that they are available so they can be distributed to customers. He said staff would work on updating the pamphlets, including information about the .pharmacy domain.

Public comment: At the request of Chairman Law, Angie Manetti of the California Retailers Association said their members were open to providing educational materials and would take a

look at the pamphlets for possible distribution. Mr. Gray indicated that seniors are at risk of buying drugs on the internet and suggested that the board reach out with the pamphlets to senior organizations as well as retailers.

#### Update on The Script Newsletter

Chairperson Law informed the board that the Summer 2016 edition of The Script was published in early September 2016. He said staff is currently working on articles for the Winter 2016/17 edition of The Script for publication by Jan. 1, 2017.

There was no public comment.

#### Update on Media Activity

Chairperson Law presented for the board's reference the following list of the executive officer's recent media interviews and inquiries.

**MPA Media**, July 14, 2016: Kathryn Feather, regulation of acupuncture needle distributors.

**Capitol Television Network News**, July 27, 2016: Jonathan Underland, drug- take back regulations.

**KPIX**, Aug. 16, 2016: Molly McCrea, opioid compound U-47700

**Veterinary Information Network News Service**, Aug. 29, 2016: Edie Lau, unlicensed business selling veterinary prescription drugs online.

**Glendale News Press**, Sept. 6, 2016: Alene Tchekmedyan , disciplinary case against Kenneth Road Pharmacy in Glendale

**The Hollywood Reporter**, Sept. 21, 2016: Peter Flax, pharmacy law re providing false information for prescriptions

There was no public comment.

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

Chairman Law presented the following list of major public outreach activities by the board's staff. He added that staff will begin informing the committee and the board about presentations in advance.

July 18: Supervising Inspector Christine Acosta presented HD compounding for CPhA.

Aug. 9: Inspector Jennifer Hall provided a review of new laws to the board's competency committee.

Aug. 18: Supervising Inspector Christine Acosta presented the new compounding regulations to Tenet health.

Aug. 24: Inspector Trang Song presented at the Vietnamese Pharmacist Association

Oct. 5: Supervising Inspector Christine Acosta presented the new compounding regulations to the Kaiser Permanente Operations Team.

Review and Discussion of the California Department of Public Health's Comparison Between the Centers for Disease Control and Prevention's *Guidelines for Prescribing Opioids for Chronic Pain* and the Medical Board of California's *Guidelines for Prescribing Controlled Substances for Pain*

Chairperson Law reported that the committee discussed the California Department of Public Health's Comparison Between the Centers for Disease Control and Prevention's Guidelines for Prescribing Opioids for Chronic Pain and the Medical Board of California's Guidelines for Prescribing Controlled Substances for Pain. He said that a copy of the California Department of Public Health's Comparison is included in Attachment 9.

Mr. Weisser asked about cooperation between the pharmacy and medical boards on developing guidelines. Ms. Herold suggested a future summit on CURES issues so that prescribers and dispensers can collaborate better. Mr. Law requested that the board provide additional public CE programs on narcotics abuse and was advised that it was included in the committee's communication plan.

#### Future Meeting Dates

Chairman Law announced the next committee meeting is set for Dec. 1, 2016.

Mr. Schaad requested a report on concerns and complaints to the board from consumers.

#### **Lunch**

The board recessed for a lunch break at 1:15 p.m. and reconvened at 1:54 p.m.

#### **Enforcement Committee Related Items**

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

University of California, San Diego, Pilot Program to Permit Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy, Including Possible Modifications to the Study Parameters - Update and Discussion and Consideration of Modifications to the Pilot Program, if Necessary

President Gutierrez reported an update on an 18-month pilot study under the auspices of the University of California, San Diego (UCSD) School of Pharmacy involving use of an automated storage device for prescription medication from which staff of Sharp Hospital in San Diego and



their families, who opted in, could pick up their outpatient medications. She said the study was originally scheduled to start in June or July of 2015 but was delayed until January 2016.

President Gutierrez said that at the February 2016 board meeting, the board approved a recommendation to ask UCSD to collect drug classification data as part of the study. At the June 2016 Enforcement and Compounding Committee meeting, Dr. Hirsch reported that the kiosk had about 200 users, which is approximately 4 percent of the 4,800 Sharp employees. The kiosk has 24-hour video surveillance and on-site monitoring.

President Gutierrez said the study needed to average 140 prescription pickups per month to reach the study target of 820; however, the current usage of only 80 pickups per month would fall short of that goal based on the current length of the study. Dr. Hirsch requested an extension to continue collecting data through December 2016 and proposed reporting back to the board in March 2017.

President Gutierrez stated that at the July 2016 board meeting, the board approved the committee's recommendation to:

- allow UCSD to collect data through the first quarter of 2017,
- allow UCSD to report the findings of the study at the May 2017 board meeting, and
- allow UCSD to continue operating the kiosk until a decision is made at the May 2017 board meeting.

President Gutierrez said that at the Aug. 31 Enforcement and Compounding Committee meeting, Dr. Hirsch provided an update of the study via telephone and responded to questions from the committee. A copy of Dr. Hirsch's presentation is included in Attachment 1. President Gutierrez said Dr. Hirsch reported there are now 289 registered users of the kiosk, which is 6 percent of the eligible campus employees.

President Gutierrez also reported the following updated study findings:

Of total prescriptions dispensed since initiation of the study: Total Medications Obtained: 943

- 72 percent were accessed during pharmacy working hours
- 28 percent were accessed after hours

New Prescription Medications Obtained: 313 (33.2 percent)

- 78 percent were accessed during pharmacy working hours
- 22 percent were accessed after hours

Refills: 237 (25.1 percent of all medication)

- 83 percent were accessed during pharmacy working hours
- 17 percent were obtained after hours

OTC: 393 (41.7 percent of all medication)

- 62 percent were accessed during pharmacy working hours
- 38 percent were accessed after hours

President Gutierrez said the committee was surprised that so much of the medication – about 42 percent – was over-the-counter medication.

President Gutierrez said that Sara Lake, a representative from the kiosk vendor Asteres who is working with Dr. Hirsch on this study, was also present at the meeting and responded to questions from board members. She commented that as prescriptions are approved and loaded into the kiosk, patients receive a text to alert them that their medication is available for pick-up. New prescriptions are placed on hold until a telephone consultation has been completed. Consultations are available 24 hours per day, seven days a week. Upon request, consultations are available for refill prescriptions and OTC medications. If a pharmacist wishes to discuss a prescription with a patient, the pharmacist can place a hold on the medication.

President Gutierrez stated that in response to questions during the meeting, Ms. Lake explained that Dr. Hirsch completed a study in 2005/06 to research the quality of counseling for refill medications and that this study is not designed to study after hours consultation. She said that a copy of that study is in Attachment 1.

President Gutierrez said reports on the UCSD study will continue to be provided at each Enforcement and Compounding Committee meeting while the study is underway.

Mr. Law said he would like to know why more employees are not using the kiosk.

There was no public comment.

CURES 2.0 Prescription Monitoring Program and Use of CURES by Pharmacists – Update and Discussion and Consideration of Next Steps, if Necessary

President Gutierrez said that as of July 1, 2016, California law requires that all pharmacists with active licenses apply with the California Department of Justice (DOJ) to access CURES. The board has made considerable efforts to ensure pharmacists with active licenses were advised of this requirement.

President Gutierrez said that at Aug. 31 Enforcement and Compounding Committee meeting, Ms. Herold estimated that perhaps 5 percent of registered pharmacists had not signed up for CURES. She said it was believed that figure represented pharmacists who were out of state or who were retired or not practicing as pharmacists or who did not know how to use a computer.

Ms. Herold informed the board that in November, staff will make another attempt to identify and reach out to pharmacists with active licenses who have not applied for access to CURES. She said it would be the third and last outreach effort to get pharmacists registered with CURES.

In response to a question from Ms. Butler, Ms. Herold told the board that pharmacists who are retired or who have an inactive license do not have to register to sign up with CURES. She said that pharmacists who are not working but still have active licenses do have to register to sign up because they could begin practicing again anytime.

Ms. Veale asked if pharmacists are actually using CURES. President Gutierrez reported statistics that are provided in Attachment 2. She said that as of Aug. 25, 38,259 dispensers were registered for CURES 2.0; most of these dispensers are pharmacists. She noted that patient activity report data indicate there are three to four times more prescribers than dispensers, yet the dispensers are running a significant number more of the patient activity reports. President Gutierrez suggested sharing the data with the Medical Board.

President Gutierrez also reported that, as approved by the board at the July Board Meeting, researchers at the University California, Davis, will be surveying pharmacists who renew their licenses in November to learn about their use and opinion of CURES 2.0. Physicians will participate in a related survey at the same time. Both survey results will be shared with the board.

President Gutierrez said that at some point the board will discuss how CURES 2.0 reporting system will be linked with other states. She said that California is one of three states not linked to other states. Ms. Herold said that she would reach out to DOJ to begin discussions about linking CURES with other states. President Gutierrez and Ms. Veale requested that DOJ be invited to an Enforcement and Compounding Committee meeting and that the issue become a regular committee item until it is resolved.

In response to a question from Ms. Veale, Ms. Herold said the board cannot identify CURES users but the DOJ can. Mr. Weisser asked how CURES systems are housed in most states, and Ms. Herold said it is done mostly by pharmacy boards. She said the board offered to take over CURES in the past but DOJ declined.

Note: Dr. Wong stepped out of the meeting at 2:11 p.m. and returned at 2:15 p.m.

Public comment: Mr. Rosati asked about possible legislation requiring prescribers to use CURES. Ms. Herold said the law requires prescribers who are prescribing more than five days' worth of drugs and who meet other conditions must check CURES once every four months. She said pharmacists are not required by law to use CURES. Mr. Rosati said that if pharmacists are

required to check CURES, the time needed to do so should not count against the time spent on filling prescriptions.

#### Discussion and Consideration of Consumer Enrollment in Automated Refill Programs for Prescription Medications

President Gutierrez said the Enforcement and Compounding Committee looked at how pharmacies have traditionally refilled prescriptions only upon the request of the patient or the patient's prescriber – but in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs (“auto-refill”). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto-refill programs are limited to drugs identified as maintenance medications.

President Gutierrez said that the argued benefit of auto-refill programs is that they increase patient compliance with drug therapy by automatically refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

President Gutierrez said that in 2012, the Los Angeles Times and other media outlets reported issues that generated over 100 auto-refill complaints to the board received from late 2012 through 2013. She said supervising inspector Anne Hunt reported to the Enforcement and Compounding Committee that patient complaints include:

Allegations pharmacy staff enrolled patients in auto-refill programs without their knowledge or consent because pharmacists were working under work quotas that directed or rewarded patient enrollment in these programs.

Patients or agents who picked up prescriptions for the patient received prescriptions the patient did not request and had difficulty returning the prescriptions for a refund.

When patients receive medications that they do not want, it increases the disposal of medication and waste.

Constant robo-calls to pick up medication that the patient did not want or request.

Patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued or changed by their prescriber.

President Gutierrez said that some of these events resulted in patient harm. She said this problem is compounded when the patient has multiple doctors and multiple prescriptions. She stated that Dr. Hunt reported that there does not appear to be a mechanism to address changes in drug therapy that occur when a prescription is discontinued, the strength is changed, or the patient has been prescribed two different drugs in the same class because one drug was not effective.

President Gutierrez reported that in response to the large number of complaints, Ms. Herold and staff worked with the various agencies to address these concerns and explore possible

violations of pharmacy laws and regulations. Ms. Herold informed the board that staff found some of the violations reported by Ms. Hunt.

President Gutierrez noted that in 2013, the Federal Centers for Medicare & Medicaid Services (CMS) proposed new regulations that resulted in additional rules for auto-refill programs for Medicare patients receiving prescriptions from mail order pharmacies. She told the board that a copy of the CMS Memorandum dated Oct. 28, 2013, regarding Clarification to the 2014 Policy on Automatic Delivery of Prescription for Employer Group Waiver Plans is included in Attachment 3.

President Gutierrez said the committee discussed developing requirements for pharmacies that choose to enroll patients in automated refills, including:

Considering how often signed consent should be obtained (e.g., annually) and whether signed consent should be obtained separately for each prescription placed on auto-refill.

With regard to pharmacies in the community practice setting, the committee may wish to consider additional requirements for pharmacies to notify patients upon pick up, both verbally and in writing (on the receipt), if the prescription was refilled automatically. Notifying the patient that the prescription was refilled because it was on auto-refill might help to eliminate some of the confusion or at least open a dialogue with the pharmacist to prevent potential harm to the patient from unwanted refills.

With regard to mail order pharmacies, the committee may wish to consider adding requirements consistent with guidance from CMS.

With respect to both community pharmacies and mail order pharmacies, the committee may wish to consider requirements for written policies and procedures related to auto-refill. The policies and procedures might include procedures to ensure discontinued medications are removed from the auto-refill program and that drug therapy reviews are conducted by the pharmacist to prevent duplicate therapies.

President Gutierrez told the board that the committee recommendation is for staff to develop an analysis and presentation for the next committee meeting to evaluate options for authorization and maintenance of auto-refill documentation in community and mail order pharmacies.

Board members expressed concerns about pharmacies auto-refilling prescriptions without patients' knowledge or consent. Mr. Weisser said auto-refills also could push Medicare patients unknowingly into the "doughnut hole" and significant financial consequences. In response to a question from Mr. Law, Ms. Herold said that a pharmacist auto-refilling a medication that has been recalled could be penalized with a citation and fine, but there is no requirement that patients sign consent for auto-refills.

Mr. Lippe said that the patient does not have to accept an auto-refill that he or she did not request; Ms. Herold said the patient frequently does not know that and may believe it was

ordered by the doctor. President Gutierrez said the Enforcement and Compounding Committee would continue to discuss the topic and report to the board.

Public comment: Brian Warren of the California Pharmacists Association said he agreed that auto-refills without patient consent are a problem and suggested that the committee invite chain pharmacies and pharmacy management software vendors. He expressed concern about making it difficult for patients to get auto-refills or more burdensome on pharmacists to enroll patients in auto-refill programs.

#### Discussion and Consideration of Statistics for Board Issued Citations and Fines

President Gutierrez reported that Chief of Enforcement Julie Ansel provided the committee with information regarding citations and fines issued by the board. She said that a copy of Ms. Ansel's presentation, which includes agenda items d and e, is included in Attachment 4.

President Gutierrez said Ms. Ansel reported the top three licensees – pharmacies, pharmacists and technicians – account for 90 percent of all fines. The remaining 10 percent of fines are spread across wholesalers, clinics and hospitals.

President Gutierrez said Ms. Herold stated that a citation and fine or letter of admonishment is not considered formal discipline; it is equivalent to a speeding ticket. She said the goal in issuing them is to get the licensee to examine what led to the violation and change his or her practices so that violations do not reoccur.

During the board meeting, Ms. Herold said that a correction note is the lowest level of enforcement, followed by a letter of education, letter of admonishment, or citation and fine. She said these are given where the board wants a pharmacist to correct a problem, but they are not considered formal discipline. For egregious violations, where the board is seeking to remove or restrict the license, formal discipline ranges from probation to license revocation. She added that a letter of public reprimand is formal discipline.

President Gutierrez said Assistant Executive Officer Anne Sodergren stated that approximately one-third of the investigations opened by the board are a result of a consumer complaint. The second leading cause of investigations is from DOJ-generated notifications to the Criminal Conviction Unit related to a licensee's arrest.

#### Discussion and Consideration of Data Describing Medication Errors for Board Issued Citations and Fines; and

#### Enforcement Statistics

President Gutierrez said Ms. Ansel clarified that her presentation includes both items d and e on the agenda – the number of citations and fines issued and a more detailed look of the medication errors. She said the committee briefly reviewed the statistics and reported that Attachment 5 includes the first quarter of enforcement statistics, SB 1441 Program Statistics and Citation and Fine Statistics for Fiscal Year 2016/17.

President Gutierrez said the information gives examples of cases in which fines were given for \$500, \$750 and \$1,000. She said that most of these cases result from patient complaints.

#### Future Committee Meeting Dates

President Gutierrez announced the next Enforcement and Compounding Committee meeting is Jan. 4, 2017. She said additional meeting dates for 2017 are April 18, July 12 and Oct. 17.

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

[Not discussed at the Aug. 31, 2016, Committee Meeting] Discussion and Consideration of Pharmacy Requests for Compliance Delays for Construction Pursuant to Title 16 California Code of Regulations sections 1735.6(f) and 1751.4(i), including:

President Gutierrez noted that at prior committee and board meetings and as permitted in the above regulation sections, the board has discussed a waiver process to permit pharmacies that need to structurally modify their facilities to comply with the new compounding regulations to obtain a delay in full compliance. She noted that the new compounding regulations take effect Jan. 1, 2017, and added that they include provisions authorizing the board to waive compliance:

*1735.6 (f) Where compliance with the January 1, 2017, amendments to Article 4.5 or Article 7 requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.*

President Gutierrez informed the board that she worked with Mr. Schaad, Ms. Herold and Ms. Acosta to develop a sample waiver form that pharmacies can use to submit waiver requests. She said sample waiver forms are provided in Attachment 5.5 that lay out the general information the board can use to make this assessment. There are separate forms for community pharmacies and for hospital pharmacies.

President Gutierrez asked the board during the meeting to discuss the process for managing the review and approval of waivers, including who would make the decisions

## Requests Received to Date Process for Reviewing Future Requests

Supervising Inspector Christine Acosta informed the board that she had received 12 waiver requests. She added that one was incomplete, so 11 completed waiver requests are ready for board action.

President Gutierrez said the group discussed having Ms. Acosta review requests and submit them to Ms. Herold to determine whether they meet the regulation standard. For requests that do not meet the standard for a waiver, the requests could be forwarded to a waiver committee that would meet twice monthly. President Gutierrez said she asked Mr. Schaad to join her on the waiver committee.

Ms. Acosta said that she anticipates many requests and expressed concern that one or two meetings would not be sufficient to process them before the regulations take effect in two months. She requested guidance on what the board would allow to be accepted as a possible waiver, citing a request from one pharmacy seeking a waiver until July 2018 with no plans for construction before that time.

President Gutierrez explained that the waiver committee could meet as often as necessary, at first in person and then by phone. She said the committee would not review all the requests – only the requests that Ms. Acosta and Ms. Herold recommend for denial.

In a series of clarifying questions, Ms. Acosta asked whether the board would approve a waiver for a pharmacy that wants to continue compounding after Jan. 1 without beginning any construction for six months. She also asked how much time a pharmacy should be allowed to continue compounding before construction begins.

During the discussion, board members said a pharmacy may need that window of time for a waiver to obtain permits. Others noted that pharmacies can include that information on a timeline with the application, which would be factored in the decision process. Ms. Herold asked if allowing compounding to continue during that period would present a risk to public safety. Ms. Acosta said the requests deal with hazardous room requirements, such as venting and non-porous surfaces. Board members said that waiver requests related to issues dealing with employee safety are less serious than issues that deal with public safety, such as clean-room standards and sterility.

Mr. Lippe said that if a waiver request includes a timeline, the waiver could be granted but would have to be monitored to ensure the construction is on schedule – otherwise, the waiver could be pulled. President Gutierrez suggested that some pharmacies might have to return to the board and adjust their timelines as construction delays and other issues arise. Board



members suggested that a waiver could be granted if a request for a reasonable delay includes a timeline.

Mr. Weisser noted that many hospital pharmacies face issues that would require OSHPD approval. President Gutierrez said OSHPD is working closely with board staff on the waiver process.

Ms. Acosta also presented information about a modular clean room made that pharmacies are asking to use as part of their waiver program. She said the manufacturer would deliver the unit to the location and that it could be rented during construction, but there are only 100 in the United States. She asked if pharmacies could get a waiver until a modular clean room is set in place. President Gutierrez suggested that board regulations on mobile pharmacies could be applicable.

In response to a question from Ms. Herold, board members indicated that they would approve a clean room if it passes inspection for sterile compounding. President Gutierrez and Mr. Schaad expressed support for helping pharmacies as much as possible and helping patients get their compounded medications.

Ms. Acosta asked about a request by a pharmacy that is not planning any construction at its current facility (i.e., suite A) but wants a waiver while it constructs another location (suite B). In response to a question from President Gutierrez, Ms. Freedman said the regulation is drafted in such a way that the board can grant a waiver as long as there is construction happening. Board members expressed support for granting a waiver even if construction is occurring at a new location.

Ms. Acosta also asked the board if a waiver could be granted for a pharmacy undergoing construction at its current location (suite A) – but the construction work makes it unsafe to continue compounding, so the pharmacy opens a temporary location (suite B), which also is not compliant with all the compounding regulations. She asked if the pharmacy can apply for a waiver on suite B as a temporary sterile compounding facility and, as part of the licensure of suite B at any point during the renovation, can the temporary but new LSC apply for a waiver at the same time the LSC license is issued.

Board members suggested that situation should be accommodated if possible without jeopardizing safety. Mr. Weisser emphasized that the board is committed to not disrupting compounding, especially at an acute facility. In response to a question from President Gutierrez about small hospitals, Ms. Acosta said modular clean rooms are available that could be placed inside and vented out of the top, as are other things that can be built that would be clean-room compliant within a room.

Ms. Veale asked if staff could inspect temporary sites more often. Ms. Acosta said sites are inspected before licensing and again at renewal. Ms. Herold said the board lacks staff to do monthly inspections and renewals while handling other responsibilities at the same time as outsourcing facilities. Dr. Wong suggested some hospitals could decide to use modular clean rooms permanently for compounding as a less costly alternative to new construction.

Public comment: Brian Warren of the California Pharmacists Association predicted that the number of waiver request would grow to several hundred. He requested that the board consider a delay in implementation of regulations for nonsterile hazardous compounding to give pharmacies more time to get construction plans in place and submit more definitive waiver requests.

Ms. Herold noted that the sterile compounding regulations build upon the nonsterile compounding regulations. She said that delaying implementation of the nonsterile compounding regulations would untie the sterile compounding regulations from their foundation.

Mr. Warren asked that the board direct staff to give greater leniency to nonsterile compounding pharmacies that do not have LSC licenses. He said that pharmacies doing nonsterile hazardous compounding for a long time did not believe that the regulations would apply to them and had not made plans to comply because there were looking forward to USP 800 implementation date of July 2018. He said delaying implementation for nonsterile compounding pharmacies that do not have LSC licenses would not raise the public safety concerns that the board has for LSCs.

Ms. Acosta noted that four of the 12 applications received so far do not have LSC licenses. As an example, she read one waiver application from a pharmacy doing hazardous, nonsterile compounding that needs to construct external ventilation for the current HD room but has not been able to reach agreement with the building owner and cannot move until later next year.

Ms. Freedman noted that the agenda item is compliance delays – specifically, waivers. She advised the board against granting blanket leniency and recommended a case-by-case approach. President Gutierrez said the board could instead give staff guidance that the focus should be on patient safety and not interrupting patient care.

Board members agreed that Ms. Acosta could look at whether a timeline is provided in deciding on waivers for both sterile and non-sterile compounding pharmacies. Ms. Herold added that staff also should consider the completion date.

President Gutierrez asked Mr. Warren to encourage pharmacists to keep copies of their waivers on hand to show to inspectors during inspections.

Steve Gray of Kaiser Permanente advised the board that some modifications, including modular units, may require a zoning variance or even a Coastal Commission variance that requires public hearings and votes by planning committees and city councils. He suggested the board also appoint an alternate member to the waiver committee in cases of absence or conflict of interest by a member.

Tracy Feng, PIC at Contra Costa Regional Medical Center, asked for clarification on waiver issues. She was informed that the some would be decided on a case-by-case basis and that staff would work with the medical center on a waiver during the licensing process for a new location.

In response to a question about what a pharmacy should do in case of timeline delays after a waiver is granted, Ms. Freedman advised the board that she saw no prohibition on a pharmacy submitting an addendum or request to extend a waiver. Ms. Herold said it would be important for pharmacies to let the board know about possible timeline delays.

**Motion:** Delegate authority to the Executive Officer to process waiver requests with parameters from the board and delegate authority for a committee assigned by the President, including the President and Mr. Schaad, to hear waiver request appeals.

M/S: Weisser/Lippe

Support: 9    Oppose: 0    Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Discussion and Consideration of Statistics on Compounding Violations Identified by the Board (2014-2016)

President Gutierrez informed the board that Supervising Inspector Christine Acosta provided an overview of compounding violations identified by the board over the last several years. A copy of her report was available in Attachment 6. Dr. Acosta noted:

Licensees do not always complete the compounding self-assessment form. This violation often occurs with new pharmacies or new PIC that fails to complete the assessment within the first 30 days. The assessment allows pharmacies to conduct their own gap analysis.

Another frequent violation is not having a master formula.

A discussion of room requirement violations revealed many licensees are not compliant with regulations with respect to compounding room requirements. Dr. Acosta provided examples, such as particle board in the clean room, not cleaning behind the hood, cardboard boxes next to the laminar flow hood, and laminar flow hoods that have non-porous material beneath them.

Ms. Veale noted that some of the data in the attachment did not add up correctly. Dr. Acosta said the problem was due to formatting errors.

President Gutierrez told the board that board inspectors are doing a tremendous amount of education to get licensees ready for the change in regulations.

President Gutierrez also said Dr. Acosta confirmed that an inspection is required each time a permit is issued or renewed and that the board is attempting to complete a full hospital inspection every two years. She said the result is that LSCs are being inspected more often than pharmacies that do not do sterile compounding. Ms. Herold said the board's goal is to inspect all pharmacies every four years.

Dr. Acosta confirmed that an inspection is required each time a permit is issued or renewed. The board is attempting to complete a full hospital inspection every two years. These inspections take two to three days to complete. Ms. Herold confirmed that our goal is to inspect all pharmacies every four years.

Dr. Wong urged more education during inspections. Ms. Herold said education is the focus during routine inspections.

There was no public comment.

#### Discussion and Consideration of Frequently Asked Questions about Sterile Compounding

President Gutierrez said Dr. Acosta developed a draft of frequently asked questions regarding compounding that can be found in Attachment 7. She said the final version was reviewed by legal counsel as well as herself and Mr. Schaad. Dr. Acosta said the FAQs have been posted on the board's website. President Gutierrez thanked staff and said the FAQs could be updated regularly.

There was no public comment.

## Discussion and Consideration of Frequently Asked Questions about Venting in Compounding Pharmacies

President Gutierrez informed the board that questions about venting are addressed in the compounding FAQs.

## Articles in the News, Including Discussion and Consideration of “Fraud Concerns Grow as Spending on Handmade ‘Compounded’ Drugs Soars”

Dr. Gutierrez reported that this article, which was published July 17, 2016, in The Washington Post, reports that government spending on compounded drugs under Medicare’s Part D rose 56 percent over the last year, with topical creams and gels among the costliest products. A copy of this article is included in Attachment 8.

The board recessed for a break at 3:40 p.m. and reconvened at 3:54 p.m.

### **Organizational Development Committee**

#### Budget Update/Report

##### Fiscal Year 15/16 Final Budget Report

President Gutierrez reported that fiscal year 2015/16 ended on June 30, 2016. Budget charts detailing the preliminary revenue and expenditure information for FY 2015/16 are provided in Attachment 1.

President Gutierrez noted that 84 percent of the board’s revenues came from license fees, and 11 percent from citations and fines. She added that the board expended \$20,968,800 and took in \$19,747,600 in FY 2015/16.

There was no public comment.

#### Fund Condition Report

President Gutierrez reported that a fund condition report provided by DCA is included in Attachment 2. She said that the information below reflects the estimated fund condition with the additional revenue from the approved fee increase signed by the governor.

<b>Fund Condition: With Fee Increase</b>		
<b>Fiscal Year</b>	<b>Fund Balance</b>	<b>Months in Reserve</b>
2015/2016	\$10,519,000	6.1

2016/2017	\$6,126,000	3.5
2017/2018	\$8,433,000	4.7
2018/19	\$10,511,000	5.8

Mr. Weisser expressed appreciation for the governor’s action. There was no public comment.

#### Governor’s Budget for Fiscal Year 2016/17

President Gutierrez reported that on June 27, 2016, the governor signed the budget for FY 2016/17. The new budget year began July 1, 2016.

President Gutierrez said the board’s spending authorization for the year is \$20,652,000, which is a 2.9 percent increase from the prior year. This includes about \$12.8 million in salary & wages and benefits, about \$2.75 million in pro rata to the DCA and state, and \$2.1 million in enforcement costs (including Office of the Attorney General and Office of Administrative Hearings).

President Gutierrez asked if the pro rata payment includes fees for BreEZe, which the board is not using. Ms. Sodergren said that the board is paying into BreEZe but not as much as other boards that do use the system. In response to a question from President Gutierrez, Ms. Sodergren said staff would find out how much of the pro rata costs is for BreEZe and report to the board on distributed cost items after meeting with DCA.

There was no public comment.

#### Board Member Reimbursement Information

President Gutierrez reported that board members may seek reimbursement for expenses and per diem payments. These are hours and expenses claimed by board members during the indicated periods and reported during each quarterly board meeting. She noted that 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 said it is important to note that these figures only represent hours where reimbursement was sought. She added that it is not uncommon for board members to waive their per diem payments. She said the final reimbursements for last fiscal year and the first quarter of fiscal year 2016/17 are provided in Attachment 3.

There was no public comment.

## Personnel Update

### Board Member Updates

President Gutierrez announced that Greg Murphy stepped down from the board at the end of August 2016. Mr. Murphy was a public member appointment by the Governor. He served on the board's Licensing Committee, Enforcement and Compounding Committee and Prescription Drug Abuse Subcommittee. President Gutierrez expressed appreciation for his service to the board.

President Gutierrez also noted the board has two vacant positions. She said both are public member appointments formerly held by Rosalyn Hackworth and Greg Murphy.

There was no public comment.

### Staff Updates

President Gutierrez directed the board's attention to a list of staff updates in her written report. Ms. Sodergren noted the list included the departure of Carolyn Klein, who retired after working for the board for more than eight years. She said Ms. Klein handled legislation and regulations for the board and was a senior manager over licensing programs and administrative functions.

Mr. Weisser suggested the board should send letters of appreciation to board members who leave and to Ms. Klein. Ms. Sodergren said staff would draft letters of appreciation for Ms. Hackworth, Mr. Murphy, Ramon Castellblanch and Ms. Klein and distribute them for personal signatures by board members at the next board meeting.

There was no public comment.

## Discussion and Consideration of the 2016-2021 Strategic Plan

President Gutierrez reported that the final draft of the plan as prepared by the DCA Strategic Organization, Leadership and Individual Development (SOLID) unit is provided in Attachment 4. She asked board members to review and discuss the document and added that upon approval of the draft plan, board staff will work with the department to develop an action plan and reporting mechanism for measuring the board's success in achieving the goals established in the plan.

Board members offered the following changes:

Move the last bullet item about the precedential decision on page 8 closer to the third bullet item mentioning the precedential decision on page 7 for consistency.

Add a separate bullet item about the board’s promulgation of drug take-back regulations after the section on Prescription Drug Abuse under the topic of Current Board and Industry Issues on page 9.

Under BreEZe Licensing System on page 9, add a general item about other ways besides BreEZe to facilitate online license renewal.

On page 10, under Pharmacy Compounding, expand the item to reference both sterile and nonsterile compounding.

On page 13, amend the Mission statement to “protects, promotes and advocates for the health and safety ...”

On page 15, add item 1.7, “Look for opportunities to expand professional practice for licensees that will enhance professional services and information to the public.”

On page 18, item 4.4, add language about using the website and publications and providing implementation guidelines on newly released regulations.

On page 19, add item 5.7, “Evaluate options for improvement of renewal licensing process.”

Under Enforcement, add item 2.7, “Investigate options for interoperability with national PDMP system.”

Under Legislation and Regulation, refine item 3.2 to add “regulatory issues and legislation.”

Under Organizational Development, on page 19, add item 5.8 about acting as a conduit for board issues relating to staff and for staff issues relating to the board.

On page 6, remove the number of board members for each committee but list president and vice president for the organizational Development Committee.

There was no public comment.

**Motion:** Approve the 2016-2021 Strategic Plan with the changes by the board.

M/S: Veale/Weisser

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			



## Future Board Meetings

Jan. 24-25, 2017

May 3-4, 2017

July 25-26, 2017

Nov. 7-8, 2017

President Gutierrez said the board's goal is to meet in various locations to increase access by board members.

## **Licensing Committee**

Discussion on Implementation of Provisions Contained in SB 1193 (Chapter 484, Statutes of 2016)

Chairperson Weiser reported that SB 1193 (Chapter 484, Statutes of 2016) was signed by the governor Sept. 22, 2016. He noted the bill contained the extension of the board's sunset date as well as many important changes to pharmacy law. He said the committee discussed and considered items from the bill. Attachment 1 includes relevant portions of SB 1193.

There was no public comment.

Incorporate Trusts as an Entity Authorized to Obtain Licensure, Proposal to Amend CCR section 1709, Names of Owners and Pharmacist In Charge

Chairperson Weisser reported that for several meetings, the committee has discussed the issue of trust ownership, primarily related to pharmacy ownership structures. During the July 2016 Board Meeting, the board approved statutory changes as the first step to allowing such ownership. These changes were included in Business and Professions Code (BPC) sections 4035, 4201, 4302, 4307 and 4308.

Chairperson Weisser said the committee was advised that staff was working toward full implementation, including review of the board's current regulations to determine if changes are necessary. As part of its discussion, the committee heard a brief presentation by Deputy Attorney General Matthew Heyn and reviewed proposed regulation changes to CCR section 1709. He said the committee discussed the basis for the proposed changes and provided direction to staff to update the language. The committee requested that the proposal be limited to changes necessary to implement the trust ownership.

Chairperson Weisser said Attachment 2 contains draft regulation language that includes the requested changes of the committee as well as changes offered by counsel to ensure consistency with terms and structure.

Mr. Law asked about ownership applications by trusts that are in limbo during the rulemaking process. Ms. Sodergren said that statutory changes made in BPC section 4035 will allow the board to consider those applications on a case-by-case basis while the rulemaking proceeds.

Public comment: Brian Warren of the California Pharmacists Association expressed concern regarding the required disclosure of beneficiaries and disclosure of changes in beneficiaries. He noted a license could be denied, suspended or revoked based on actions of the beneficiaries. He said a beneficiary would not have any beneficial interest or control over the pharmacy until the trustor dies, at which time a new ownership application would have to be filed.

Ms. Sodergren said Mr. Heyn explained that Pharmacy Law requires beneficial ownership. In addition, she said, there are some cases where a pharmacy transfer from one entity to another in a trust would not trigger a change of ownership application because the trust is continuing to own the pharmacy.

Ms. Freedman concurred with Ms. Sodergren's explanation. She added that an action by a beneficiary would not be an issue within the board's discretion and would not necessarily trigger a license revocation. Ms. Sodergren noted that the board also would have to demonstrate a substantial relationship between the beneficiary's action and the pharmacy license as part of a denial.

Mr. Lippe questioned treating revocable and irrevocable trusts the same way. Mr. Room explained that in cases where someone is using a trust solely for the purpose of hiding ownership or control of the pharmacy, it would be possible for a settlor, beneficiary and trustee to collude in a way to hide the true ownership.

In response to a question from Ms. Veale, Mr. Warren asked that the references to beneficiaries in the second sentence in section 1709(d)(3) and in section 1709(d)(4)(B) be removed. Mr. Room noted that statutes define "owner" as anyone who has a beneficial interest, and he added that a trust beneficiary does have a beneficial interest in a pharmacy license, even though that interest does not mature until the death of the settlor.

Board members and legal counsel discussed and considered various ownership scenarios involving revocable and irrevocable trusts. Board members expressed concerns about the possibility of control of a pharmacy transferring inside a trust from a settlor to a beneficiary without the board's notice.

Ms. Sodergren suggested that board members could consider the issues and possible changes to the language as the proposed regulation moves through the rulemaking process, including agency pre-review and public comment. Ms. Veale suggested that Mr. Warren propose possible language during the comment process.

**Committee Recommendation:** Approve proposed regulation change to CCR section 1709 that includes the provisions relating to the trust ownership as well as formatting changes. Remove provisions that are not related to the trust ownership.

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

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

M/S: Gutierrez/Veale

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Licensure of Outsourcing Facilities

Chairman Weisser informed the board that under federal law, an outsourcing facility is a facility that compounds human drugs if the following conditions are met:

1. The facility compounds sterile drugs.
2. The facility has elected to register as an outsourcing facility.
3. The facility complies with all of the requirements of section 503B.
4. The facility is not licensed as a pharmacy, but may be compounding under the direct supervision of a license pharmacist.
5. The compounding may or may not be for identified individual patients.

Chairman Weisser said the FDA notes that registration as an outsourcing facility does not mean that a facility complies with good manufacturing practice requirements or the other requirements of Section 503B. He said there are currently 65 facilities registered with the FDA, four of which are in California.

Chairman Weisser reported the committee briefly discussed the provisions in SB 1193 that establish the board's ability to issue licenses and regulate outsourcing facilities that provide compounded medications in California. The committee noted that, similar to the board's regulation of sterile compounding pharmacies, outsourcing facilities will be inspected before a license is issued or renewed.

Chairman Weisser said the committee was advised that necessary changes to the board's computer systems most likely will not occur until July 1, 2018. As such, staff is developing an implementation strategy that includes a manual process for the near future and a long-term solution, including modifications to our computer systems (which will automate some functions) that will begin when department resources are available.

Chairman Weisser reported the committee also was provided with the timetable for releasing the application and instructions to allow for submissions in advance of the January 1, 2017, effective date.

Chairman Weisser said the committee did not take action on this item.

In response to question by Mr. Schaad, Ms. Sodergren explained that the board will begin licensing outsourcing facilities that are within or ship products into California on Jan. 1, 2017. She said the board will have to process applications manually for at least a year, until necessary computer changes are made. She said staff is preparing the necessary application packages so that the board can begin issuing license on or around Jan. 1, 2017, assuming inspections are completed.

There was no public comment.

## Email Notification List Requirement

Chairman Weisser reported for many years the board has used an e-mail subscriber alert system as a quick and efficient way to communicate with licensees. Under current law (BPC section 4013), businesses licensed by the board are required to join the board's email notification list within 60 days of obtaining a license or at the time of renewal. Further this section requires the facility to update its e-mail address within 30 days of a change and allows for a single subscription for the owner of two or more facilities.

Chairman Weisser said the committee noted that under proposed provisions in SB 1193, effective July 1, 2017, BPC section 4013 will be amended to establish a similar requirement for individuals licensed by the board, including:

pharmacists

interns

pharmacy technicians

designated representatives-3PL

Chairman Weisser also told the board that the committee also discussed a drafting error that inadvertently omitted the designated representative license category was inadvertently not included. He said the committee reviewed a proposal that would fix the drafting error in an omnibus statute next year. A copy of the proposed statutory language was included in Attachment 3.

There was no public comment.

**Committee Recommendation:** Approve the proposed statutory change to amend section 4013(d)(1) to include designated representatives to the list of individuals required to join email notification list.

Support: 9

Oppose: 0

Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Discussion and Consideration of Possible Revisions to the Board’s Fee Schedule (Title 16 CCR section 1749) to Implement the Provisions Contained in SB 1039 (Chapter 799, Statutes of 2016)

Chairman Weisser reported that the board has been discussing for several years that its budget includes a structural imbalance in that its authorized expenditures exceed its revenue. To address this issue, the board worked with the Department of Consumer Affairs on a fee analysis, where the department determined the cost the board incurs to provide various services.

Chairman Weisser said the results of this analysis were included in the board’s Sunset Report and served as the baseline for the development of the legislative proposal to recast the board’s fees. He said the proposal was included in SB 1039 and was signed by the governor. The new fees will take effect July 1, 2017.

Chairman Weisser said the committee noted that because the fee analysis did not include all fees, a regulation is necessary to provide the board’s regulated public with a clear understanding of the fees that will be assessed for the various services, including application and renewal as well as delinquent fees. He reported the committee said the goal is to have the regulations in effect by July 1, 2017. A copy of SB 1039 and the proposed amendment to section 1749 is included in Attachment 4.

**Committee Recommendation:** Approve the draft regulation proposal to amend CCR section 1749.

Support: 9                      Oppose: 0                      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**Motion:** Delegate authority to the EO to make clarifying changes consistent with the board’s policy direction upon recommendations by control agencies.

M/S: Gutierrez/Lippe

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Discussion and Consideration of Next Steps Necessary to Implement SB 952 Relating to Pharmacy Technician Licensure Requirements (SB 952, Chapter 150, Statutes of 2016) Including Proposal to Add section 1793.65 to Title 16 CCR

Chairman Weisser informed the board that BPC section 4202 provides the general pathways to licensure as a pharmacy technician. SB 952 modified the requirements to expand the certification requirement to include other agencies. Because of the language in the measure, the board is required to approve certification programs.

Chairman Weisser reported the committee has previously heard presentations on a certification program offered by the Pharmacy Technician Certification Board (PTCB) and a second one offered by the National Healthcareer Association (NHA) known as the ExCPT. Further, as part of its March 2016 committee meeting, the committee compared the two programs and was advised that both certification programs are accredited by the National Commission for Certifying Agencies.

Chairman Weisser said the committee discussed actions necessary to facilitate implementation of this new provision as the statutory language now requires the board to approve pharmacy technician certification programs. The committee discussed draft regulation language that could be used to specify the pharmacy technician certification programs approved by board, including both the PTCB and the ExCPT.

Chairman Weisser said the committee also discussed the need to have an interim approval process to ensure the certification pathway to licensure can be achieved prior to implementation of the regulation.

Chairman Weisser said the committee noted its current efforts to reevaluate the pharmacy technician program and determined that it would be appropriate to include an expiration date on its approval of the programs. This will ensure the board has the opportunity to reevaluate programs, which seems appropriate given both the committee as well as the board’s consideration of possible changes to the pharmacy technician program in California.

Chairman Weisser said the committee heard public comment in support of its discussion and was advised that there was a drafting error in the proposed regulation language in name of the certification program offered by NHA. He added that Attachment 5 includes the chaptered version of SB 952, the revised draft regulation language as well as a letter on behalf of NHA requesting board approval of their certification program.

Public comment: An unidentified speaker thanked the board for supporting SB 952 and urged support of the Licensing Committee’s recommendations.

**Committee Recommendation:** Recommend to the board to approve the proposed regulation language with an amendment to include an expiration date of January 1, 2021, and to correct the name of the NHA program.

**Motion:** Delegate authority to the EO to make clarifying changes consistent with the board’s policy direction upon recommendations by control agencies.

M/S: Gutierrez/Lippe

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

**Committee Recommendation:** Recommend interim approval of the NHA’s ExCPT and the PTCB certification programs until the effective date of the regulation.



Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Discussion and Consideration of Amendments to Title 16 section 1780 *et seq.*, to Include Operational Requirements for Third-Party Logistics Providers

Chairperson Weisser said that at the July 2015 board meeting, the board approved proposed regulation text to amend Title 16 CCR section 1780 *et seq.*, to establish the regulatory framework for Third-Party Logistics Providers. The proposed regulations would establish the minimum standards by which such providers would need to comply which are consistent with current minimum standards for wholesalers.

Chairperson Weisser said staff later identified additional modification may be necessary and returned the matter to the Licensing Committee for review.

Chairperson Weisser said the committee discussed the proposal and noted that the primary change in the current version of the proposed language is the removal of a reference to a prior version of the United States Pharmacopoeia Standards in Section 1780(b). He said the committee was advised that board staff and counsel have confirmed that compliance with the USP standards is already established as a requirement in federal law, both in the U.S. Code as well as in the Code of Federal Regulations; therefore, removal of the reference is appropriate. Attachment 6 contains the proposed language approved by the committee.

There was no public comment.

**Committee Recommendation:** Recommend to the board approval of the proposed regulation language in section 1780 *et seq.*

**Motion:** Approve the committee recommendation and delegate authority to the EO to make clarifying changes consistent with the board’s policy direction upon recommendations by control agencies.

To Amend Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**Article 10. Wholesalers Dangerous Drug Distributors**

To Amend Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1780. Minimum Standards for Wholesalers.**

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

- (a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (1990, 22nd Revision) official compendium.
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
  - (1) All facilities shall be equipped with an alarm system to detect entry after hours.
  - (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
  - (3) The outside perimeter of the ~~wholesaler~~ premises shall be well-lighted.
- (d) All materials must be examined upon receipt and/or before shipment.
  - (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
  - (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
  - (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
  - (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
  - (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (1990, 22nd Revision).
- (f) Policies and procedures must be written and made available upon request by the board.
  - (1) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying,

recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) ~~Each wholesaler and third-party logistics provider drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler ~~and third-party logistics provider~~ shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code; Section 321 of Title 21, U.S. Code; and Section 205.05 of Title 21, Code of Federal Regulations.

**To Amend** Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1781. ~~Exemption Certificate~~ Designated Representative.**

A registered pharmacist, ~~or an~~ designated representative or designated representative –3PL certified in accordance with Section 4053, 4053.1 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's, ~~or wholesaler's~~ or a third-party logistics provider's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053, 4053.1 or 4054, Business and Professions Code.

**To Amend** Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1782. Reporting Sales of Drugs Subject to Abuse.**

~~All~~ Each manufacturers, ~~and~~ wholesalers and third-party logistics provider shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Authority cited: Sections 4005 and 4164, Business and Professions Code; ~~and Section 26692, Health and Safety Code~~. Reference: Sections 4053.1, 4081, 4164, and 4332, Business and Professions Code; ~~and Section 26692, Health and Safety Code~~.

**To Amend** Section 1786 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1783. ~~Manufacturer, or Wholesaler or Third-Party Logistics Provider~~ Furnishing Drugs and Devices.**

(a) A manufacturer, ~~or wholesaler~~ or third-party logistics provider shall furnish dangerous drugs or

devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or wholesaler~~, or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

- (b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or wholesaler~~ or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
- (c) Dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler~~ or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or wholesaler~~ or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or wholesaler~~ or third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or wholesaler~~ or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.
- (d) A manufacturer, ~~or wholesaler~~ or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the permit for the authorized person; and (2) on an account bearing the name of the permittee.
- (e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler~~ or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or wholesaler~~ or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4053.1, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

M/S: Veale/Brooks

Support: 9

Oppose: 0

Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			

Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

a. Presentation by the Office of Statewide Health Planning and Development (OSHPD) on the Health Professions Education Foundation

Chairperson Weisser said in 2002 the California Pharmacist Scholarship and Loan Repayment Program was established with OSHPD. To fund the program, pharmacists and pharmacies can voluntarily contribute \$25.00 as part of the renewal of a licensure. The fund is designed to provide scholarships or loan forgiveness to pharmacists and pharmacy students who serve in medically underserved communities.

Chairperson Weisser said the committee heard a presentation from an OSHPD representative on the Health Professions Education Foundation, which is administered through OSHPD. The presentation included information on the foundation, which awards scholarships and loan repayments to qualified health professionals, including pharmacists. The committee was advised that two pharmacists were awarded loan repayments in fiscal year 2015/16.

Chairperson Weisser added that the committee was advised that OSHPD currently does not have staff available to administer the California Pharmacist Scholarship and Loan Repayment Program. A copy of the presentation provided to the committee is in Attachment 7.

There was no public comment.

b. Discussion and Consideration of Pharmacist Examination Matters

1. The National Association of Boards of Pharmacy’s Change in Policy Relating to the 91-Day Waiting Period for Candidates Who Fail the NAPLEX
2. Evaluation of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chairperson Weisser said BPC section 4200 establishes the requirements for

licensure as a pharmacist, including passage of the North America Pharmacist Licensure Examination (NAPLEX). BPC section 4200.4 specifies that an applicant that fails the national examination may not retake the examination for at least 90 days or for a period established by regulation adopted by the board in consultation with the Office of Professional Examination Services (OPES).

Chairperson Weisser said the committee was advised that in late July 2016 the NABP released information about changes in the administration of the NAPLEX, including a change in the current time a candidate must wait to retake the examination. (Currently, an individual that fails that NAPLEX must wait 90 days under NABP rules as well as pharmacy law.)

Chairperson Weisser said the committee discussed the proposed changes in the NAPLEX as well as the upcoming change in the NAPLEX waiting period, which is reduced from 90 days to 45 days. He said California law will still require a 90-day waiting period for the NAPLEX. The committee discussed if the proposed change to the waiting period is appropriate and whether the board should consider a change to the waiting period for the CPJE. As provided in the statute, the committee discussed that any change to the current waiting period for the NAPLEX would require consultation with OPES.

Chairperson Weisser said the committee recommended working with OPES to evaluate the exams (NAPLEX & CPJE) to determine the appropriate waiting period and referring the matter back to the Licensing Committee for future discussion based on the outcome of the work with OPES. Attachment 8 includes a copy of the notification from NABP and the relevant law section.

Public comment: Rebecca Cupp advised the board that the 90-day waiting period makes it difficult for students because there are not enough slots available to take the test in a timely manner.

- c. Consideration of Request from Marshall B. Ketchum University, College of Pharmacy, for Recognition by the Board under Title 16, California Code of Regulations Section 1719, for Purposes of Issuing Intern Licenses

Chairperson Weisser said the Marshall B. Ketchum University, College of Pharmacy is a new program that has been granted pre-candidate status by the ACPE. This means that the school is progressing to meet the ACPE accreditation standards but has not yet completed the process nor graduated its first class. He said that in such cases, the board must recognize the school for purposes of issuing an intern license in order to allow students to secure the training expected by ACPE.

Chairperson Weisser said the board received a request from Dr. Edward Fisher, professor and dean, asking for board recognition of its program for purposes of issuing intern pharmacist licenses to students. A copy of the letter is provided in Attachment 9.

Ms. Veale informed the board that she was a member of the ACPE committee who reviewed the school. She said the committee was very impressed with the school.

There was no public comment.

**Committee Recommendation:** Recommend to the board recognition of Marshall B. Ketchum University, College of Pharmacy for purposes of issuing intern permits

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

d. Licensing Statistics

Chairperson Weisser informed the board that licensing statistics for the first three months of the fiscal year, July 1 to Sept. 30, are included in Attachment 10. He said the board has received almost 6,000 applications, including:

- 1,548 pharmacy technicians
- 1,223 intern pharmacists
- 607 pharmacist exam applications
- 951 initial pharmacist licensing applications

Chairperson Weisser reported that the board has issued 3,357 licenses and renewed 16,322 licenses. He said the board currently has 138,799 active licenses, including:

- 44,167 pharmacists
- 6,625 intern pharmacists
- 73,173 pharmacy technicians
- 6,566 pharmacies

- 519 hospitals and exempt hospitals

There was no public comment.

e. Future Committee Meeting Date for 2016

Chairperson Weisser announced the Licensing Committee's future meeting dates:

- January 10, 2017
- April 4, 2017 (Pharmacy Technician Summit)
- June 29, 2017
- September 19, 2017

There was no public comment.

President Gutierrez adjourned the meeting for the day at 5:17 p.m.

**Thursday, Oct. 28, 2016**

**XIII. Call to Order and Establishment of Quorum**

**9:04 a.m.**

President Gutierrez called the meeting to order at 9:04 a.m. Board members present: Albert Wong, Valerie Muñoz, Allan Schaad, Amy Gutierrez, Deborah Veale, Stan Weisser, Victor Law, Lavanza Butler and Greg Lippe.

**XIV. Petitions for Reinstatement of Licensure or Other Reduction of Penalty**

- a. Asher Kashanchi, RPH 56942
- b. Entirelypets Pharmacy, PHY 50832

Administrative Law Judge Juliet Cox presided over the petition for early termination of probation for Asher Kashanchi, RPH 56942.

The board recessed for a break at 9:55 a.m. and reconvened at 10:07 a.m.

Administrative Law Judge Juliet Cox presided over the petition for early termination of probation for Entirelypets Pharmacy, PHY 50832.

**XV. Closed Session**

- a. Pursuant to Government Code section 11126(c)(3), the Board will Convene in Closed Session to Deliberate on Disciplinary Matters, Including the Above Petition, Proposed Decisions, Stipulated Decisions, Defaults, and Any Other Disciplinary Matters.
- b. Pursuant to Government Code section 11126(e), the Board will Convene in Closed Session to Discuss Pending Litigation



c. The Board Will Reconvene in Open Session

The board recessed into closed session at 11:14 a.m. and reconvened in open session at 11:50 a.m.

**XVI. Legislation and Regulation Committee**

Chairperson Lippe announced that all the bills in the committee's report have been signed by the Governor and chaptered. He added that the text of the bills is included in attachments in the meeting packet.

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

a. Board Sunset Regulation

1. SB 1193 (Hill, Chapter 484, Statutes of 2016) California State Board of Pharmacy

Chairperson Lippe said SB 1193:

- extends the operations of the California Board of Pharmacy and the board's authority to appoint an executive officer until January 1, 2021,
- establishes the framework for the licensure of outsourcing facilities,
- authorizes the board to synchronize license renewal dates and aggregate fees for clinics,
- authorizes the board to issue a temporary permit for specified licenses,
- repeals obsolete provisions related to electronic data transmission prescriptions in the Health and Safety Code,
- authorizes the board to issue a cease and desist order for unlicensed activity violations,
- establishes registration requirements for automated drug delivery systems, and
- makes other technical changes.

There was no public comment.

2. SB 1039 (Hill, Chapter 799, Statutes of 2016) Professions and Vocations)

Chairperson Lippe reported this measure sets forth a new fee schedule, which is needed to sustain board operations.

There was no public comment.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. AB 1069 (Gordon, Chapter 316, Statutes of 2016) Prescription Drugs: Collection and Distribution Program

Chairperson Lippe reported this measure allows a pharmacy to repackage donated medications for dispensing to indigent patients if such repackaging is performed and dispensed through a dedicated pharmacy.

There was no public comment.

2. AB 1114 (Eggman, Chapter 602, Statutes of 2016) Medi-Cal: Pharmacist Services

Chairperson Lippe reported this measure establishes the process for a pharmacist to be reimbursed for specified services provided as a benefit under Medi-Cal. Such services include furnishing naloxone, furnishing travel medication, furnishing self-administered hormonal contraception, initiating and administering immunizations, and providing tobacco cessation counseling and furnishing of nicotine replacement therapy. As an urgency measure, the provisions of the bill went into effect on September 25, 2016.

Chairperson Lippe said the committee was advised during public comments that there was confusion regarding when pharmacists may seek reimbursement. He explained that the measure requires action by Medi-Cal and perhaps the federal government.

There was no public comment.

3. AB 1386 (Low, Chapter 374, Statutes of 2016) Emergency Medical Care: Epinephrine Auto-Injectors

Chairperson Lippe reported this measure authorizes a pharmacy to furnish epinephrine auto-injectors to authorized entities.

There was no public comment.

4. AB 1748 (Mayes, Chapter 557, Statutes of 2016) Pupils: Pupil Health: Opioid Antagonist

Chairperson Lippe reported this measure authorizes a pharmacy to furnish naloxone hydrochloride or other opioid antagonist to a school district, county office of education or charter school under certain conditions. He said Ms. Herold advised the committee that a prescription will be required to provide the naloxone.

There was no public comment.

5. SB 482 (Lara, Chapter 708, Statutes of 2016) Controlled Substances: CURES Database

Chairperson Lippe said this measure requires a prescriber to access the CURES system under specified conditions, to include checking the system before prescribing a Schedule II, III or IV medication for the first time and at least every four months. The law also limits the dispensing of a controlled substance in specified settings to either a 5- or 7-day supply.

Chairperson Lippe reported that Ms. Herold advised the committee that the provisions do not take effect until the system is certified and that this would not happen before Jan. 1, 2017. He said the committee asked for clarification about whether a pharmacist who acts as a prescriber also must check the CURES system.

There was no public comment.

6. SB 952 (Anderson, Chapter 150, Statutes of 2015) Pharmacy Technicians: Licensure Requirements

Chairperson Lippe said this measure modifies licensure requirements for pharmacy technicians by expanding the certification requirement to also include other agencies as a pathway to licensure.

There was no public comment.

7. SB 999 (Pavley, Chapter 499, Statutes of 2016) Health Care Coverage: Contraceptives: Annual Supply

Chairperson Lippe said this measure authorizes a pharmacist to dispense prescribed, FDA-approved, self-administered hormonal contraceptives either as prescribed or, at the patient's request, in a 12-month supply, unless the prescriber specifically indicates no change to quantity. The measure also requires a health care service plan or health insurance policy, on or after January 1, 2017, to cover a 12-month supply of a self-administered hormonal contraception dispensed at one time by a prescriber or dispenser.

There was no public comment.

8. SB 1229 (Jackson, Chapter 238, Statutes of 2016) Pharmacies: Secure Drug Take-Back Bins

Chairperson Lippe said this measure encourages good-faith participation of authorized entities to provide secure drug take-back bins to provide consumers with a safe disposal option for unused pharmaceuticals.

There was no public comment.

c. Legislative Items for Future Meeting

No items were discussed.

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

a. Board Adopted – Approved by the Office of Administrative Law

1. Regulations to Add Title 16 CCR section 1730.2 related to Advanced Practice Pharmacists – Certification Programs

Chairperson Lippe reported that in December 2015, the board initiated a formal rulemaking to add Title 16 CCR section 1730.2, establishing the certification program criteria for advanced practice pharmacist. At the February 2016 board meeting, the board adopted the final regulation text. Chairperson Lippe said the rulemaking was submitted to the Office of Administrative Law (OAL) for final review on June 29, 2016, and was approved on Aug. 10, 2016, with an immediate effective date.

There was no public comment.

2. Regulations to Add Title 16 CCR section 1746.5 related to Travel Medications

Chairperson Lippe reported that in July 2015, the board initiated a formal rulemaking to add Title 16 CCR section 1746.4 to specify the requirements for a pharmacist to administer vaccinations. On July 1, 2016, the board adopted the final regulation text. Chairperson Lippe said the rulemaking was submitted to OAL for final review on July 14, 2016, and was approved on Aug. 25, 2016, with an immediate effective date.

There was no public comment.

3. Regulations to Add Title 16 CCR section 1735 and 1751 *et seq.* related to Compounding

Chairperson Lippe reported that in May 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1735 and 1751 *et seq.*, related to compounded drug preparations. On Jan. 19, 2016, the board adopted the final

regulation text. Chairperson Lippe said the rulemaking was submitted to OAL for final review on Aug. 1, 2016, and was approved on Sept. 13, 2016. The regulation becomes effective on Jan. 1, 2017.

Chairperson Lippe said the committee discussed requirements for nonsterile compounding of items such as topical ointments that are patient-specific and the costs associated with testing. He said the committee was advised that requirements, which may include testing, have been a requirement of the law since 2003.

There was no public comment.

- b. Board Adopted – Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law
  - 1. Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and Amend section 1749 related to Advanced Practice Pharmacists

Chairperson Lippe reported that in July 2015, the board initiated a formal rulemaking to add Title 16 CCR sections 1730, 1730.1, and amend section 1749 related to the licensing requirements for advanced practice pharmacist. At the February 2016 board meeting, the board adopted regulation text and the rulemaking file was submitted to OAL for review in June 2016.

Chairperson Lippe said that because OAL expressed concerns with the file, the rulemaking was returned to the board. At the July 2016 board meeting, the board voted to modify the text to address OAL's concerns and initiated a 15-day comment period. At the August 2016 board meeting, the board adopted final regulation language and resubmitted the final rulemaking file to the Department of Consumer Affairs (DCA) on Sept. 20, 2016.

There was no public comment.

- 2. Proposed Regulations to Add Title 16 CCR sections 1746.5 related to Travel Medications

Chairperson Lippe reported that in September 2015, the board initiated a formal rulemaking to add Title 16 CCR section 1746.5, related to the furnishing of travel medications. At the April 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the DCA for review on May 9, 2016.

At the request of Mr. Law, Ms. Freedman said she would check on the status of the rulemaking process.

There was no public comment.

3. Proposed Regulations to Amend Title 16 CCR section 1760 related to the Board's Disciplinary Guidelines

Chairperson Lippe reported that in September 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1760 related to the board's disciplinary guidelines. At the April 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to DCA for review on Aug. 4, 2016.

There was no public comment.

4. Proposed Regulations to Amend Title 16 CCR section 1744 related to Drug Warnings

Chairperson Lippe reported that in April 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1744 related to drug warning labels. At the July 2016 board meeting, the board adopted the final regulation text. The rulemaking file was submitted to the DCA for review on Aug. 17, 2016.

There was no public comment.

5. Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient-Centered Labels

Chairperson Lippe reported that in January 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1707.5 related to the inclusion of "generic for" on a patient-centered drug label. At the August 2016 board meeting, the board adopted final regulation text. The rulemaking file was submitted to the DCA for review on Sept. 21, 2016.

There was no public comment.

6. Proposed Regulations to Amend Title 16 CCR section 1732.05, 1732.2 and 1732.5 related to Continuing Education

Chairperson Lippe reported in September 2015, the board initiated a formal rulemaking to amend Title 16 CCR sections 1732.05, 1732.2, and 1732.5 related to the board's continuing education requirements. At the September 2016 board meeting, the board adopted final regulation text. The rulemaking file was submitted to the DCA for review on October 3, 2016.

There was no public comment.

- c. Board Adopted – Rulemaking File Being Prepared by Staff for Submission to the Department of Consumer Affairs or the Office of Administrative Law

Proposed Regulations to Amend Title 16 CCR section 1703 related to Delegation of Certain Functions

Chairperson Lippe reported that in October 2013, the board approved draft text to delegate to the executive officer the authority to adopt regulation changes that are deemed to be “without regulatory effect” in accordance with Title 1 CCR section 100. Thereafter, at the February 2016 board meeting, the board approved proposed text to delegate to the executive officer the authority to approve prescription drug label waivers in accordance with Business and Professions Code section 4076.5(d). The rulemaking was initiated on April 22, 2016.

Chairperson Lippe noted that at the July 2016 board meeting, following the 45-day comment period, the board adopted final regulation text. He added that staff is compiling the rulemaking package to submit to the DCA for administrative review.

There was no public comment.

- d. Board Approved to Initiate Rulemaking – Open Comment Period

Proposed Regulations to Add Title 16 CCR section 1715.65 related to Inventory Reconciliation Report of Controlled Substances

Chairperson Lippe reported that in July 2016, the board initiated a formal rulemaking to add Title 16 CCR section 1715.65 related to inventory reconciliation report of controlled substances. The 45-day comment period began on Sept. 16, 2016, and concludes on Oct. 31, 2016.

There was no public comment.

Chairperson Lippe informed the board of proposed meeting dates for the Legislation and Regulation Committee:

- Jan. 24, 2017, immediately before the board meeting
- April 12, 2017
- June 27, 2017
- Oct. 18, 2017

- e. Consideration and Discussion of Proposed Regulations to Amend Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13 (rev. 10/16), 17M-14 (rev. 10/16), and 17M-26 (rev. 10/16)

Chairperson Lippe informed the board that the committee recommended imitating rulemaking to amend Title 16 CCR sections 1715 and 1784, which require a Pharmacist-in-Charge (PIC) and a Designated Representative-in-Charge (DRIC) to complete a self-assessment no later than July 1 of each odd-numbered year and at other times as specified.

Chairperson Lippe said section 1715 applies to the self-assessment of a pharmacy by the PIC and incorporates by reference Form 17M-13, "Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment," and Form 17M-14, "Hospital Pharmacy Self-Assessment." Section 1784 applies to the self-assessment of a wholesaler by the DRIC and incorporates by reference Form 17M-26, "Wholesaler."

There was no public comment.

**Committee recommendation:** Initiate the formal rulemaking process to amend the text of Title 16 CCR sections 1715 and 1784 and amend the self-assessment forms incorporated by reference in those sections, as proposed.

**Amend Section 1715 in Article 2 of Division 17 of Title 16 to read:**

**§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.**

- (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  - (1) A new pharmacy permit has been issued, or
  - (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
  - (3) There is a change in the licensed location of a pharmacy to a new address.
- (c) The components of this assessment shall be on Form 17M-13 (Rev. 10/14) (Rev. 10/16) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 (Rev. 10/14) (Rev. 10/16) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
- (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.



Authority: Business and Professions Code §4005 and §4127. Reference: Business and Professions Code §4021, §4022, §4029, §4030, §4037, §4038, §4040, §4050, §4052, §4070, §4081, §4101, §4105, §4113, §4115, §4119, §4127, §4305, §4330, §4332 and §4333.

**Amend Section 1715 in Article 2 of Division 17 of Title 16 to read:**

**§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.**

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self- assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

- (1) A new pharmacy permit has been issued, or
- (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
- (3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 (Rev. 10/14) (Rev. 10/16) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self- Assessment" and on Form 17M-14 (Rev. 10/14) (Rev. 10/16) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

Authority: Business and Professions Code §4005 and §4127. Reference: Business and Professions Code §4021, §4022, §4029, §4030, §4037, §4038, §4040, §4050, §4052, §4070, §4081, §4101, §4105, §4113, §4115, §4119, §4127, §4305, §4330, §4332 and §4333.

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz	X			
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

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

M/S: Gutierrez/Butler

Support: 9      Oppose: 0      Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz	X			
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

President Gutierrez informed board members that she and Ms. Veale are working with Ms. Herold and Ms. Freedman to prioritize some of the committee’s issues as much as possible. She noted that time with legal counsel and DCA is limited, and she asked members to be patient with the process.

Dr. Wong requested that a discussion of the DUI penalty be added to the board agenda next month. Ms. Freedman said penalties would be part of the disciplinary guidelines, which are being reviewed. Dr. Wong asked the board to consider modifying the guidelines.

Dr. Wong welcomed Ms. Muñoz to the board. He urged all public members on the board to become informed about retail pharmacy operations.

The meeting adjourned at 12:09 p.m.