



**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE MEETING
MINUTES**

DATE: March 24, 2016

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

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Lori Martinez, Staff Manager
Laura Hendricks, Staff Analyst

**BOARD MEMBERS
PRESENT:** Gregory Lippe, Chairperson
Albert Wong, PharmD
Deborah Veale, RPh
Ramon Castellblanch, PhD., Public Member
Lavanza Butler, RPh

**BOARD MEMBERS
NOT PRESENT:**

Thursday, March 24, 2016

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

Chairperson Lippe called the meeting to order at 8:30 a.m.

Board members present: Gregory Lippe, Ramon Castellblanch, Lavanza Butler and Deborah Veale.

Note: Albert Wong arrived at 8:40 a.m.

II. Public Comments on Items Not on the Agenda

Pat Whalen, representing NHA, asked if the committee would be discussing SB 952. Ms. Sodergren explained that SB 952 would be discussed at the March 30, Licensing Committee meeting.

III. Legislation Report

a. Board Sponsored Legislation

SB 1193 (Hill) California State Board of Pharmacy: Executive Officer

Version: February 18, 2016 - Introduced

Location: Senate Business Professions and Economic Development

Chairperson Lippe explained that this measure would extend the operations of the California Board of Pharmacy and the board’s authority to appoint an executive officer until January 1, 2021.

Ms. Herold stated that this is the board’s Sunset bill and asked the committee to support the bill.

Steve Gray, representing Kaiser, offered his support of the bill. Mr. Gray asked if there was a hearing scheduled for the bill. Ms. Herold stated that there was no hearing scheduled yet.

Mr. Gray asked how the public could find out what concerns that the Senate Business Professions and Economic Development committee had with the board’s Sunset Report. Ms. Sodergren explained that this information could be found in the Senate Business Professions and Economic Development Committee Report.

Mr. Castellblanch asked how many terms a member could be appointed for. Ms. Herold explained that a member could serve two full terms. She added that if a member takes over for someone who left their position before their term ended, they could serve the remainder of that term and two full additional terms.

Motion: Support SB 1193

M/S: Veale/Butler

Support: 5

Oppose: 0

Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Butler	x			
Castellblanch	x			
Lippe	x			

Veale	x			
Wong	x			

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

1. AB 45 (Mullin) Household Hazardous Waste

Version: January 21, 2016 Amended

Location: Senate Environmental Quality Committee

Position: Oppose Unless Amended (prior version: 4/30/15)

Chairperson Lippe stated that the bill adds Article 3.4 “Household Hazardous Waste Collection and Reduction” to the Public Resources Code. The bill would require the Department of Resources Recycling and Recovery (CalRecycle) to adopt one or more model ordinances for a comprehensive program for the collection of household hazardous waste, and then post the ordinance(s) on CalRecycle’s web site. Thereafter, a local jurisdiction that provides for the residential collection and disposal of solid waste that proposes to enact an ordinance governing the collection and diversion of household hazardous waste may adopt one of the model ordinances posted by CalRecycle.

Chairperson Lippe explained that the bill establishes various definitions, including but not limited to “comprehensive program for the collection of household hazardous waste,” “household hazardous waste,” and “home-generated pharmaceutical waste.”

Chairperson Lippe reported that the bill requires CalRecycle to determine whether a nonprofit organization has been created and funded to make grants to local jurisdictions for specified purposes related to household hazardous waste disposal. This bill would specify if CalRecycle makes no such determination by December 31, 2018, then the provisions of the bill are repealed on January 1, 2019.

Chairperson Lippe added that for the prior version of the bill (4/30/15) the board voted to oppose unless amended, and to seek amendments that would require mail back of dangerous drugs. The requested amendments were not accepted.

Ms. Herold reported that staff has made appointments with the author’s office to discuss the bill, but their staff has been unavailable. Ms. Herold recommended keeping the board’s position on the prior version of the bill (oppose unless amended).

Dr. Wong stated that pharmacies are taking steps to create take-back programs for their customers. He referenced a recent news article that Walgreens will be adding take-back receptacles at many of their locations.

Dr. Gray, from Kaiser, asked for clarification on the mail back requirement in the bill.

Ms. Sodergren explained that this bill is not specific to pharmaceutical products; it applies to all household hazardous waste. She explained that the board would want mail back for prescription drugs.

Dr. Gray asked if this bill is intended to preempt local ordinances. Ms. Sodergren stated that the bill is not intended to preempt local ordinances. Ms. Herold noted that many local ordinances are opposed to this AB 45.

Motion: Oppose AB 45 unless amended.

M/S: Veale/Butler

Support: 5

Oppose: 0

Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Butler	x			
Castellblanch	x			
Lippe	x			
Veale	x			
Wong	x			

2. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

Version: July 1, 2015 Amended

Location: Senate Appropriations Committee (7/7/2015)

Position: Oppose Unless Amended

Chairperson Lippe explained that AB 1069 would expand the provisions under which a county-established repository and distribution program allows the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

Chairperson Lippe reported that board staff has worked with the author's office to secure amendments to address many of the legal conflicts the measure initially contained, but there are still some concerns with the bill in its current form. Currently, the bill would remove a pharmacist from several aspects of the redistribution program of prescription drugs; would allow a "participating entity" to transfer drugs like a distributor without appropriate licensure and control; and would permit what is currently unlawful repackaging and co-mingling of previously dispensed medications, including donated medications from various sources, all to the detriment of patient safety.

Chairperson Lippe concluded that staff continues to reach out to the author's office.

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

3. AB 1386 (Low) Emergency Medical Care: Epinephrine Auto-Injectors

Version: January 13, 2016 Amended

Location: Senate Health

Coauthors: Assembly Members Chang, Daly and Wilk, and Senator Huff

Chairperson Lippe reported that this measure would amend Pharmacy Law and other provisions of the Civil Code and Health and Safety Code to authorize a health care provider to issue a prescription, and a pharmacy to furnish, epinephrine auto-injectors to an authorized *entity*, as defined. The bill calls for specific labeling on any epinephrine auto-injectors dispensed pursuant to the bill's provisions. Chairperson Lippe clarified that authorized entities include any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course, as defined.

Chairperson Lippe explained that as is with current law, authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors shall be established and approved by the California Emergency Medical Services Authority.

Brian Warren, representing CPHA, stated they support the bill. He added that in the future they would like to see pharmacists being able to furnish these without a doctor needing to be involved. The committee agreed that Advanced Practice Pharmacists would be well positioned to furnish the auto-injectors thus expanding access to those who need them.

Dr. Gray, representing CSHP offered their support of the bill. He noted that CSHP would work with the author to see if they will amend the bill to allow pharmacists to furnish the auto-injectors.

Motion: Support AB 1386. Offer amendments allowing pharmacists to furnish the auto-injectors.

M/S: Veale/Butler

Support: 5

Oppose: 0

Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Butler	x			
Castellblanch	x			
Lippe	x			
Veale	x			
Wong	x			

Ms. Veale stated that if this bill does not pass or passes without allowing pharmacists to furnish the auto-injectors the board should sponsor legislation next year.

4. AB 1977 (Wood) Health Coverage: Abuse-Deterrent Opioid Analgesics

Version: February 16, 2016 Introduced

Location: Referred to Assembly Health

Chairperson Lippe explained that as introduced, AB 1977 would make changes to the Health and Safety Code and to the Insurance Code regarding coverage of abuse-deterrent opioid analgesic drug products. In its current form the measure does not appear to impact the board's jurisdiction or board operations.

Chairperson Lippe stated that board staff was advised that the measure will most likely be amended to include provisions that would impact the board. Board staff was unable to secure a copy of the proposed amendments and the amended version is not yet in print. He concluded that board staff will continue to monitor this measure and will bring it to the full board during the April Board Meeting if appropriate.

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

5. AB 2144 (Rodriguez) Pharmacy: Prescriptions

Version: February 17, 2016 Introduced

Amended March 18, 2016 in Assembly Health

Chairperson Lippe reported that as amended this measure would amend Section 4074 of the Business and Professions Code to specify that a health facility shall require each patient to acknowledge in writing that a patient has received specified drug warning, storage and other specified information at the time of discharge.

Dr. Castellblanch stated that he supports this bill as it promotes patient's knowledge of their medication. Chairperson Lippe stated he also supports this bill.

Dr. Gray, representing Kaiser, stated that there could be some technical issues with this bill, for example if the patient cannot sign the acknowledgement who can sign on their behalf.

Ms. Herold stated that currently many patients don't get any information on their medication when they are discharged from the hospital.

Mr. Warren representing CPHA reminded the committee that this is a spot bill.

Motion: Support AB 2144.

M/S: Castellblanch/Veale

Support: 5

Oppose: 0

Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Butler	x			
Castellblanch	x			
Lippe	x			
Veale	x			
Wong	x			

6. AB 2592 (Cooper) Prescriptions

Version: February 19, 2016 Introduced
Amended March 18, 2016 in Assembly Health

Chairperson Lippe reported that as amended this measure will require the Department of Public Health, if funding is available, to create an Opioid Abuse Prevention Pilot Program to award grants. Further, this measure would specify that a pharmacy that applies for and receives a grant shall offer all patients who are prescribed an opioid with a medicine locking closure package if a patient consents. Further, this section defines a medicine locking closure package as one that can only be unlocked with a user generated, resettable alphanumeric code. This measure includes a sunset date for this pilot project.

Note: Dr. Castellblanch recused himself from the discussion.

The committee briefly discussed the bill, but took no position.

7. SB 482 (Lara) Controlled Substances: CURES database

Version: April 30, 2015
Location: Held at Assembly Desk (5/28/15)

Chairperson Lippe explained that this measure would require a prescriber to access the CURES system under specified conditions, to include checking the system before prescribing a Schedule II or Schedule III medication for the first time and at least annually.

The committee expressed their support of this bill stating that prescribers should be checking CURES to ensure that patients are not doctor shopping.

Ms. Sodergren asked the committee if pharmacists should be required to use the CURES system in a mandated fashion similar to those in SB 482. The committee did not feel that at this time pharmacists should have the same mandated requirements as prescribers.

Dr. Gray stated that this bill is premature as there are still problems with the CURES system. Ms. Sodergren stated that the DOJ must certify that the CURES system has the capability to handle the workload that would be created by the bill.

Motion: Support SB 482.

M/S: Veale/ Castellblanch

Support: 5

Oppose: 0

Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Butler	x			
Castellblanch	x			
Lippe	x			
Veale	x			
Wong	x			

8. SB 999 (Pavley) Health Insurance: Contraceptives: Annual Supply

Version: February 10, 2016 Introduced

Status: Referred to Senate Business, Professions and Economic Development and to Senate Health

Hearing: April 4, 2016 Senate Business, Professions and Economic Development

Chairperson Lippe reported that SB 999 would require 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. This bill would also authorize 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 committee did not take a position on this bill as the board has no jurisdiction of insurance requirements.

Ms. Sodergren asked the committee if they would like staff to continue tracking the bill. Chairperson Lippe responded that staff did not need to track this bill.

9. SB 1217 (Stone) Healing Arts: Reporting Requirements: Professional Liability

Version: February 18, 2016 Introduced

Location: Senate Business, Professions and Economic Development

Hearing: April 11, 2016

Chairperson Lippe reported that this measure would increase the mandatory reporting from \$3,000 to \$10,000 where there is a judgment or settlement requiring the licensee or licensee's insurer to pay damages for any claim that injury or death was proximately caused by the licensee's negligence, error or omission in practice, or rendering unauthorized professional service.

Ms. Herold explained that the board currently receives reports on settlements of \$3,000 or more, which staff then uses to open investigations on the pharmacist. She reported that over the past four years the board has opened 562 cases based on these reports. Ms. Herold added that other healthcare professionals have higher thresholds for reporting settlements to their regulatory agency.

Dr. Gray explained that because pharmacists have a lower threshold for reporting settlements (for example doctors are mandated to report settlements of \$10,000 or more) healthcare teams hesitate to include pharmacists. Dr. Gray asked the committee to support the bill as it will encourage pharmacists to be included in healthcare teams.

Chairperson Lippe stated that he was unclear if this bill would benefit or harm consumers.

Ms. Veale expressed her concern that raising the threshold would prevent the board from finding out about claims where patients were harmed.

Ms. Butler stated that the board should support the bill as it would encourage pharmacists to be included on healthcare teams.

Motion: Support SB 1217.

M/S: Butler/Wong

Support: 2 Oppose: 2 Abstain: 1

Name	Support	Oppose	Abstain	Not Present
Butler	x			
Castellblanch			x	
Lippe		x		
Veale		x		
Wong	x			

10. SB 1229 (Senator Jackson and Assembly Member Stone) Pharmacies: Secure Drug Take-Back Bins

Version: February 18, 2016 Introduced

Location: Senate Environmental Quality

Hearing: April 6, 2016

Chairperson Lippe explained that Senate Bill 1229 would require a pharmacy that owns or operates a secure drug take-back bin, as defined, in a publicly accessible location to take reasonable steps to ensure the proper disposal of the pharmaceutical waste contained in the bins. The bill would provide that the owner or operator is not liable for civil damages arising from the use of the secure drug take-back bin if the owner or operator takes reasonable steps, as specified, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of the pharmaceutical waste contained in the bins.

Chairperson Lippe reported that the author's office has indicated that SB 1229, as introduced, is a substantive spot bill, and that amendments are expected to be in print by the end of March. Ms. Sodergren noted that the amendments are not available yet.

The committee opted not to take a position on the bill until the amendments are available for review.

11. SB 1230 (Stone) Pharmacies: Compounding

Version: February 18, 2016 Introduced

Location: Senate Business, Professions and Economic Development

Hearing: April 11, 2016

This bill would allow a pharmacy to compound nonpatient-specific medications, as specified, to a clinic if a professional compounding services agreement is in place.

Anne staff has been working with the author's office to find out what the intent of the bill is as the current draft creates a discrepancy between state and federal law. She added that additional information would be provided at the April 2016, Board meeting.

Dr. Gray noted that there is currently conflict between state and federal compounding law and the author of this bill intends to clarify the states authority regarding compounding.

The committee did not take a position on the bill.

12. SB 1346 (Allen) Pharmacists: Drug Labeling: Medication Guides: Electronic Delivery

Version: February 19, 2016 Introduced
Location: Senate Business, Professions and Economic Development
Hearing: April 4, 2016

This measure would allow a pharmacist to provide medication guides via e-mail at the request of a patient.

Dr. Castellblanch stated that when patients get their medication they receive multiple medication guides from various sources, he asked which information would be provided electronically.

Staff agreed that there are different medication guides provided to patients and stated that they would contact the author to clarify which one this bill applies to.

Members of the public stated that the FDA has always required medication handouts be provided in hard copy. Ms. Sodergren noted that she had been in contact with the FDA and it seems that they may have changed this requirement to allow information to be provided to patients electronically.

The committee expresses support of patients having the option to receive information electronically. They asked board staff to clarify which medication information the bill would apply to and to contact the FDA to ensure that the bill would not create a conflict between state and federal law.

Motion: Support SB 1346 as long as it complies with the FDA medication guide requirements.

M/S: Veale/Butler

Support: 5 **Oppose:** 0 **Abstain:** 0

Name	Support	Oppose	Abstain	Not Present
Butler	x			
Castellblanch	x			
Lippe	x			
Veale	x			
Wong	x			

13. SB 1454 (Stone) Pharmacy

Version: February 19, 2016 Introduced
Location: Senate Rules

Chairperson Lippe reported that the author's office has indicated that SB 1454, as introduced, is a spot bill. Staff will continue to watch this measure and will provide the

committee with any updates, as needed.

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

c. Legislation Impacting Board Operations

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

Version: August 19, 2015

Location: Last location was Senate Appropriations / Held under submission

Position: Oppose (4/22/15 text version)

Chairperson Lippe explained that AB 12 would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018, and establish reporting requirements. The bill was amended on August 19, 2015, but there are no substantive differences from the prior version.

Ms. Sodergren stated that staff recommends the board maintain its oppose position.

Motion: Oppose AB 12.

M/S: Veale/Castellblanch

Support: 4 **Oppose:** 0 **Abstain:** 1

Name	Support	Oppose	Abstain	Not Present
Butler	x			
Castellblanch	x			
Lippe	x			
Veale	x			
Wong			x	

2. AB 1939 (Patterson) Licensing Requirements

Version: February 12, 2016 Introduced

Location: Assembly Business & Professions

Chairperson Lippe stated that the author's office has indicated that this is a spot bill. No analysis is provided, and staff will continue to monitor this measure. If needed, staff will provide an update at the April Board meeting.

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

IV. Regulation Report

a. Board Approved – Submitted for Administrative Review to the Department of Consumer Affairs or the Office of Administrative Law

1. Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) Sections 1715 and 1784 related to Self-Assessment Forms for Community Pharmacies/Hospital Outpatient Pharmacies (17M-13), Hospital Pharmacies (17M-14), and Wholesalers (17M-26)

Chairperson Lippe reported that in March 2015, the board initiated a formal rulemaking process to amend the text of Title 16 CCR sections 1715 and 1784 and to amend the Self-Assessment Forms incorporated by reference therein. Existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s).

Chairperson Lippe stated that on January 19, 2016, following the completion of two 45-day comment periods, the board adopted the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law for final review on March 10, 2016.

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

2. Proposed Regulations to Add Title 16 CCR section 1746.4 related to Vaccinations

Chairperson Lippe stated that in July 2015, the board initiated a formal rulemaking to add Section 1746.4 to Title 16 of the California Code of Regulations to specify the requirements for a pharmacist to administer vaccinations.

Chairperson Lippe noted that on January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs for final review on January 29, 2016.

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

3. Proposed Regulations to Amend Title 16 CCR sections 1735 and 1751 et seq. related to Compounding

Chairperson Lippe stated that on May 8, 2015, the board initiated a formal rulemaking related to compounded drug preparations. He added that on January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs for final review on March 10, 2016.

There were no comments from the committee or the public.

b. Board Approved – Rulemaking File Being Prepared by Staff for Submission 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 1749 related to Advanced Practice Pharmacists

Chairperson Lippe reported that in July 2015, staff initiated a formal rulemaking to add Sections 1730, 1730.1, and amend section 1749 of Title 16 of the California Code of Regulations related to the licensing requirements for advanced practice pharmacist. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. Upon drafting the final rulemaking package to submit for administrative review by the Department of Consumer Affairs and the Office of Administrative Law, board staff identified comments received during the 45-day and two 15-day comment periods that were not brought to the board for review. These comments were brought to the board at the February 2016 board meeting.

Staff noted that the final rulemaking package had been submitted for administrative review by the Department of Consumer Affairs and the Office of Administrative Law on March 19.

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

2. Proposed Regulations to Add Title 16 CCR section 1730.2 Related to Advanced Practice Pharmacists – Certification Programs

Chairperson Lippe reported that at the November 2015 Board Meeting, the board approved proposed text to add Section 1730.2 of Title 16 of the California Code of Regulations, establishing the certification program criteria for advanced practice pharmacist. The 45-day comment period began on December 25, 2015 and ended February 8, 2016.

Chairperson Lippe explained that at the February 2016 board meeting, the board adopted the final regulation text.

Staff noted that the final rulemaking package had been submitted for administrative review by the Department of Consumer Affairs and the Office of Administrative Law on March 19.

3. Proposed Regulations to Amend Title 16 CCR section 1760 Related to Board’s Disciplinary Guidelines

Chairperson Lippe stated that in September 2015, staff initiated a formal rulemaking to amend Section 1760 to Title 16 of the California Code of Regulations related to the

board's disciplinary guidelines. At the February 2016 board meeting, the board adopted the final regulation text. Upon drafting the final rulemaking package to submit for administrative review by the Department of Consumer Affairs and the Office of Administrative Law, board staff identified documents that needed to be added to the rulemaking file.

Chairperson Lippe concluded that board staff will be submitting a 15-day notice to add the documents to the rulemaking file and, upon completion, the file will be routed for final approval with the Department of Consumer Affairs and the Office of Administrative Law.

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

4. Proposed Regulations to Amend Title 16 CCR section 1746.5 related to Travel Medications

Chairperson Lippe explained that at the June 2015 Board Meeting, the board approved proposed text to add Section 1746.5 of Title 16 CCR, related to the furnishing of travel medications. On January 19, 2016, following the completion of a 45-day comment period and a 15-day comment period, the board adopted the final regulation text.

Staff manager Lori Martinez explained that legal counsel had concerns with the use of the word "certification" in the regulation language. The DCA legal office recommended the board look at the language again and consider changing the word "certification" to "certificate." Ms. Martinez stated that this regulation will be discussed during the March 28, 2016 teleconference meeting and at that time the board could decide if the language should be modified.

c. Board Approved – Comment Period Closed; Awaiting Action by Board / Licensing Committee

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

Chairperson Lippe reported that at the April 2015 Board Meeting, the board approved proposed text to amend Section 1744 of Title 16 of the California Code of Regulations to amend the drug warnings label requirements. The 45-day comment period closed on November 9, 2015.

Chairperson Lippe concluded that that the comments are pending review by the full Board at the April 2016 board meeting.

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

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

Chairperson Lippe stated that at the October 2014 Board Meeting, the board approved proposed text to amend section 1707.5(a)(1)(B) of Title 16 CCR to add “Generic for _____” and translation services. The 45-day comment period closed on December 7, 2015, and the comments are pending review by the full board at the April 2016 board meeting.

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

3. Proposed Regulations to Add Title 16 CCR section 1715.65 related to Reconciliation and Inventory of Controlled Substances

Chairperson Lippe stated that at the July 2015 Board Meeting, the board approved proposed text to add Section 1715.65 of Title 16 of the California Code of Regulations related to reconciliation and inventory of controlled substances. The 45-day comment period ended on November 30, 2015. The comments are pending review by the full Board in April 2016.

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

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

Chairperson Lippe reported that in 2013, the board approved a proposal to initiate a formal rulemaking to amend the text of 16 California Code of Regulations Sections 1732.05, 1732.2, and 1732.5 relative to continuing education. At the October 2014 board meeting, the board discussed and thereafter voted to add “compounding education” as a sixth area of subject-specific continuing education in Section 1732.5. At the April 2015 board meeting, the board discussed and thereafter voted to add “Including Indicated of Red Flags and a Pharmacist’s Corresponding Responsibility” to area five “Substance Abuse”.

Chairperson Lippe explained that the 45-day comment period ended on December 28, 2015. At the February 2016 board meeting, the board voted to return the language to the licensing committee to review the six subject-specific areas for possible consolidation.

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

d. Board Approved – Currently Undergoing 15-Day Comment Period

1. Proposed Regulation to Add Title 16 CCR section 1746.1 related to Self-Administered Hormonal Contraception

Chairperson Lippe reported that in May 2015, the board initiated a formal rulemaking to

add Section 1746.1 Title 16 California Code of Regulations related to Self-Administered Hormonal Contraception. On January 19, 2016, the Board adopted the final regulation text.

Chairperson Lippe explained that on March 2, 2016, the Office of Administrative Law requested that additional information be added to the Initial Statement of Reasons. On March 9, 2016, a revised Initial Statement of Reasons was noticed for a 15-day comment period. He added that the comment period closes on March 24, 2016 and the comments would be reviewed at the April 2016 board meeting.

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

e. Board Approved – Awaiting Notice

1. Proposed Regulation to Amend Title 16 CCR section 1703 (Title 1, CCR, Section 100 changes)

Chairperson Lippe reported that at the October 2013 Board Meeting, the board approved proposed text to amend Section 1703 of Title 16 of the California Code of Regulations related to “Section 100” requirements which delegate to the Executive Officer the authority to initiate a rulemaking to adopt “changes without regulatory effect.” Additionally, at the February 2016 Board Meeting, the board approved proposed text to delegate to the Executive Officer the authority to “approve waivers pursuant to Section 4076.5(e)” regarding patient-centered labels.

Chairperson Lippe concluded that Board staff is preparing the required notice documents and anticipates initiating the rulemaking process in April 2016.

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

2. Proposed Regulations to Amend and/or Add Title 16 CCR section 1702, 1702.1, 1702.2, and 1702.5, related to Renewal Requirements

Chairperson Lippe explained that at the July 2013 Board Meeting, the board approved proposed text to amend Sections 1702, 1702.1, 1702.2, and 1702.5 of Title 16 of the California Code of Regulations 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.

Chairperson Lippe stated that this regulatory change is currently pending and board staff anticipates initiating the rulemaking process in May 2016.

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

3. Proposed Regulations to Amend and/or Add Title 16 CCR sections 1780 – 1786, et seq., related to Third Party Logistics Providers

Chairperson Lippe reported that at the July 2015 Board Meeting, the board approved proposed text to amend and/or add Sections 1780 et seq. to Title 16 of the California Code of Regulations to establish the regulatory requirements for Third-Party Logistics Providers.

Chairperson Lippe concluded that board staff is preparing the required notice documents and anticipates initiating the rulemaking process in April 2016.

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

Ms. Herold thanked Lori Martinez and Debbie Damoth for their work on getting pending regulations finalized and submitted for the required reviews by various control agencies.

Chairperson Lippe adjourned the meeting at 10:15 a.m.