



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

**DATE:** April 12, 2017

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

**COMMITTEE MEMBERS PRESENT:** Greg Lippe, CPA, Chairperson, Public Member  
Lavanza Butler, Vice-Chairperson, Licensee Member  
Albert Wong, Pharm D, Licensee Member  
Victor Law, Licensee Member

**COMMITTEE MEMBER ABSENT:** Valerie Munoz, Public Member

**STAFF MEMBERS PRESENT:** Virginia Herold, Executive Officer  
Anne Sodergren, Assistant Executive Officer  
Desiree Kellogg, Deputy Attorney General  
Laura Hendricks, Associate Analyst

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

Chairperson Lippe called the meeting to order at 9:10 a.m. Roll call was taken with the following members present: Albert Wong, Lavanza Butler, Victor Law and Greg Lippe. A quorum was established.

**II. Public Comment for Items Not on the Agenda, Matters for Future Meetings\***

*\*(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

No public comments were provided during this portion of the meeting.

**III. Legislation Report**

Chairperson Lippe highlighted some key legislative deadlines, including that the last day for bills to pass out of their house of origin is June 2, 2017.

## **a. Board Sponsored Legislation**

### **1. Omnibus Provisions**

Chairperson Lippe advised the committee that the board is sponsoring five measures this year.

Mr. Lippe highlighted the two omnibus provisions that include amending BPC section 4013 (d)(1) to add designated representative to the list of individuals that need to join the email subscriber list and BPC section 4316 to clarify the board's authority to issue a cease and desist for unlicensed activity and that the issuing of the order will be delegated to the executive officer. The committee was advised that provisions will be included in the Senate Business, Professions and Economic Development proposal; however, the measure is not yet in print.

### **2. SB 351 (Roth) Hospital Satellite Compounding Pharmacy: License: Requirements**

Mr. Lippe reviewed the status of Senate Bill (SB) 351 relating to the creation of a hospital satellite compounding pharmacy license as well as the expansion of the conditions under which a hospital can secure additional pharmacy licenses. It will be heard in the Senate Appropriations Committee on April 17, 2017. The committee briefly discussed this measure, noting its support of the policy.

### **3. SB 443 (Hernandez) Pharmacy: Emergency Medical Services Automated Drug Delivery System**

Chairperson Lippe reviewed the provisions contained in SB 443 relating to the proposed licensure of emergency medical services automated drug delivery system (EMADDS) that is located within a county operated fire department. The committee noted that this measure would allow the board to issue a license for the use of the EMADDS that could be used to restock medications in an ambulance. As with the prior measure, this bill creates an option, not a mandate.

### **4. SB 510 (Stone) Pharmacies: Compounding**

The committee was advised that SB 510, a measure that repeals an outdated statutory requirement related to the environments in which a pharmacy may compound sterile products, has been referred to the Assembly.

### **5. SB 752 (Stone) Pharmacy: Designated Representative-Reverse Distributors**

Mr. Lippe advised the committee that SB 752 establishes the creation of a designated representative license reverse distributor and will be heard by the Senate Business, Professions and Economic Development committee on April 17, 2017.

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

The committee also discussed measures that impact either board operations or the board's jurisdiction.

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

Mr. Lippe advised the committee that AB 12 would require each state agency to, on or before January 1, 2020, review regulations; identify any regulations that are duplicative, overlapping, inconsistent or out of date; revise those identified regulations, as provided; and report to the Legislature and Governor, as specified. The committee discussed the policy behind the proposal as well as the fiscal impact the measure would have to the board totaling \$478,000 (FY 2018/19) and \$454,000 (FY 2019/20).

The committee was advised that possible amendments could be for staff to either to expand the time and/or synchronize efforts with Sunset review.

**Motion:** Recommend an oppose unless amended (OUA) position on AB 12.

**M/S:** Law/Wong

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

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

Mr. Lippe reviewed the provisions contained in AB 40 which would require the Department of Justice to make the electronic history of controlled substances dispensed to an individual under a health care practitioner's care, based on data contained in the CURES database, available to the practitioner through either an online internet web portal or an authorized health information technology system, as defined. This bill contains other related provisions and other existing laws.

The committee noted that the board has a long history of supporting CURES and its use.

**Motion:** Recommend a support position AB 40.

**M/S:** Law/Wong

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

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

The committee was advised that AB 182 would require the Department of Health Care Services (department) to develop and implement an education campaign (HOPE) to combat the growing heroin and opioid medication epidemic in California in consultation with stakeholders. As part of its discussion the committee noted the measure includes some of the information that must be used as part of the campaign as well as targeted audiences.

The committee was reminded of the education campaign under development by the Communication and Public Education Committee.

**Motion:** Recommend a Support position AB 182.

**M/S:** Law/Wong

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

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

Mr. Lippe discussed the proposed changes in AB 208 including changes from the deferred entry of judgment program to a pretrial program. Deputy Attorney General Kellogg expressed concern with the provisions in the measure that expands the conditions under which someone would be eligible for the program and the reduction in the length of the program.

The committee was advised on an analysis of administrative cases closed in the past three years that involved an arrest or conviction revealed that 119 of these cases would have been eligible for the pretrial program being proposed under this bill. In each of those cases the board would need to prove the arrest and underlying conduct.

The committee also discussed the challenges this measure would present in the board pursuing license restrictions under the authority granted under Penal Code 23.

The committee discussed the stated policy of the measure and whether there were amendments that could be sought to preserve the board's ability to fulfill its mandate without impacting the overall policy being sought through the measure. The committee discussed requesting amendments that could prohibit healing arts licensees from eligibility into a pre-trial program as well as mandatory disclosure as part of the application process for an applicant seeking licensure.

**Motion:** Recommend an OUA position AB 208.

**M/S:** Law/Butler

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

5. AB 241 Dababneh (Personal Information: Privacy: State and Local Agency Breach)

The committee briefly discussed the provisions contained in AB 241, which would require an agency, in this case DCA, to offer identity theft prevention and mitigation services for at least 12 months to a person when the individual is impacted by a security breach of data caused by the agency. As part of its discussion, the committee noted the potential significant economic impact as well as the legal requirement for the board to collect personal information, including Social Security numbers and tax identification numbers.

The committee did not make a recommendation on this measure but directed staff to continue to monitor it.

6. AB 265 (Wood) Prescription Drugs: Prohibition on Price Discount

The committee discussed AB 265 which would prohibit a manufacturer from providing a discount, rebate or other price inducement if a lower cost brand name or non-brand name prescription drug is therapeutically equivalent. The committee noted that this measure is intended to address the rising prescription drug prices. The committee discussed the policy of the measure, noting that consumers are induced to take a specific brand of a prescription medication that may ultimately result in higher costs to the consumer after rebates, etc. expire.

Staff notes that clarification will be sought from the author's office on enforcement of the provisions as well as how this measure would impact possible regulation of Pharmacy Benefit Managers (PBM), which may, as a requirement for a contract, prohibit a pharmacy from sharing cost information with consumers.

The committee did not make a recommendation on this measure but directed staff to continue to monitor it.

7. AB 315 (Wood) Pharmacy Benefits Management

The committee noted that the board recently took a support position on AB 315, which would establish the regulatory framework for Pharmacy Benefits Managers (PBMs), including licensure by the board.

The committee heard public comment from CVS Caremark who again expressed concern with the board's regulation of PBMS. As part of the remarks it was noted that the measure had been amended after the board established its support position and advised the committee of a letter prepared by the Federal Trade Commission (FTC) regarding the regulation of PBMs as it relates to policy adopted by Mississippi.

Board staff advised the committee that as amended the measure retained the board's licensure of PBMs and that staff will review the FTC letter.

The committee did not make a recommendation on this measure but referenced the board's current support position.

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

Chair Lippe provided an overview of the provisions contained in AB 401 relating to telepharmacy and the creation of a new remote dispensing site pharmacy intended to provide pharmacy services in medically underserved areas. The committee discussed the overall policy of the measure, which would provide for pharmacy services in rural areas that may not otherwise have access to a pharmacist.

The committee discussed concern with the expansion of supervision a pharmacist would have at the remote sites as well as if the measure had appropriate controls in place for controlled substances.

The committee did not make a recommendation but requested that staff work to address some of the issues identified.

9. AB 444 (Ting) Medical Waste: Home-Generated Sharps Waste

The committee was advised that although AB 444 currently relates to the collection and disposal of home-generated sharps waste, staff was advised that the author's office indicated that the measure would be amended to address the larger issue of pharmaceutical drug takeback. The committee questioned the locations of current collection sites and was advised that locations are currently determined at the county level.

The committee did not make a recommendation on the measure but requested that staff continue to monitor the measure.

10. AB 602 (Bonta) Pharmacy: Nonprescription Diabetes Devices

Chair Lippe provided an overview of AB 602 relating to nonprescription diabetes devices and indicated that under the provisions of this measure, pharmacies that dispense nonprescription diabetes test devices pursuant to a prescription would be required to retain records. AB 602 also would make it unprofessional conduct for a licensee to seek reimbursement for such devices under specified conditions.

The committee discussed the policy behind the measure, including the issue of counterfeit diabetic test strips. Staff suggested that it may be appropriate to seek amendments to the measure to allow the board to embargo such test strips when it has reason to believe the product is counterfeit. Staff also advised the committee of the unprofessional conduct it has investigated related to pharmacies seeking reimbursement from payers for dispensing the counterfeit products.

**Motion:** Recommend a Support If Amended (SIA) position AB 602.

**M/S:** Butler/Law

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

11. AB 703 (Flora) Professions and Vocations: Licenses: fee waivers

Chair Lippe provided an overview of AB 703, which would require the board to grant a fee waiver for application and issuance of a license to a military spouse if the individual is licensed in another jurisdiction.

The committee discussed the board's current process of expediting applications for such individuals and noted the slight fiscal impact the measure would have.

The committee heard public comment in support of the measure.

**Motion:** Recommend a Support position on AB 703.

**M/S:** Law/Butler

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

12. AB 710 (Wood) Department of Consumer Affairs

Mr. Lippe provided an overview of AB 710, which would require a board to meet, at least once every other calendar year in rural northern California. The committee noted policy behind the measure and noted that a mandate is not required for the board to meeting in rural California.

The committee did not make a recommendation on this measure but requested that staff continue to watch the measure as well as convey the board's fiscal impact.

13. AB 767 (Quirk-Silva) Master Business License Act

Chairperson Lippe described the provisions in AB 767, which would create a business license center within the Governor's Office of Business and Economic Development that shall be responsible for administering a master business license system to simplify the process of engaging in business in this state. The committee noted the significant fiscal impact to the board, which included one-time costs of \$948,623.85 and ongoing costs of \$24,220.18.

The committee did not make a recommendation on this measure but requested that staff continue to watch the measure as well as convey the board's fiscal impact.

14. AB 827 (Rubio) Department of Consumer Affairs: Task Force: Foreign-Trained Professionals

The committee briefly discussed the provisions in AB 827, which would require DCA to establish a task force to study and issue a report regarding licensing of foreign trained professionals into the state's workforce. Staff noted that the measure may be more appropriate for handling by the California Workforce Development Board and that staff has sought information from the DCA on the estimated fiscal impact.

The committee did not make a recommendation on this measure but requested that staff continue to watch the measure.

15. AB 835 (Dababneh) Consumer Affairs

Mr. Lippe provided an overview of AB 835, which would specify that any person selling any fraudulent, forged, fictitious or counterfeited license is guilty of a misdemeanor. The committee noted that this measure would primarily be used by law enforcement, but the policy behind the measure was good.

**Motion:** Recommend a Support position on AB 835.

**M/S:** Law/Butler

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

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

The committee discussed the provisions contained in AB 845, which would authorize prescribing and dispensing a controlled substances prescription that contains cannabidiol if the federal government reschedules such products.

Staff commented that according to the sponsor, the intent of the legislation to allow for the immediate prescribing and dispensing of such products upon action by the federal government. Staff and counsel noted that in its current form, the measure would prevent a pharmacist from exercising professional judgment by stating in the statute that it shall be deemed for a legitimate medical purpose. DAG Kellogg explained the consequences for such an approach and how it runs contrary to the board's enforcement efforts. Ms. Herold noted the significant effort the board has taken to educate licensees about corresponding responsibility and that the measure is contrary to the board's policy in its current form. Staff suggested offering amendments to the author's office to address this concern.

**Motion:** Recommend an OUA position on AB 845.

**M/S:** Law/Butler

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

17. AB 912 (Oberholte) Small Business: California Small Business Regulatory Fairness Act

Mr. Lippe provided an overview of AB 912, noting that it would require a state agency to provide assistance to a small business in achieving compliance with laws and to assist the business during an enforcement action. Board staff and DCA counsel expressed concerns with portions of the measure relating to the proposed requirement for the board to assist a business that it is taking enforcement action against, noting that such a requirement appears to violate the Administrative Procedures Act.

As part of its discussion the committee noted the policy behind the measure, which is to

assist small business. The committee noted the role the board could play in assisting with licensure but the conflict in the enforcement provisions. Ms. Herold reminded the committee of the self-assessment form, which provides assistance to all business entities in understanding and complying with pharmacy law.

The committee noted that the board's role as a regulator and the need to fulfill its consumer protection mandate and conduct investigations while also serving as an educator, indicating that this conflict needs to be addressed.

**Motion:** Recommend an OUA position on AB 912.

**M/S:** Law/Butler

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

18. AB 1005 (Calderon) Department of Consumer Affairs

The committee briefly discussed the provisions in AB 1005, which would require OPES to conduct an occupational analysis of every profession and vocation within the DCA with an examination to determine if the examination should be offered in languages other than English. Board staff advised the committee that it has not received the estimated fiscal impact from the department.

The committee indicated that it did not want to continue to track this measure but requested that staff follow up on the fiscal impact.

19. AB 1048 (Arambula) Health Care: Pain Management and Schedule II drug prescriptions

Mr. Lippe provided an overview of the provisions in AB 1048, which would authorize a pharmacist to dispense a partial fill of a Schedule II drug if requested by the patient or the prescribing physician. The committee discussed the policy behind the measure, noting some of the challenges it presents as well as some of the possible benefits.

The committee did not make a recommendation on the measure but requested that staff continue to watch the measure.

20. AB 1156 (Chiu) Professions and Vocations: Healing Arts Local Governments

The committee was advised that AB 1156 was amended and no longer applies to the board. As such the measure was not discussed.

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

Chair Lipped provided an overview of AB 1589, which would require the board to review the pharmacist-to-pharmacy technician ratio on a biennial basis and would require the board to provide a report to the Legislature with recommendations if the board decides a change is necessary. Staff noted the anticipated fiscal impact to the board's operations, including the need for a part-time staff person.

The committee heard public comment from a representative from the California Retailers Association who advised the committee of its support of the measure.

The committee did not make a recommendation on the measure but noted that the



Licensing Committee is evaluating pharmacy technician roles.

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

The committee discussed the policy behind SB 17, which is aimed at gaining some transparency in drug pricing by establishing reporting requirements for prescription drugs cost and volume for health plans and reporting requirements for drug manufacturers regarding rate increases. As part of its discussion the committee noted the need to reduce the costs of prescription medications and noted that a patient cannot receive the benefits of a prescription if he or she cannot afford it.

The committee noted that this measure may be a first step in helping to make prescriptions drugs more affordable.

**Motion:** Recommend a Support position on SB 17.

**M/S:** Butler/Law

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

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

Mr. Lippe provided an overview of SB 27, which would require every board within the Department of Consumer Affairs to grant a fee waiver for the application for and the issuance of an initial license to an applicant who supplies satisfactory evidence, as defined, to the board that the applicant has served as an active duty member of the California National Guard or the United States Armed Forces and was honorably discharged. The committee noted that the board had a support position on a similar measure last year.

**Motion:** Recommend a Support position on SB 27.

**M/S:** Law/Butler

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

24. SB 70 (Bates) Health Care Professionals

The committee was advised that SB 70 was amended and no longer applies to the board. As such the measure was not discussed.

25. SB 212 (Jackson) Medical Waste

Mr. Lippe provided an overview of SB 212, which would amend the existing definition of "home generated pharmaceutical waste" to include prescription and over-the-counter human or veterinary home-generated pharmaceutical. The committee was advised that the board's drug take back regulations are still undergoing review by the DCA/Agency and that staff would be seeking input from the California Department of Public Health regarding hazardous pharmaceutical waste.

The committee did not make a recommendation on the measure but requested that staff continue to watch it.

26. SB 419 (Portantino) Oxycodone: Prescriptions

Mr. Lippe reviewed SB 419, which would prohibit a person from prescribing oxycodone to a patient under 21 years of age. The committee expressed concern with the policy of the measure but did not make a recommendation.

27. SB 496 (De Leon) Department of Consumer Affairs: Regulatory Boards: Removal of Board Members

The committee was advised that SB 496 was amended and no longer applies to the board. As such the measure was not discussed.

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

Chairperson Lippe provided a brief overview of SB 528, which would allow a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B through the use of an automated drug dispensing system (ADDS) under specified conditions. Staff noted that the measure in its current form did not contain many of the safeguards required for use of ADDS in other areas of pharmacy law.

The committee heard public comment from Kevin Rew on behalf of the sponsors of the measure. Mr. Rew advised the committee that amendments would be forthcoming to include additional details and noted that the bill in its current form is incomplete. Mr. Rew noted his agreement to work with staff.

The committee did not take action on this measure but requested that staff continue to watch it.

29. SB 555 (Morrell) Regulations: 5-Year Review and Report

Mr. Lippe noted the requirements of SB 555, which would require a state agency to provide a report five years after the date a regulation is adopted or amended to address specific elements, including the effectiveness of the regulation in achieving the objective, consistency of the regulation with state and federal law, enforcement provisions, a summary of written criticisms of the regulation, cost impact and future actions that may be taken by the agency. The committee noted the policy behind the measure and indicated that not all state agencies may review and update law as the board does.

Staff noted the estimated fiscal impact and need for an additional staff person to complete the work required.

The committee did not make a recommendation on the measure but directed staff to convey the board's estimated fiscal impact.

30. SB 572 (Stone) Healing Arts Licensees: Violations: Grace Period

Mr. Lippe provided a description of SB 572, which would prohibit boards from taking disciplinary action against, or otherwise penalizing, a healing arts licensee who violates provisions but corrects the violations within 15 days if the violations do not cause irreparable harm. As part of its discussion the committee noted that the board's consumer protection mandate requires the board to act on behalf of consumers. To do that, the board must retain flexibility in how it can address violations that occur. Staff noted that in many cases,

the board learns of alleged violations from other sources, e.g. consumers who have received the wrong medication.

The committee was provided with information regarding corrections currently identified as part of the inspection process as well as the considerations that must be made when assessing fines including the extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violations.

The committee did not take a position on the measure but requested that staff continue to monitor it.

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

The committee discussed SB 641, which would limit the conditions under which a law enforcement or regulatory board may access CURES and would establish a multidisciplinary advisory committee to assist, advise and make recommendations for the establishment of rules and regulations necessary to insure the proper administration and enforcement of the CURES database. As part of the discussion, DAG Kellogg expressed concern with some of the provisions in the measure, including challenges with law enforcement gaining access to the information needed. Staff also expressed concern with stakeholders developing policy recommendations on the appropriate administration and enforcement of the CURES database. Staff suggested that amendments could be offered to address the concerns by removing those provisions.

**Motion:** Recommend an OUA position on SB 641.

**M/S:** Butler/Law

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

32. SB 716 (Hernandez) California Board of Pharmacy

Mr. Lippe provided an overview of SB 716, which would increase the number of board members to 14 by adding one pharmacy technician member who would be appointed by the Governor.

The committee heard comments in support of the proposal from the California Society of Health Systems Pharmacists which is sponsoring the measure. The committee also heard support from the California Council for the Advancement of Pharmacy.

**Motion:** Recommend a Support position on SB 716.

**M/S:** Butler/Law

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

IV. Regulations for Discussion and Consideration

a. **Board Adopted - Approved by the Office of Administrative Law**

Mr. Lippe advised the committee of three regulations packages that were approved by the Office of Administrative Law since the committee's last meeting. Specifically, Mr. Lippe noted that the proposed amendments to Title 16 CCR section 1744 Related to Drug

Warnings were approved by the Office of Administrative Law on January 31, 2017, and took effect April 1, 2017.

Mr. Lippe also advised the committee that the amendments to Title 16 CCR section 1707.5 Related to Patient-Centered Labels were approved by the Office of Administrative Law on March 3, 2017, and will take effect July 1, 2017. Mr. Lippe reminded the committee that the regulation changes modified the patient-centered labeling requirements to include “generic for” on the prescription label. Additionally, the regulation was amended to include policies and procedures in place to provide translation services for patients with limited or no English proficiency.

The third regulation package was approved by OAL on March 20, 2017, and related to changes in continuing education. Specifically this regulation amends the board’s continuing education (CE) requirements. Specifically, the amended regulation will grant CE credits for serving on a committee developing the California Practice Standards and Jurisprudence Examination (CPJE), and for attending board or committee meetings. Additionally, the regulation defines a specialized subject area necessary to meet the CE hour renewal requirement. The committee was advised that the changes take effect July 1, 2017.

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

Chairperson Lippe advised the committee of four regulation packages that are currently undergoing review by either the DCA or the OAL.

Specifically, Mr. Lippe noted that the proposed regulations to amend and/or add to Title 16 CCR sections 1702, 1702.1, 1702.2 and 1702.5 relating to renewal requirements was submitted to the department for review on February 7, 2017.

The committee was advised that the proposed regulations to add Title 16 CCR sections 1776 et seq. establishing the regulatory requirements for prescription drug take-back programs was submitted to the department on December 12, 2016, and the proposed amendments to Title 16 CCR section 1703 related to delegation of certain functions to the board’s executive officer were submitted to the department for review October 27, 2016.

Lastly, Mr. Lippe advised the committee that the proposed regulations related to travel medications were resubmitted to the department on March 6, 2017.

**c. Board Adopted – Rulemaking File Being Prepared by Staff for Submission and Review by the Department of Consumer Affairs or the Office of Administrative Law:**

The committee was advised that the proposed amendments to Title 16 CCR section 1760 and the board’s disciplinary Guidelines, which are incorporated by reference, will be prepared and submitted to the department for review prior to resubmittal to the OAL.

**d. Board Approved to Initiate Rulemaking – Undergoing Pre-Notice Review by the**

**Department of Consumer Affairs or the Business, Consumer Services and Housing Agency:**

The committee was advised of proposed regulation changes that are undergoing pre-review by the department or the Business, Consumer Services and Housing Agency, including the board's proposed fee schedule. The committee was advised that the regulation was submitted for the pre-notice review on November 4, 2016; however because of the delay in completion of the pre-review, the regulations would not be in effect by July 1, 2017, when the fees increase via statute. Board staff will work to educate licensees about the changes to reduce confusion about appropriate fees.

Chairperson Lippe advised the committee that the proposed amendments to Title 16 CCR sections 1780-1783, et seq. relating to third-party logistics providers were submitted for pre-review on February 9, 2017. The proposed regulations to amend Title 16 CCR sections 1793.5 and 1793.6 and add section 1793.65 relating to pharmacy technician applications and training program requirements were submitted for pre-notice review on January 23, 2017.

The proposed regulations to amend Title 16 CCR Section 1735.2 Related to the Compounding Self-Assessment and the proposed amendments to regulation section 1715 and 1784 relating to self-assessment forms for pharmacies and wholesalers were submitted on February 2, 2017 and January 20, 2017. The committee was advised that neither of these regulations would be in place by July 1, 2017, as initially intended. Board staff is working with counsel to find an alternative way to update the self-assessment forms more timely.

The committee was advised that the proposed amendments to Title 16 CCR section 1709 related to ownership reporting requirements were submitted to the department for pre-review on January 26, 2017. The regulation was subsequently returned to board staff for changes. Depending on the scope of the changes, the proposed regulation may need to be brought back to the board for consideration again prior to initiating the 45-day comment period.

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

The committee was advised of two regulation packages that are currently pending awaiting board staff's completion of necessary documentation to submit to the department for pre-notice review. Specifically Mr. Lippe noted that the proposal to amend Title 16 CCR section 1707 Related to Offsite Storage was approved by the board January 24, 2017 and the proposed changes to amend Title 16 CCR sections 1735.1 and 1735.6 related to compounding were also approved by the January 24, 2017.

Chairperson Lippe adjourned the meeting at 12:15 p.m.

