

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

DATE: June 27, 2017

LOCATION: Department of Consumer Affairs Headquarters

First Floor Hearing Room 1625 N. Market Blvd. Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Greg Lippe, Chairperson, Public Member

Lavanza Butler, Vice Chairperson, Licensee Member

Victor Law, Licensee Member Valerie Muñoz, Public Member

COMMITTEE MEMBER ABSENT: Albert Wong, PharmD, Licensee Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer

Anne Sodergren, Assistant Executive Officer

Laura Freedman, DCA Staff Counsel

Lori Martinez, Staff Manager

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

Chairperson Lippe called the meeting to order at 9:02 a.m. Roll call was taken with the following members present: Lavanza Butler, Victor Law, Valerie Munoz, 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 for Discussion and Consideration

a. Board Sponsored Legislation

1. Omnibus Provisions

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

Chairperson Lippe highlighted the omnibus provisions that include amending BPC section 4013 (d)(1) to add designated representative to the list of individuals who 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 to delegate issuing of the order to the executive officer. The committee was also advised that the measure also repeals section 4001.5, which established a requirement for the Joint Committee to review the state's shortage of pharmacists and make recommendations on a course of action to alleviate the shortage. Chairperson Lippe noted that the repeal is not board sponsored but was included by the Senate Business, Professions, and Economic Development Committee. Finally, the committee was advised that the measure has been referred to the Assembly Business and Professions Committee.

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

Chairperson 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. The committee was advised that the measure has been referred to the Assembly Business and Professions Committee.

Steve Gray asked for clarification on section 4127.15(c)(2), which limits the ratio of pharmacists to pharmacy technicians to 1:2. Dr. Gray indicated this would limit the board's authority to set the ratio in hospitals as allowed by 4115(f)(2). Dr. Gray also asked for clarification on the meaning of "immediate supervision" as specified in section 4127.15(c)(3), which reads "Ensure immediate supervision[...]." Dr. Gray expressed concern that the pharmacy technicians would need to stop working if the pharmacist needs to leave the room to counsel a patient.

LoriAnne DeMartini, California Society of Health-Systems Pharmacists, also expressed concern regarding the pharmacist/pharmacy technician ratio and the lack of flexibility the measure provides. Additionally, she expressed concern that "immediate supervision" would diminish the clinical aspects of a pharmacist.

Virginia Herold, the board's executive officer, thanked Dr. Gray for his questions and indicated that board staff would take a look at the measure and the questions he raised prior to the July board meeting.

3. <u>SB 443 (Hernandez) Pharmacy: Emergency Medical Services Automated Drug Delivery</u> System

Chairperson Lippe reviewed the provisions contained in SB 443, which creates an

option for county emergency medical services to restock ambulances through use of an emergency medical services automated drug delivery system (EMADDS) that is located within a county operated fire department. As part of the measure, the board would issue a license for the use of the EMADDS and specify the conditions under which it may be used.

As part of the Senate Business, Professions and Economic Development Committee hearing, the committee requested that the board consider amendments to allow the proposed provisions to also apply to city fire departments and special districts. Board staff has also received requests to allow a nurse or paramedic to stock the device. If such amendments are included, registration of a nurse or paramedic with the board should be required.

The committee was advised that the measure has been referred to the Assembly Business and Professions Committee.

Ms. Herold advised the committee that staff has been working with the board president on drafting amendments to broaden the measure to allow EMS agencies to stock the device. The amendments will not include nurses, but they will allow paramedics registered with the board to restock the device at the request of the EMS agencies. Ms. Herold indicated those amendments are in the final drafting stage and will be available at the July board meeting.

Dr. Gray requested clarification if a DEA registration would be required.

Ms. Herold indicated that the DEA has begun issuing DEA permits to fire stations without healthcare oversight and this measure is designed to establish the regulatory oversight over the existing practice.

4. SB 510 (Stone) Pharmacies: Compounding

Chairperson Lippe advised the committee 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 ordered to the Third Reading File by the Assembly.

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

Chairperson Lippe advised the committee that SB 752, a measure that establishes the creation of a designated representative license for a reverse distributor, has been referred to the Assembly Appropriations Committee following a hearing on June 20, 2017.

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

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

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

Chairperson 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. Chairperson Lippe said recent amendments to the measure do not indicate a change in policy but rather provide clarification. The committee was advised that the measure is in Senate Business, Professions and Economic Development Committee with a hearing scheduled for July 3, 2017, and the board has a support position.

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

Chairperson Lippe reviewed the provisions contained in AB 182, which 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. The measure includes some of the information that must be used as part of the campaign as well as targeted audiences. The department would also be required to submit a report on at least an annual basis summarizing its activities and assessment of the effectiveness of the program. Chairperson Lippe said recent amendments to the measure clarify the intent of the measure and establish a sunset date of Jan. 2, 2023. The committee was advised that the measure is in the Senate Health Committee with a hearing scheduled for June 28, 2017, and the board has a support position.

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

Chairperson Lippe reviewed the provisions contained in AB 208 which would change the deferred entry of judgment program to a pretrial program, expand the conditions under which someone would be eligible for the program and reduces the conditions under which someone could be removed from the program, reduces the length of the program compliance to six from 12 months, and prohibits information sharing once someone is in the program. Chairperson Lippe advised the committee that the measure is in Senate Public Safety Committee with a hearing scheduled for July 11, 2017 and the Board has an oppose unless amended position.

4. AB 315 (Wood) Pharmacy Benefits Management

Chairperson Lippe advised the committee that AB 315, a measure that would establish the regulatory framework for pharmacy benefits managers (PBMs), including licensure by the board, is currently in the Senate Health Committee with a hearing scheduled for July 5, 2015. Chairperson Lippe said the board has a support position and that the measure was amended on May 30, 2017.

Anne Sodergren, the board's assistant executive officer, advised the committee that as amended the board no longer has a role in regulation of PBMs.

Ms. Herold advised that committee that, as amended, the Department of Managed Healthcare will be responsible for regulating PBMs.

The committee discussed the overall policy and made a recommendation to continue to support the bill as amended.

Motion: Recommend a Support position on AB 315.

M/S: Law/Muñoz

Support: 3 Oppose: 0 Abstain: 1

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

Chairperson 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 serve medically underserved areas. Chairperson Lippe said the measure is in Senate Business, Professions and Economic Development Committee with a hearing scheduled for July 10, 2017 and the board has a support if amended position.

Chairperson Lippe advised the committee as amended, the remote dispensing site pharmacy must be owned and operated by a pharmacist(s) and must be supervised by a pharmacy also owned by a pharmacist. Further, a pharmacy may only supervise one telepharmacy location under the current version. Under the prior version of the bill a supervising pharmacy could supervise two locations.

Ms. Sodergren advised the committee that board staff has not had an opportunity to work with the author's office and that a meeting is scheduled for the end of June. She indicated that the board is seeking amendments to address training requirements for the pharmacy technicians and implementation issues.

Dr. Gray asked for clarification on whether a pharmacist must own the telepharmacy. He expressed concern that this ownership requirement would exclude a nonprofit.

Ms. Sodergren indicated that, as written, a pharmacist is required to be part of the ownership structure and that government owned facilities could not use the model proposed in the measure.

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

Chairperson 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. Chairperson Lippe said AB 602 is in the Senate Appropriations Committee, that the board currently has a support if amended position, and that the measure was amended on June 13, 2017.

Chairperson Lippe said the measure, as amended, includes an urgency provision. Further, amendments were incorporated to provide the board with the authority to address the board's concerns, including the ability to embargo devices under specified

conditions, and amending the board's unprofessional conduct statute to include purchasing of such products from an unauthorized source.

The committee discussed the policy behind the measure and staff recommended that the committee consider a recommendation to change the board's position to support.

Dr. Gray indicated that the bill is vague in its description of "devices" and said it is restrictive to a pharmacy filling a prescription because it would not apply to testing strips that are sold over the counter.

Motion: Recommend a Support position on AB 602.

M/S: Law/Butler

Support: 4 Oppose: 0 Abstain: 0

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

Chairperson Lippe reviewed 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. Chairperson Lippe advised the committee that AB 845 is currently in the Senate Appropriations Committee, that the board currently has an oppose unless amended position, and that the measure was amended on June 7, 2017.

Chairperson Lippe said the author accepted the board's amendments regarding a pharmacist's ability to exercise professional judgment as reflected in the current version of the bill. Staff recommends that the committee consider a recommendation to change the board's position to neutral.

Ms. Sodergren said the question for staff from a policy perspective was whether the board should support a specific type of drug treatment or remain neutral. Based on that question, staff recommended a neutral position.

Motion: Recommend a Neutral position on AB 845.

M/S: Butler/Law

Support: 4 Oppose: 0 Abstain: 0

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

Chairperson Lippe reviewed the provisions contained in SB 17, a measure aimed at gaining transparency in drug pricing by establishing reporting requirements for prescription drug costs and volume for health plans and reporting requirements for drug manufacturers regarding rate increases. Chairperson Lippe said the measure is in the Assembly Health Committee with a hearing scheduled for June 27, 2017, and the board has a support position.

9. 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. Chairperson Lippe said SB 528 is currently in the Assembly Appropriations Committee, the board currently has a support if amended position, and the measure was amended on June 12, 2017.

Chairperson Lippe said the author accepted the board's amendments regarding licensure of the ADDS and establishing a fee. Staff recommends that the committee consider a recommendation to change the board's position to support.

Motion: Recommend a Support position on SB 528.

M/S: Muñoz/Lippe

Support: 4 Oppose: 0 Abstain: 0

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

Chairperson Lippe provided a brief overview of 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. Chairperson Lippe said SB 641 is currently in the Assembly Public Safety Committee with a hearing scheduled for July 11, 2017, and that the board currently has an oppose unless amended position.

Ms. Sodergren indicated that the measure would create barriers for both the board and law enforcement agencies to access and use the systems for investigative purposes. A letter was sent to the author's office voicing the board's concerns, and the board has not been contacted by the author's office.

The committee discussed the overall policy and elected to maintain the oppose unless amended position.

11. SB 716 (Hernandez) California Board of Pharmacy

Chairperson Lippe provided an overview of SB 716, which would increase the number of board members to 15 by adding one pharmacy technician appointed by the governor and one public member appointed by the governor. The bill would require the pharmacy technician member to have at least five years of experience and to continue to work in California as a pharmacy technician. Chairperson Lippe said SB 716 is currently in the Assembly Business and Professions Committee and that the board currently has an oppose unless amended position.

Ms. Sodergren reminded the committee to remain focused on how adding members would impact the board's ability to perform its job as a consumer protection agency. Ms. Sodergren indicated it would be helpful for staff to hear and understand the policy concerns with how this bill would or would not impact the board's ability to meet its consumer protection mandate.

Chairperson Lippe recommended that the board take a neutral position.

Ms. Sodergren indicated that the board can take a neutral position or change the

position to no position.

Victor Law expressed concern about the knowledge a pharmacy technician would have after just five years of work experience.

Ms. Herold reminded the committee that the focus of the board is public protection not on the profession.

Ms. Sodergren reminded the committee that there is no work experience requirement for a pharmacist.

Valerie Muñoz voiced concern that a public member does not have education or training in pharmacy law but still is part of the board. The board is appointed for consumer protection, and a pharmacy technician would bring another aspect and resource to the board.

Lavanza Butler voiced support for having a pharmacy technician on the board and asked if a neutral position would equal support for the bill.

Ms. Herold indicated that a neutral position would mean others would make the decision and the board would not voice a position.

Chairperson Lippe indicated that he felt there is a possible conflict with the board taking a position and the board would be in a better position with a neutral position.

Ms. Herold reminded the committee members that everyone on the board works toward the same goal of consumer protection and one's professional status should not matter when working towards consumer protection. Ms. Herold indicated that by advocating to maintain a professional majority, the board diminishes the role of the public member. Ms. Herold indicated that the board may be better positioned with a no position or a neutral position and let the legislature and governor decide.

Michelle Revis, California Pharmacist Association (CPHA), recommended that the board continue the oppose unless amended position. While CPHA supports the addition of a pharmacy technician to the board, it has strong concerns about the educational and training differences between a pharmacist and a pharmacy technician. CPHA disagrees with calling a pharmacy technician a professional member.

The committee heard comments in support of the proposal from the California Society of Health-Systems Pharmacists (CSHP), which is sponsoring the measure. CSHP specified that pharmacy technicians are considered allied health care professionals. CSHP indicated there are 72,000 licensed pharmacy technicians in California, and they should have representation on the board. Additionally, pharmacy technicians will be the first line of care at telepharmacies under AB 401. CSHP encouraged the board to support the measure.

The committee also heard support from Steve Gray, speaking on his behalf, who noted that pharmacy technicians have a lot of experience via the military or Veteran's Administration, and some have experience that pharmacists do not have. Additionally, he indicated that pharmacy technicians have a lot of offer, are licensed health care

professionals and are mandatory reporters of child or elder abuse – and therefore should be a professional member.

Paige Talley, California Council for the Advancement of Pharmacy, also voiced support for the bill.

Motion: Recommend a Neutral position on SB 716.

M/S: Lippe/Law

Support: 3 Oppose: 0 Abstain: 1

c. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction Currently Being Watched.

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

Chairperson Lippe provided an overview of AB 285, which would prohibit a manufacturer from providing a discount, rebate or other price inducement if a lower cost brand name or nonbrand prescription drug is therapeutically equivalent and specifies that this prohibition does not apply to drugs required under an FDA REMS. Chairperson Lippe said the measure was amended on June 22, 2017, and in its current form includes a provision that enforcement of the prohibition shall only be in response to a complaint that alleges a violation of BPC section 650 (which prohibits prescribers from receiving a rebate or other compensation for referring patients, etc.) Further, as amended each substantiated violation can result in a fine of up to \$50,000 and/or imprisonment. The measure specifies that the Department of Public Health is responsible for enforcement; the prior version did not specify which department was responsible for enforcement. Chairperson Lippe further said the measure is in the Senate Health Committee with a hearing scheduled for July 5, 2017.

Ms. Sodergren advised the committee that the bill author is attempting to remove inducements that ultimately lead to higher costs in patient care. The policy behind the measure remains the same, and the amendments specify the enforcement provision of the policy. The committee had previously requested that staff watch the bill and, while the policy has not changed and staff is not recommending a position be taken, staff wanted to let the committee know about the amendments.

Ms. Herold advised the committee that the measure is another approach to addressing the high cost of prescription drugs.

The committee discussed the measure and determined that staff should continue to watch the bill; however, a position would not a taken.

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

Chairperson Lippe provided an overview of AB 444, which would establish definitions for "home-generated medical waste," "home-generated pharmaceutical waste" and "home-generated sharps waste." The bill also would require the California Environmental Protection Agency to develop a statewide program for disposal of such items. Chairperson Lippe said the measure has been referred to the Senate Environmental Quality Committee.

3. AB 710 (Wood) Department of Consumer Affairs

Chairperson 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. Chairperson Lippe said the measure is in the Senate Business, Professions and Economic Development Committee and that a hearing scheduled for June 26, 2017, had been cancelled at the request of the author.

4. <u>AB 827 (Rubio) Department of Consumer Affairs: Task Force: Foreign-Trained</u> Professionals Information

Chairperson Lippe provided an overview of AB 827, which would require DCA to establish a task force to study and issue a report regarding licensing of foreign trained professionals in the state's workforce. Chairperson Lippe said the measure is in the Senate Professions and Economic Development Committee and that a hearing was scheduled for June 26, 2017.

Victor Law asked whether this measure applies to all professionals or just one profession and what the rationale is behind the measure.

Ms. Sodergren indicated that the measure applies to state employees as well as licensed professionals. She indicated the measure is focused on the licensing requirements for health care professionals.

Ms. Herold indicated that the measure is attempting to ease the licensing requirements for individuals coming from outside the United States.

5. AB 1048 (Arambula) Health Facilities: Pain Management

Chairperson Lippe provided an overview of 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. Chairperson Lippe said the measure was amended on June 21, 2017, to specify that a pharmacy would have 30 days to fill the remainder of the prescription from the date the prescription was written. The prior version of the bill provided a pharmacy with 30 days from the date the first partial fill was dispensed. Additionally, Chairperson Lippe indicated that the measure passed out of committee on June 26, 2017, and was referred to the Senate Appropriations Committee.

6. SB 70 (Bates) Health Care Professionals [former title]

Chairperson Lippe advised the committee that SB 70 failed to meet the legislative deadline and was no longer moving forward.

7. SB 212 (Jackson) Medical Waste

Chairperson 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 waste. Chairperson Lippe said the measure has been referred to the Assembly Environmental Safety and Toxic Materials Committee.

8. SB 715 (Newman) Department of Consumer Affairs: Removal of Board Members

Chairperson Lippe provided an overview of SB 715, which would specifically include that failure to attend board meetings as one example of continued neglect of duties required by law that the governor can use as a reason to remove a board member. Chairperson Lippe said the measure was referred to the Assembly Third Reading File on June 20, 2017.

The committee recessed for a break at 10:15 a.m. and resumed at 10:24 a.m.

IV. Regulations for Discussion and Consideration

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

Chairperson Lippe said three regulations packages were approved by the Office of Administrative Law (OAL) since the committee's last meeting. Specifically, Chairperson Lippe noted that the proposed amendments to Title 16 CCR section 1703 related to the Delegation of Certain Functions to the Executive Officer was approved by the OAL on May 30, 2017, and will take effect July 1, 2017.

Chairperson Lippe also said Title 16 CCR sections 1776-1776.6 related to Prescription Drug Take-Back was approved by the OAL on June 6, 2017, and the regulations took effect June 6, 2017. Chairperson Lippe said the regulation establishes requirements for prescription drug take-back programs offered by pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board.

The third regulation package, approved by OAL on June 8, 2017, establishes the requirements and training for pharmacists to furnish travel medications not requiring a diagnosis. The committee was advised that the regulation took effect June 8, 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 two regulation packages undergoing review by either the DCA or OAL.

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

Lori Martinez, staff manager, advised that committee that the regulation was referred to the Business, Consumer Services and Housing Agency for final review on June 15, 2017, with a final submittal date to OAL of Aug. 10, 2017.

Additionally, 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, was resubmitted to the department for review on April 27, 2017.

Ms. Martinez said the regulation is currently being reviewed by the Department and the final submittal date to OAL is in September 2017.

c. Board Approved to Initiate Rulemaking – Comment Period Closed; Awaiting Further Action by Board

Chairperson Lippe said two regulation packages have been noticed for public comment and the comments are pending review by the board in July

Specifically, Chairperson Lippe noted that the comment period on the proposed regulations to amend Title 16 CCR section 1749 relating to the board's fee schedule closed on May 30, 2017.

Ms. Martinez advised the committee that one comment was received and that the comment will be provided to the board in July.

Ms. Herold said the regulation amends the fee schedule in regulation to match the statutory fee changes that take effect July 1, 2017.

Lastly, the committee was advised that the second 15-day comment period on the proposed regulation to add Title 16 CCR section 1715.6, which establishes the regulatory requirements for inventory reconciliation reporting of controlled substances, closed on May 31, 2017.

Ms. Herold advised the committee that comments were received during the comment period and they would be provided to the board in July for review.

d. Board Approved to Initiate Rulemaking – Undergoing Pre-notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency, or returned to Board Staff for Revisions Pursuant to Such Review

The committee was advised of proposed regulation changes that are undergoing prereview by the department or the Business, Consumer Services and Housing Agency. Ms. Sodergren said these regulations have subsequently been returned to board staff for changes and that staff is reviewing the requested changes. Depending on the scope of the changes, the proposed regulation may need to return to the board for consideration again before initiating the 45-day comment period.

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 Feb. 9, 2017. The proposed regulations to amend Title 16 CCR sections 1793.5 and 1793.6 and to add section 1793.65 relating to pharmacy technician applications and training program requirements were submitted for pre-notice review on Jan. 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 Feb. 2, 2017 and Jan. 20, 2017, respectively. The committee was advised that a subscriber alert was sent to board licensees advising them to use the draft version of the self-assessment forms.

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 prereview on Jan. 26, 2017.

The committee was advised that the proposed amendments to Title 16 CCR section 1707 related to waiver requirements for off-site storage of records was submitted to the department for pre-review on April 27, 2017.

The committee was advised that the proposed amendments to Title 16 CCR section 1746.3 related to the naloxone fact sheet were submitted to the department for pre-review on May 31, 2017.

 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 one regulation package that is currently awaiting board staff's completion of documentation to submit to the department for pre-notice review. Specifically Chairperson Lippe noted the proposal to amend Title 16 CCR sections 1735.1 and 1735.6 related to compounding was approved by the board Jan. 24, 2017.

V. Future Meeting Dates

Ms. Sodergren advised the committee that future meeting dates have been scheduled and posted to the board's website.

Chairperson Lippe adjourned the meeting at 10:55 a.m.