California State Board of Pharmacy
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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: January 19, 2016

LOCATION: Department of Consumer Affairs
1St Floor Hearing Room
1625 North Market Blvd.
Sacramento, Ca 95834

BOARD MEMBERS PRESENT:
Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Stanley Weisser, RPh
Gregory Lippe, Public Member
Allen Schaad, RPh
Ramon Castellblanch, Public Member
Albert Wong, PharmD

BOARD MEMBERS NOT PRESENT:
Lavanza Butler, RPh
Rosalyn Hackworth, Public Member
Ryan Brooks, Public Member
Ricardo Sanchez, Public Member
Gregory Murphy, Public Member

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

Note: The webcast of this meeting may be found at:
http://www.pharmacy.ca.gov/about/meetings.shtml

Tuesday, January 19, 2016

Call to Order **9:06 a.m.**

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

President Gutierrez called the meeting to order at 9:06 a.m. Board members present: Stanley Weisser, Amy Gutierrez, Victor Law, Albert Wong, Deborah Veale, Ricardo Sanchez and Greg Lippe.

Note: Allen Schaad arrived at 9:15 a.m. and Ramon Castellblanch arrived at 9:35 a.m.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

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

III. Petitions for Reinstatement of Licensure or Other Reduction of Penalty

Administrative Law Judge Karen Brandt presided over the petition for reinstatement of licensure for Keith Chung, RPH 50486.

The board recessed for a break at 10:06 a.m. and resumed at 10:15 a.m.

Administrative Law Judge Karen Brandt presided over the petition for reinstatement of licensure for Erin Rodrick (Maloney), RPH 46916,

IV. Closed Session

Pursuant to Government Code Section 11126(c)(3), the Board convened closed session at 11:00 a.m. to deliberate on the petitions for reinstatement of licensure.

V. Reconvene Open Session

The board reconvened open session at 12:42 p.m.

VI. Regulations

a. Board Approved – Notice Period Pending or Completed

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

   Chairperson Lippe reported that on March 20, 2015, the board initiated a formal rulemaking process to amend the text of 16 California Code of Regulations 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 the rulemaking was open for two 45-day comment periods: the first from March 20 to May 6, 2015 – and then from May 29 through July 13, 2015. Thereafter, in November 2015, board staff compiled the final rulemaking documents and submitted the file to the Office of Administrative Law to begin the administrative review process.

Chairperson Lippe reported that the Office of Administrative Law returned the rulemaking to the board for the purpose of reviewing a comment on the Hospital Pharmacy Self-Assessment. Specifically, the board was asked to determine if the self-assessment form should be modified to explain or further clarify what "personally registered with the federal Drug Enforcement Administration" means.

Chairperson Lippe explained that board staff determined this was a non-substantive issue and that clarification was not required; however, the Office of Administrative law requested that the board consider the comment before completing its review of the rulemaking record.

Note: The comments received were provided in the board meeting materials.

Ms. Herold explained that when a pharmacist prescribes a controlled substance they are required to have a DEA number.

Mr. Law stated that he had been informed that pharmacists would not be issued DEA numbers. Ms. Herold responded that pharmacists *are* issued mid-level practitioner DEA numbers. President Gutierrez and Mr. Schaad added that the DEA website states that pharmacists are issued DEA numbers.

Dr. Steve Gray, from Kaiser Permanente, confirmed that pharmacists are registered with the DEA as mid-level practitioners.

Ms. Freedman explained that the board must determine if the self-assessment form needs to be modified in response to the comments received. She added that the staff recommendation is to not modify the language.

As pharmacists must have DEA numbers in order to prescribe controlled substances, the board determined that the phrase "personally registered with the federal Drug Enforcement Administration" was appropriate and should remain in the self-assessment.

Motion: Adopt the noticed regulatory language, and delegate to the executive officer the authority to make technical or non-substantive changes as may be

required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

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

2. Proposed Regulations to Add Title 16 CCR sections 1730 and 1730.1 related to Advanced Practice Pharmacists

Chairperson Lippe reported that in June 2015, staff initiated a formal rulemaking to add Section 1730 to Title 16 of the California Code of Regulations related to Advanced Practice Pharmacist. Following the 45-day comment period, the board modified the proposed text and thereafter, from October 9-23, 2015, issued a 15-day public comment period. He noted that a second 15-day public comment was initiated from November 20-December 5, 2015.

Chairperson Lippe explained that at this meeting, the board will consider comments received during the 15-day comment period that closed on December 5.

Note: The comments received were provided in the board meeting materials.

Staff reviewed the three comments received during the 15-day comment period. Staff noted that the comments could be rejected by the board as they were outside of the scope of the comment period. The board elected not to amend the regulation in response to the comments received during the 15-day comment period.

Ms. Herold explained that pharmacist Douglas Barcon was unable to attend the board meeting and asked staff to provide his comments to the board in the form of a letter. The letter from Dr. Barcon is provided immediate following these

minutes.

The board discussed the recommended changes to the regulation language that Dr. Barcon provided in his letter. However, the board elected not to further amend the regulation language in response to Dr. Barcon's written comments.

President Gutierrez stated that it is important for the board to move forward with the regulation. She added that in the future the board can modify the language in response to any issues that may arise.

Ms. Herold explained that all of the SB 493 regulations will become effective immediately upon filing with the Secretary of State.

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

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

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

3. Proposed Regulations 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 Title 16 California Code of Regulations section 1746.1 related to Self-Administered Hormonal Contraception. The 45-day comment period concluded on June 22, 2016, and the board approved the final language at the September 2015 Board Meeting.

Chairperson Lippe stated that board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on October 13, 2015. On December 30, 2015, a 15-day comment period began to add several documents to the rulemaking file and to revise the economic impact assessment within the Initial Notice documents. The comment period closed January 14, 2016.

Note: A copy of the one comment received during the 15-day comment period was provided in the meeting materials.

The board reviewed the comment received during the 45 day comment period, which stated that pharmacists should not be allowed to dispense hormonal contraception without a prescription because of the unnecessary hardship it will place on the pharmacist. The board rejected the comment as it was outside of the scope of the comment period and contradicted the statute.

Ms. Herold noted that this regulation will become effective immediately upon its completed review and filing with the Secretary of State.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Weisser/Gutierrez

Support: 9 Oppose: 0 Abstain: 0

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

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

Chairperson Lippe reported that on September 25, 2015, the board initiated a formal rulemaking to add Title 16 California Code of Regulations Section 1746.5 related to Travel Medications. He added that the 45-day comment period closed on November 9, 2015.

Chairperson Lippe explained that at this meeting, the board will consider the comments received during the 45-day public comment period.

Note: The comments received during the comment period were provided in the board meeting materials.

The board reviewed the comments submitted by Scott Clark during the 45-day comment period. After discussion, Mr. Clark's comments were rejected by the board.

The board reviewed the comments submitted by Brian Warren, Mary Staples and Angie Manetti. Mr. Warren clarified the comments he submitted during the comment period. He suggested modifying the language as follows.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:
(1) Completion of an immunization certificate program that meets the requirements of Section 1746.4,
(2) Completion of a ~~approved~~ travel medicine training program, which must consist of at least 10 ~~20~~ hours of training and cover ~~each~~ relevant elements of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012),
~~(2)~~ (3) Completion of the CDC Yellow Fever Vaccine Course, and
~~(3)~~ (4) Current basic life support certification.

The board noted that the comments submitted by Dr. Jeff Goad were similar to those submitted by Mr. Warren (above); the only difference a variation in the wording. The board elected to use the language provided by Mr. Warren as it better clarified the training requirements and still achieved the intended outcome of Dr. Goad's proposed language.

DCA counsel Laura Freedman, cautioned the board that removing the word "each" and replacing it with "relevant" could cause problems with getting the regulation approved by the Office of Administrative Law (OAL). She explained that the term relevant is ambiguous. In response to Ms. Freedman's statement the board amended the language as follows.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:
(1) Completion of an immunization certificate program that meets the requirements of Section 1746.4,
(2) Completion of a ~~approved~~ travel medicine training program, which must consist of at least 10 ~~20~~ hours of training and cover ~~each relevant~~ **medically relevant** elements of the

International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012),
~~(2)~~ (3) Completion of the CDC Yellow Fever Vaccine Course, and
~~(3)~~ (4) Current basic life support certification.

President Gutierrez asked if the board should remove the year "2012" from the language as provided below.

…elements of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine ~~(2012)~~.

Ms. Freedman explained that per OAL, the year must remain in the regulation. Staff noted that upon initial review of the language, OAL specifically stated that the year must be provided.

The board discussed Dr. Goad's suggestion to remove the primary care provider reporting requirement. Supervising Deputy Attorney General Joshua Room, explained that the reporting requirement is in statute so it cannot be removed.

The board elected to update the language so that the term "furnished" is used consistently throughout the regulation.

Motion: Modify the regulation language as provided below. Initiate a 15-day comment period.

Proposed Text
Add §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1746.5 Pharmacists Furnishing Travel Medications.

(a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications "not requiring a diagnosis" means a prescription medication that is either:
(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention's (CDC) Health Information for International Travel (commonly called the Yellow Book), or
(2) A prophylactic.
(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.
(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:
(1) Completion of an immunization certificate program that meets the requirements of Section 1746.4,
(2) Completion of a ~~an approved~~ travel medicine training program, which must consist of at least 10 ~~20~~ hours of training and cover ~~each~~ **medically relevant** elements of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012),

~~(2)~~ (3) Completion of the CDC Yellow Fever Vaccine Course, and
~~(3)~~ (4) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board's website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of ~~dispense~~ furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052, Business and Professions Code.

M/S: Gutierrez/Weisser

Support: 9 Oppose: 0 Abstain: 0

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

Wong	x			

Motion: If no comments are received during the 15-day comment period, delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Gutierrez/Lippe

Support: 9 Oppose: 0 Abstain: 0

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

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

Chairperson Lippe reported that on July 24, 2015, the board initiated a formal rulemaking to add Title 16 California Code of Regulations section 1746.4 related to Vaccinations. The 45-day comment period concluded on September 7, 2015.

Chairperson Lippe explained that in response to the comments received, the board approved modifications to the language and thereafter issued modified text for a 15-day comment period. Following the review of comments received, the board again modified the text of the regulation and issued a second 15-day comment period from November20 through December 5, 2015.

Note: The comments received during the 15-day public comment period that closed on December 15 were provided in the board meeting materials.

Staff explained that the two comments received both objected to pharmacists being required to report immunizations into the national registry. Additionally, one of the commenters asked the board to consider allowing entities to receive waivers from the reporting requirement. The board rejected the comments.

Staff noted that one of the commenters also asked the board to remove the requirement for pharmacists to report immunizations to primary care doctors. The board rejected this comment.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Weisser/Veale

Support: 9 Oppose: 0 Abstain: 0

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

Ms. Herold noted that this regulation will become effective immediately upon its completed review and filing with the Secretary of State.

President Gutierrez stated that the board's website is being updated to make the status each pending regulation clearer to interested parties.

6. <u>Proposed Regulations to Amend Title 16 CCR sections 1735 et seq., and 1751 et seq., Relating to Compounding</u>

Chairperson Lippe reported that on May 8, 2015, the board initiated a formal rulemaking related to compounding. The 45-day comment period concluded on June 22, 2015. The board held a regulation hearing on June 25, 2015.

Chairperson Lippe stated that at the July 2015 Board Meeting, the board reviewed the 45-day comments received and modified the language of the rulemaking. A 15-day comment period ran from July 31 through August 15, 2015. Thereafter, at the October Board Meeting, the board reviewed the comments and again approved modified language for public comment. Chairperson Lippe reported that a second 15-day comment period concluded on December 5.

Note: The comments received during the second 15-day comment period were provided in the board meeting materials.

Chairperson Lippe explained that at this meeting, the board will review the regulation; the comments received and determine whether or not to adopt the language approved in October, or make further modifications and initiate another comment period.

Supervising Inspector Michael Ignacio explained that the last 15-day comment period was limited to typographical errors and language clarification. Mr. Room explained that staff reviewed the comments received during the comment period and does not recommend modifying the language in response to the comments.

Dr. Ignacio reported that board staff worked with President Gutierrez, Mr. Schaad and legal counsel to make clarification and typographical changes to improve the language. President Gutierrez noted that all the modifications made by staff were non-substantive and would not require the board to initiate another 15-day comment period.

President Gutierrez and Mr. Schaad stated that they would recommend approving the regulation (with the non-substantive changes provided by staff) so that the board inspectors can begin enforcing the new regulations and improve patient safety. President Gutierrez added that the regulations would need to be updated on an ongoing basis as the practice of compounding is always evolving.

Ms. Freedman recommended that the board adopt the regulation as noticed, without the non-substantive changes made by board staff. She explained that the board could delegate the authority to the executive officer to make non-substantive changes to the language. Ms. Freedman stated this would make for a cleaner rulemaking file and would still achieve the board's intent to incorporate the non-substantive changes provided by staff.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Weisser/Sanchez

Brian Warren, CPhA, asked the board to consider modifying 1751.7(e). He recommend modifying subparagraph (B) of paragraph (2) to allow for a 14-day course of therapy, as testing for sterility and pyrogens takes up to 14 days to complete. The board did not modify the language based on Mr. Warren's comment.

Mr. Warren also asked the board to modify 1751.7(e)(1) because as written it would eliminate alternative sterility testing methodologies. Dr. Ignacio stated that the comments related to alternative testing methodologies were reviewed and it was

determined that as the testing methodologies have not been approved by the FDA, the language should not be modified.

Dr. Navid Vahedi and Dr. Eric Feinstein, representing Fusion Rx, stated that they had an alternative testing method called ScanRDI®. Dr. Vahedi asked the board to modify the language to allow the use of alternative testing methodologies.

The board recessed for a break at 2:20 p.m. to set-up a presentation on ScanRDI® and resumed at 2:30p.m.

Dr. Feinstein provided a presentation on the testing methodologies used by ScanRDI®.

Note: the materials presented to the board by Dr. Navid Vahedi and Dr. Eric Feinstein are provided immediately following these minutes.

The board asked if ScanRDI® is approved by the FDA. Dr. Feinstein stated that it has been assigned a "Drug Master File Number (DMF)" by the FDA. President Gutierrez responded that according to the FDA a DMF is assigned to documents submitted to the FDA, it does not mean it has been approved by the FDA.

Mr. Schaad stated that in order for the board to modify the language to allow alternative testing methodologies, the board needs to have proof that the FDA has approved this new technology.

Dr. Vahedi asked the board not to approve the compounding regulation until they have had time to obtain documentation of approval from the FDA.

Supervising Inspector Christine Acosta expressed concern regarding the use of ScanRDI® and recommended that the board not modify the language in response to the request by Dr. Vahedi and Dr. Feinstein.

Ms. Herold asked if Fusion Rx is registered with the FDA as an outsourcing facility. Dr. Vahedi responded that they are planning on becoming registered in the future.

Ms. Herold recommended to the board that they move forward with the compounding regulation. She added that if Fusion Rx can provide a letter from the FDA stating that the testing has been approved for use, then the board can consider pulling back the regulation and start another proceeding. Ms. Herold explained that the regulation would have to be updated in the future as the practice of compounding changes (i.e. implementation of USP 800).

Mr. Weisser and agreed that the board should move forward with the regulation and not delay it while the board awaited the approval documentation from the FDA. The board decided to vote on the motion previously made by Mr. Weisser and Mr. Sanchez to move the regulation forward.

Motion: Adopt the proposed regulatory changes as noticed, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required to complete the rulemaking file.

M/S: Weisser/Sanchez

Support: 9 Oppose: 0 Abstain: 0

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

b. Awaiting Notice

1. Proposed Regulations to Add Title 16 CCR sections 1776 et seq., related to Drug Take-Back.

Chairperson Lippe explained that at the October 2015 Board Meeting, the board approved proposed text to add Sections 1776 et seq. to Title 16 of the California Code of Regulations related to Drug Take-Back with specific modifications.

Chairperson Lippe stated that the modified proposed text has been provided in the board meeting materials and would be discussed at today's meeting.

Ms. Herold explained that the text was modified at the request of the board to change the liner requirements. She stated that the liner changes resulted in a significant re-numbering of the language, so out of an abundance of caution the language is being brought back to the board for re-approval.

Dr. Castellblanch expressed concern that the modified language was not provided to the public in a timely manner. Mr. Room noted that if the board approved the language it would move to comment period, and interested partied would have 45-days to review the language and submit comments. Ms. Herold added that the board has discussed drug-take back programs and presented draft language at

several meetings over the past year. She recommended officially begining the regulation process so stakeholders can submit comments for the record.

Staff noted that Tim Goncharoff, of Santa Cruz, was unable to attend the meeting and submitted written comments. The comments were provided to the board and to the public. The comments have been provided immediately following these minutes.

President Gutierrez recommended modifying the language to clarify that only the physical take-back receptacle would be voluntary, counties could still mandate the use of mail-back envelopes.

Dr. Castellblanch stated that we would like board to modify the language to state that take-back programs are voluntary unless required by local or federal law.

Mr. Weisser stated that the board needs to decide how much an entity other than the Pharmacy Board should be able to regulate what occurs in a pharmacy.

Ms. Veale stated that she would not like counties to mandate the use of mail-back envelopes as they place an undue financial burden on pharmacies.

President Gutierrez reminded the board members that it is the Board of Pharmacy's mandate to protect consumers, and the regulations should focus on how to safely implement take-back programs.

Mr. Weisser stated that pharmacy staff should be focused on giving patients healthcare advice, and expressed concerned that mandating take-back programs will take way a pharmacist's time with a patient. Dr. Castellblanch reported that he visited a pharmacy that participates in a take-back program, and the pharmacist stated that maintaining the bin takes approximately 20 minutes per week.

Dr. Castellblanch stated that the board needs to address the opioid abuse epidemic and the safe disposal of unused medications is an important step in that process.

President Gutierrez stated that a pharmacist-in-charge should not be required to place a take-back receptacle in their pharmacy if they do not feel that they can safely operate it. She added that if a county wants to mandate a take-back program and the pharmacy does not want to host a receptacle, then the pharmacy should use the mail-back program to comply with the county ordinance.

President Gutierrez reported that statistics show that only eight out of every 100 mail-back envelopes actually are used by consumers. Dr. Castellblanch responded that he would consider the use of eight out of 100 envelopes a success. Ms. Veale reminded that board that the even though only eight envelopes were used, the pharmacy still had to pay for all 100 envelopes. Dr. Wong agreed that the envelopes may be too expensive for some pharmacies to provide.

Ms. Veale stated that take-back programs (both mail-back and physical receptacles) should be voluntary.

Mr. Lippe stated that pharmacies may want to participate because hosting a receptacle will bring more customers into the pharmacy.

Mr. Law explained pharmacies should be allowed to decide it they can safely operate a take-back receptacle, as in some neighborhoods a receptacle may attract drug addicts and increase burglaries.

Dr. Castellblanch asked legal counsel if the board has the authority to preempt county ordinances.

Mr. Room stated the board clearly has the authority to regulate how licensees participate in take-back programs. However, there is not a clear answer as to whether the board's regulation would preempt county ordinances. Mr. Room recommended that the board clearly state if it intends to preempt county ordinances or if it wants to allow counties to mandate programs. Ms. Freedman agreed and added that counties could bring the preemption issue to court and it would be decided by the court if the board's regulation preempts county ordinances.

Mr. Law and Dr. Wong stated that small community pharmacies may have financial difficulty participating in a mandatory take-back program. President Gutierrez stated that in Alameda County drug manufactures fund the take-back programs.

Heidi Sanborn, Executive Director of the California Product Stewardship Council, explained that there are two types of take-back programs, those that are funded by the pharmacies and those that are funded by the drug manufacturers. She added that in most other countries the take-back programs are funded by drug manufacturers.

Mr. Weisser stated that small pharmacies may have difficulty finding room for the receptacles. Ms. Sanborn responded that there are receptacles of varying sizes.

Ms. Veale asked Ms. Sanborn if the California Product Stewardship Council would support voluntary or mandated programs. Ms. Sanborn responded that they have always supported voluntary programs. However, she noted that they are very concerned with the board preempting counties who have decided it is in the best interest of the public health to mandate take-back programs.

Ms. Sanborn recommended the board proceed with the regulations so that stakeholders could submit written comments for the record.

Mr. Schaad asked if pharmacies can accept controlled substances. Ms. Herold responded that the pharmacy must register with the DEA in order to take back controlled substances. President Gutierrez added that patients do not know the difference between controlled and non-controlled medications and will therefore place all of them in the bin.

President Gutierrez recommended changing section 1776.3 to allow the pharmacist-in-charge to refuse installation of a take-back receptacle if in his or her professional opinion; it cannot be operated in a safe manner. Ms. Veale agreed that receptacles may not be appropriate for some pharmacies and the pharmacist-in-charge should have the ability to make that determination.

President Gutierrez recommended changing section 1776.3(b) to require the receptacles be locked when the pharmacy is closed.

President Gutierrez also recommended requiring that the receptacle be physically blocked when the pharmacy is closed. She clarified that in big-box stores the pharmacy may be closed while the rest of the store is still opened. Physically blocking the receptacle would prevent customers from placing items on top of the receptacle.

Dr. Castellblanch asked if the receptacles could be placed behind the pharmacy counter. Ms. Herold explained that the DEA requirements would not allow this.

Ms. Herold recommended the board focus on creating requirements for safely operating a take-back receptacle. She added that if a pharmacy cannot meet the requirements for the receptacle, then they can choose to implement a mail-back program.

Dr. Wong stated that he would support the board making take-back programs voluntary.

Dr. Castellblanch motioned to make take-back programs voluntary unless required by local or federal law. There was no second to the motion.

Ms. Veale motioned for the board to move forward with the language as provided in the board meeting materials (the language has been provided following these minutes). Mr. Law seconded the motion.

President Gutierrez asked if Ms. Veale would amend her motion to include the requirement for the receptacle to be physically blocked when the pharmacy is closed. Ms. Veale and Mr. Law agreed to amend the language as follows.

> 1776.3 (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for

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

Dr. Castellblanch stated that he would be voting against the motion as it was clear to him that it was the intent of the board to make take-back programs voluntary.

President Gutierrez opened the floor for public comment.

A representative from Sacramento County asked the board not to preempt county ordinances.

Megan Harwood representing the Orange County Prescription Drug Abuse Coalition stated that their organization is concerned that there are not enough reverse distributors to handle the volume of the drugs being returned. Ms. Herold explained that the DEA requires the use of reverse distributors.

Ms. Harwood also expressed concern that if drug manufacturers are required to fund take-back programs they will raise the price of medication.

Ms. Sanborn, Executive Director of the California Product Stewardship Council, stated that many other countries have take-back programs that are funded by the drug manufacturers. She explained that in an Alameda county court case there were stipulated facts that showed that the cost of a take-back program would be one-cent per every ten dollars spent. Ms. Sanborn stated that in Alameda county one billion dollars' worth of drugs were sold; the cost for drug manufacturers to fund a take-back program would have only been one million dollars.

A representative from Santa Rosa asked the board not to remove the option for counties to mandate take-back programs. He also expressed concern with the requirement to physically block the receptacle.

A representative from San Francisco explained that the county of San Francisco currently has twelve pharmacies participating in their pilot take-back program. She stated that the San Francisco program will be funded by drug manufactures and will require five take-back locations for every supervisorial district (55 total pharmacies). She concluded that San Francisco does not anticipate the need to mandate the program; however, they would like the option to mandate participation if they cannot meet the required number of participants.

The California Retailers Association, the National Association of Chain Drug Stores, and CPhA offered their support of the board's motion, including making the programs voluntary.

A representative from Walgreens thanked the board for their in-depth discussion and offered support of the board's motion.

Lauren Burton with CVS Health stated their support of the board's motion. Ms. Burton explained that in counties with mandated programs, CVS complies by utilizing mail-back envelopes.

Don Gilbert representing Rite Aid stated their support of the board's motion.

President Gutierrez called for the vote on Ms. Veale's prior motion.

Motion: Move forward in the regulation process with the language provided in the board meeting materials with the amendment to 1776.3 (a) as provided below.

> 1776.3 (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner. In hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block patients from access to the collection receptacle by some means.

M/S: Veale/Law

Support: 7 Oppose: 1 Abstain: 1

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

Dr. Castellblanch stated that he is very concerned with the opioid epidemic and the rise in overdose deaths. He added that in his opinion, the board is making it harder for patients to dispose of unwanted opioids.

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

1. Proposed Regulations to Add Title 16 CCR section 1746.2 related to Nicotine Replacement Products

   Chairperson Lippe reported that at the January 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 California Code of Regulations section 1746.5 for Nicotine Replacement Products. The 45 day comment period began on May 8, 2015 and ended on June 22, 2015. He added that board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process at the end of July 2015.

   Chairperson Lippe reported that on December 15, 2015, the file was submitted for final review by the Office of Administrative Law for final approval, pursuant to the Administrative Procedures Act. The estimated date of completion is January 29, 2016. He noted that board staff has requested an immediate effective date upon completion of the review.

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

2. Proposed Regulations to Add Title 16 CCR section 1746.3 related to Naloxone Hydrochloride (Non-Emergency)

   Chairperson Lippe stated that at the April 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the emergency regulation text of 16 California Code of Regulations Section 1746.3. The 45 day comment period began on May 22, 2015 and ended on July 13, 2015.

   Chairperson Lippe explained that a 15 day comment period was required due to an error made with the incorrect proposed text being noticed in May 2015. The 15-day comment period began on September 4, 2015 and ended September 19, 2015.

   Chairperson Lippe reported that the Board approved the final language at the September 2015 Board Meeting. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on the October 16, 2015. As of December 15, 2015, the file is being reviewed by the Office of Administrative Law for final approval, pursuant to the Administrative Procedures Act.

   Chairperson Lippe stated that the estimated date of completion is January 29, 2016. He noted that board staff has requested an immediate effective date upon completion of the review.

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

President Gutierrez asked if there were any further comments from the board. Dr. Castellblanch asked that the board agendize a review of the disciplinary process, specifically the fact patterns the board considers when determining the severity of the disciplinary action it will take against a licensee.

President Gutierrez adjourned the meeting at 5:10 p.m.