July 12, 2016
Draft Board Meeting Minutes

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

DATE: July 12, 2016

LOCATION:

Staff Location
Van Nuys State Office Building – Room #315
6150 Van Nuys Blvd.
Van Nuys, CA 91404

Additional Teleconference Locations
Carlyle Hotel
1731 New Hampshire Ave., NW
Washington DC, 20009

1418 S. San Gabriel Blvd. Ste A
San Gabriel, CA 91776

UC San Diego Police Department
9500 Gilman Dr., Building B
La Jolla, CA 92093

STAFF PRESENT:
Virginia Herold, Executive Officer
Laura Freedman, DCA Staff Counsel
Lori Martinez, Staff Manager

BOARD MEMBERS PRESENT:
Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Albert Wong, PharmD
Gregory Murphy, Public Member
Gregory Lippe, Public Member
Victor Law, RPh, Treasurer
Lavanza Butler, RPh

BOARD MEMBERS NOT PRESENT:
Stanley Weisser, RPh
Ryan Brooks, Public Member
Allen Schaad, RPh
Ricardo Sanchez, Public Member
Ramon Castellblanch, Public Member

Tuesday, July 12, 2016

Call to Order 2:35 p.m.

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

Vice President Deborah Veale called the meeting to order at 2:35 p.m. Board members present: Amy Gutierrez, Debbie Veale, Gregory Lippe, Gregory Murphy, Albert Wong, Victor Law, and Lavanza Butler.

Vice President Veale asked if there were any members of the public at the teleconference locations. Members of the board confirmed there were no members of the public attendance at any of the teleconference locations.

Note: This meeting was not webcast.

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

A member of the public expressed concern about the workload of pharmacists at chain pharmacies. She asked the board to examine pharmacist's workload and survey all pharmacists as patient safety is being impacted because of overworked pharmacists.

A second member of the public requested that laws be clarified to allow a pharmacist to partner with a physician to provide immunizations.

III. Closed Session

Vice President Veale adjourned the meeting to closed session at 2:50 p.m.

IV. Reconvene Open Session

Vice President Veale returned the meeting to open session at 3:30 p.m. and adjourned the meeting at 3:31 p.m.

July 27-28, 2016
Draft Board
Meeting Minutes

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

DATE: July 27-28, 2016

LOCATION: Department of Consumer Affairs
1st Floor Hearing Room
1625 N. Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Greg Lippe, Public Member
Stanley Weisser, RPh (July 27th only)
Lavanza Butler, RPh
Ramon Castellblanch, Public Member
Albert Wong, PharmD
Ricardo Sanchez, Public Member

BOARD MEMBERS NOT PRESENT:
Ryan Brooks, Public Member
Gregory Murphy, Public Member
Allen Schaad, R.Ph.

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Janice Dang, Supervising Inspector
Kristina T. Jarvis, Deputy Attorney General
Lori Martinez, Staff Manager
Debbie Damoth, Staff Manager
Laura Hendricks, Staff Analyst
Victor Perez, Information Systems Analyst
Bob Dávila, Public Information Officer

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

Wednesday, July 27, 2016

Call to Order 9:05 a.m.

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

President Gutierrez called the meeting to order at 9:05 a.m.

Board members present: Gregory Lippe, Victor Law, Lavanza Butler, Deborah Veale, Amy Gutierrez, Stanley Weisser, Ricardo Sanchez and Albert Wong.

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

Peter Speranza, general counsel for One Point Patient Care LLC, addressed the issue of pharmacy ownership by trusts. At President Gutierrez's request, he agreed to hold his comments until the board would discuss the issue during an item on trust ownership scheduled later on the agenda.

III. Approval of the Board Meeting Minutes of February 24-25, 2016; June 7-8, 2016; June 8, 2016; and July 1, 2016

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

Motion: Approve the February 25-25, 2016, Board Meeting minutes.

M/S: Weisser/Lippe

Support: 7 Oppose: 0 Abstain: 0

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

Motion: Approve the June 7-8, 2016, and June 8, 2016, Board Meeting minutes.

M/S: Weisser/Lippe

Support: 7 Oppose: 0 Abstain: 0

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

Motion: Approve the July 1, 2016, Board Meeting minutes.

M/S: Veale/Law

Support: 7 Oppose: 0 Abstain: 0

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

IV. Recognition and Celebration of Pharmacists Licensed In California for 50 Years

The board recognized Loyal Hutchison, Kingman Siu and Phillip Grauss for 50 years of service as pharmacists.

Note: Mr. Sanchez arrived at 9:19 a.m.

V. Licensing Committee

a. Consideration of Possible Revisions to Regulation(s) Regarding Pharmacy Technician Training Programs (Title 16 CCR §1793.6)

Chairperson Weisser reported that the committee had been discussing the requirements for licensure as a pharmacy technician during several meetings. As part of its discussion, the committee reviewed the various pathways to licensure as well as enforcement actions and denials of applications. The committee heard presentations about the certification exams used for

licensure, presentations by various employers about their training programs, and a presentation about upcoming changes to technician training programs accredited by the American Society of Health Systems Pharmacists.

Chairperson Weisser said the committee and board had expressed concern about some individuals who are seeking licensure through technician training programs (programs that can be quite costly) who have criminal backgrounds that will most likely result in denial of their applications. The committee recognized that not all such training programs are equal in terms of the quality of the program, but members expressed concern that the minimum requirements established in law for such programs may no longer be adequate.

During the January 2016 Board Meeting, the board agreed in concept with the recommendations of the committee to modify Title 16 CCR section 1793.6 to strengthen the requirements of some pharmacy technician programs by including a minimum age of 18, requiring a criminal background check and requiring the administration of at least one drug test. Further, the program would be required to administer a final examination.

The committee discussed these possible changes again during its March meeting and advised the board during the April Board Meeting that it was continuing its efforts.

Chairperson Weisser said that the committee discussed the proposal language in detail and heard public comment in support of the regulation. He read the text of the proposed changes specifying the requirements for a minimum age of 18, criminal background checks, drug testing and a final exam.

1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(~~1~~ A) Knowledge and understanding of different pharmacy practice settings.

(~~2~~ B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(~~3~~ C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(~~4~~ D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
(~~5~~ E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
(~~6~~ F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
(~~7~~ G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.
(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:
(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.
(B) Administer at least one drug screening to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine acceptance into the course of training or appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.
(C) Require students to be at least 18 years of age prior to the beginning of instruction.
(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Board members clarified that the proposed section only applies to training courses, and that pharmacy technicians still may pass PTCB and receive a license. There was no public comment.

Committee Recommendation: Approve proposed amendments to section 1793.6 incorporating the changes suggested by legal counsel.

Support: 8 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. Freedman explained that the board's action initiates the formal rulemaking process. She said staff would prepare the necessary documents and send them out for public notice and start the formal process for public comment.

Note: Dr. Castellblanch arrived at 9:33 a.m.

b. Consideration of the Duties of a Pharmacy Technician and Discussion on the Pharmacist-to-Pharmacy Technician Ratio in the Community Pharmacy Setting

Chairperson Weisser noted that Business and Professions Code section 4115 specifies that a pharmacy technician may perform packaging, manipulative, repetitive or other nondiscretionary tasks only while assisting – and under the direct supervision and control of – a pharmacist. Further, Title 16 California Code of Regulations section 1793.2 specifies duties that may be performed by a pharmacy technician, as listed below:

- Removing the drug or drugs from stock
- Counting, pouring, or mixing pharmaceuticals
- Placing the product into a container
- Affixing the label or labels to the container
- Packaging and repackaging

Chairperson Weisser stated that during the April Board Meeting the board requested that the Licensing Committee discuss the current pharmacist-to-pharmacy-technician ratio.

Chairperson Weisser reported that at the committee meeting board staff provided information on how various states regulate pharmacy technicians. The information indicated that 45 states require registration/licensure, highlighted various tasks performed by technicians and illustrated that ratio requirements vary greatly from state-to-state.

Chairperson Weisser noted that, in California, a single pharmacist on duty may supervise only one pharmacy technician; however, if a second pharmacist begins working, the second pharmacist may supervise two pharmacy technicians. He added that California allows clerks to input information into a computer for the pharmacist, and there is no limitation on the number of clerks permitted in the pharmacy.

Chairperson Weisser said the committee discussed whether there was a need and/or a demand to change the current ratio. Members noted that a change in the ratio requirement may be appropriate if it makes the pharmacist more accessible to consumers. The committee recognized the benefits of a good pharmacy technician and noted that an increase in the ratio could be a double-edged sword: An increase in the number of pharmacy technicians would result in additional prescriptions being filled that will require a final check by a pharmacist.

The committee also heard from several members of the public. Some were in support of an

increase in the ratio, while others were more cautious.

During the board meeting, members discussed the pharmacist-to-pharmacy technician ratio in the context of various roles that technicians perform on the job. Chairperson Weisser and President Gutierrez noted that technicians often do tasks that do not fall into specified duties, such as handling prior authorizations and processing refills. Ms. Herold explained that a technician may perform tasks that do not require a pharmacy technician license, but he or she is acting as a pharmacy technician only when working inside a pharmacy under the supervision of a pharmacist and doing specific tasks authorized by law.

Ms. Butler said that it is unclear that the current ratio is being observed when several technicians are working behind the counter at a pharmacy and only one pharmacist is on duty. She added that even if only one of the technicians working is actually performing pharmacy technician duties, the pharmacist is ultimately responsible for everything that all the technicians are doing in the pharmacy.

Board members agreed that increasing the ratio to allow more pharmacy technicians on duty under a pharmacist's supervision would free the pharmacist to engage more with consumers and provide consultations. On the other hand they said having more technicians would increase the number of filled prescriptions that must be checked by the pharmacist, thereby increasing the pharmacist's workload. Chairperson Weisser said these issues should be explored as the Licensing Committee considers any changes to the pharmacist-to-pharmacy-technician ratio and as the roles of both pharmacy technicians and pharmacists continue to evolve. President Gutierrez said it is important to solicit input from stakeholders in any discussion of changing the ratio.

Fred Meyer of Pharmacists Planning Services spoke in support of convening a summit of stakeholders to explore possible changes in the pharmacist-to-pharmacy-technician ratio. He said pharmacies should add more pharmacists behind the counter – not more pharmacy technicians, which he said would only increase the workload of pharmacists.

Committee Recommendation: Convene a summit with stakeholders to discuss the issue of pharmacist-to-pharmacy technician ratios.

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			

c. Consideration of Possible Revisions to Pharmacist Renewal Requirements and Content-Specific Continuing Education (Title 16 CCR §1732.5)

Chairperson Weisser reported that in November 2015, the board initiated a rulemaking to amend Section 1732.5 to amend continuing education requirements to specify that six of the 30 hours required for pharmacist license renewal shall be completed in one or more of the following subject areas:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Ethics
- Substance Abuse, Including Indications of Red Flags and a Pharmacist's Corresponding Responsibility
- Compounding

Chairperson Weisser explained that during the February 2016 board Meeting, the board expressed concern that the proposal may be overregulating the continuing education requirements. Some members of the public said that a pharmacist should be allowed to use his or her professional judgment to select what continuing education; others indicated that the board should consider simplifying the list of specified coursework. He added that at the conclusion of the board's discussion in February, the board voted to refer the proposal back to the Licensing Committee to review the continuing education content areas and report back to the board.

Chairperson Weisser said the committee noted that while many of the specified areas on the list were important – including substance abuse – the topics may not be relevant for all pharmacists. Additionally the committee noted that some of the topics would be appropriate for licensees who are cited for violations. The committee also heard public comment in support of requiring law updates as part of the continuing education requirements.

Chairperson Weisser said the committee ultimately decided to keep the status quo and not require any specific subjects for CE units. He said pharmacists are responsible enough to use their own judgment to choose the CE subjects they need to remain competent.

Chairperson Weisser noted that the Legislation and Regulation Committee also reviewed the question of required CE subjects and arrived at a different conclusion.

At Ms. Freedman's suggestion, President Gutierrez announced that the board would consider the two agenda items together.

Mr. Lippe, chairman of the Legislation and Regulation Committee, said some board members in the past believed that some CE topics on the list should apply to everyone, including ethics and emergency disaster response. He said that other state boards have set requirements for specific CE subjects for their licensees. He said that it is not overregulating to require pharmacists to take one course in one of the areas that were considered by the Licensing Committee, and he urged the board not to abandon the entire list of proposed CE subjects. Dr. Castellblanch said that some

of the subjects on the list should be required of all pharmacists – specifically, ethics and substance abuse.

Mr. Law disagreed, saying that less than 1 percent of pharmacists are disciplined for ethics and substance abuse violations, so there is no need to require 99 percent to take those specific CE courses. He said that if pharmacy corporations believe their pharmacists need CE in a specific area, they could require it on their own as a company policy without the need for a board regulation. Ms. Butler said pharmacists should be allowed to exercise their own professional judgment in deciding what CE subjects they need.

Jon Roth, CEO of California Pharmacists Association, expressed support for the Licensing Committee's recommendation not to require specific CE subjects. He said data shows that pharmacists are using their judgment to determine what CE courses they need to maintain competency.

In response to a question from Ms. Veale about what data he was citing, Mr. Roth said he was making a general reference to data showing that there is not an overwhelming number of pharmacists being cited for ethics or substance abuse violations. Mr. Lippe said the board reviews about 50 disciplinary cases a month and that a number of them concern ethics and corresponding responsibility. Dr. Castellblanch said complaints about substance abuse and corresponding responsibility have increased to become the second most-common type of complaint.

Ms. Veale said the issue is not necessarily about how many pharmacists are disciplined, but whether pharmacists are competent. She said that she was trying to balance a desire not to over-regulate with the board's mandate to protect consumers by ensuring that pharmacists are competent.

Steve Gray speaking as an individual said he was concerned that many pharmacists are not up to date on laws, regulations and hot topics, and that there is no requirement that they have to be. He said the problem could be resolved by requiring two hours of CE on law and ethics for license renewal, which he said would inform pharmacists about hot topics, including changes in laws, regulations and policies. He noted that boards that regulate other professions, including law, do set mandatory CE subjects for their members. He said that, although the board publishes an annual update on changes in the law in its newsletter, it is not seen or read by many pharmacists because it is only available online.

Mr. Gray urged the board to ask the Licensing Committee to revisit the issue and narrow the list of required CE topics rather than eliminate the entire list. He said that he supported training programs taught by CPhA and CHSP, but he added that their combined membership represents less than 9 percent of all California pharmacists.

Dr. Castellblanch said it seemed to him that the number of disciplinary cases involving substance abuse had increased in recent years.

Ms. Butler said that although pharmacists should be allowed to exercise their own professional judgment, maybe the board should require that all pharmacists take two hours – not six hours – dealing with corresponding responsibility and law.

Chairperson Weiser said that pharmacists do not need to be required by the board to take CE classes in law, ethics and corresponding responsibility, because pharmacists already view those topics as priorities. He also said that, for those pharmacists who have problems in those areas, requiring two, six or 100 hours of CE would not change the nature of those who do not take those matters seriously.

LuGina Mendoz-Harper of Prime Therapeutics and member of the New Mexico Board of Pharmacy, said that her board requires two hours of law CE every two years for pharmacist renewing their license. She said the board itself provides the CE through their inspectors who provide in-person training on changes in the law. For pharmacists who practice but do not live in New Mexico, the board accepts ACPE approved law courses. She said the approach is one of dialogue and consultation between pharmacists and inspectors.

Ms. Herold noted that California has close to 40,000 licensed pharmacists throughout the state, and the logistics of educating them all in live sessions would be difficult. However, she added that the board recently had done an educational webinar on sterile compounding with the California Hospital Association, and she noted that she often speaks publicly on corresponding responsibility and other topics at CPhA events. She said there is an opportunity for the board to use webinars for training, although live presentations pose logistical challenges for staff and pharmacists.

Dr. Castellblanch said that Pennsylvania, Iowa, New York, Florida and other states do mandate CE topics for pharmacists.

Chairperson Weisser informed the board that the Licensing Committee voted 4-0 in support of a formal recommendation to withdraw the proposed regulation change to California Code of Regulations section 1732.5. Ms. Sodergren advised the board that the Legislation and Regulation Committee did not vote on the issue because the board had referred the matter to the Licensing Committee. She said the Legislation and Regulation Committee discussed the issue and that members expressed concerns that they intended to bring to the full board.

Chairperson Weisser reiterated the Licensing Committee's recommendation to withdraw the proposed regulation change to California Code of Regulations section 1732.5. He explained that the committee's recommendation would leave the existing regulation untouched and that none of the six proposed CE subjects would be required for license renewal.

Board members embarked on a lengthy discussion about the Licensing Committee's review and recommendation regarding section 1732.5. Chairperson Weisser and Mr. Law said that the board charged the committee with considering whether six of the 30 CE hours required for license renewal should be required in one or more of the six topics listed – and the committee decided not to require any of the topics. Ms. Veale, Mr. Lippe and Dr. Castellblanch disagreed, saying the board had directed the Licensing Committee to pare down the list of six proposed subjects to a two-hour CE requirement – not to eliminate the list entirely.

During the board's discussion, Ms. Herold and Ms. Freedman reminded the board that, in addition to Section 1732.5, the board was considering proposed changes regarding CE in sections 1732.05 and 1732.2, which were discussed by the Legislation and Regulation Committee. Ms. Herold

suggested that the board carve out the issue of dedicated CE under discussion in section 1732.5, allow the rest of the proposed regulation changes to move forward, and then decide what to do with the dedicated CE issue.

Board members embarked on a lengthy discussion of parliamentary procedure. Ms. Freedman advised the board to simply vote on the Licensing Committee recommendation and then board members afterward could make another motion.

Licensing Committee Recommendation: Withdraw the proposed regulation change to California Code of Regulations Section 1732.5.

Support: 6 Oppose: 3 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			x

Mr. Lippe made a motion to modify section 1732.5 so that two hours are required in the area of law and ethics. Dr. Castellblanch seconded the motion.

Dr. Wong said six hours or two hours made no difference to him and that he would prefer that the board go to different areas of California and offer free courses on substance abuse and law and ethics. Ms. Veale said that the Licensing Committee should consider requiring regular webinars that licensees could watch instead of mandated CE.

Ms. Freedman advised the board Ms. Veale's recommendation would present a conflict with a one-year limitation on the rulemaking process. She explained that if the Licensing Committee modified any text, there would not be enough time for a 15-day comment period before the deadline. She said the problem would be solved if the board accepted Ms. Herold's suggestion to bifurcate section 1732.5 from sections 1732.05 and 1732.2 and send section 1732.5 to the Licensing Committee in a subsequent rulemaking process.

Mr. Law offered an amendment to Mr. Lippe's motion to mandate licensees to attend a board-sponsored CE every two years on law and ethics. Mr. Lippe accepted the amendment. Ms. Herold said the board already puts on CE classes, but educating all 40,000 pharmacists with active licenses would have to be done through measures including the newsletter, webinars and in-person sessions.

Mr. Lippe restated an amended motion to require pharmacists to attend by webinar or another

means, at least every two years, a board-provided, two-hour update in legal and ethics areas. Dr. Castellblanch seconded the amended motion and said a test also would be required for CE. Board members clarified that the board would provide the update, track attendance and give CE certificates. Ms. Herold said that using the newsletter and webinars would allow out-of-state licensees to participate.

Rebecca Cupp of Ralph's expressed concern about requiring CE that is "board provided" rather than "board approved" She said that a lot of platforms are already available that pharmacists can easily access, such as Pharmacist Letter. She said that it's a very easy and very trackable way of having CE, but the board would have control of the content and what is required during a particular license renewal cycle.

Jon Roth, CEO of California Pharmacists Association, said that requiring board-provided CE raises issues of costs, which eventually could impact licensing fees. He said that if the board wants to mandate CE, it should do so through approved CE providers. He added that the association also opposed the measure on principle and believes it should be left to pharmacists to use professional judgment in deciding what CE courses to take.

Ms. Mendoz-Harper said that by having its inspectors provide CE content in live meetings, the New Mexico board is able to control and focus the content on specific laws, regulations and policies. She added that one of the reasons for the live meetings is that the New Mexico board does not have the technology to provide the information in webinars.

After the public comment, Dr. Wong said the he would prefer live training. Ms. Herold said the board staff would try to offer live training as well as webinars.

President Gutierrez called for a vote on the amended motion.

Motion: At least two of the 30 hours required for pharmacist license renewal shall be completed by participation in a board-provided CE course in law and ethic. The requirement would apply to pharmacists renewing licenses that expire on or after July 1, 2019.

M/S: Lippe/Castellblanch

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			x

The board recessed for a break at 11:25 a.m.

The meeting resumed at 11:37 a.m. President Gutierrez announced that the board would hear from the executive director of the Medical Board of California before returning to the Licensing Committee report.

VI. Update from the Executive Director of the Medical Board of California on Issues Affecting Both Boards

Kimberly Kirchmeyer, executive director of the Medical Board of California, read a statement advising the board on efforts to form a partnership with the boards of Pharmacy, Registered Nursing, Osteopathic Physicians and Physician Assistants to collaborate on public education and consumer protection issues. A meeting among the boards' executive officers is being scheduled for August. In addition, she said, an update from Ms. Herold was set to be presented at the Medical Board's next meeting.

Ms. Kirchmeyer said the Board of Pharmacy would be a huge asset on key issues, including CURES and efforts to end the opioid epidemic. She said the Medical Board is pleased to be working with the Board of Pharmacy, the Osteopathic Medical Board and UC Davis on a CURES survey. She also complimented the Board of Pharmacy on the CURES registration countdown clock on the board's website.

Ms. Kirchmeyer also provided an update on key programs and activities by the Medical Board, including outreach to physicians about CURES registration. She described an educational campaign advising the public to check on physicians' licenses and a Legislative Day event at the Capitol.

President Gutierrez asked Ms. Kirchmeyer whether the Medical Board was planning to update its guidelines on prescribing opioids following recent prescribing guidelines issued by the Centers for Disease Control. Ms. Kirchmeyer replied that the Medical Board was not planning to revise its guidelines, because they were just issued at the end of 2014. But she noted that the Medical Board guidelines and the CDC guidelines complement each other and said that the Medical Board is studying the CDC guidelines. She added that the Medical Board has done outreach efforts to inform physicians about the guidelines.

Dr. Castellblanch asked about CURES 2.0. Ms. Kirchmeyer replied that the Medical Board received many calls about physicians having trouble getting into the system to register. She said data indicated that more physicians are using the system now than previously, and the Medical Board is working with the Department of Justice to identify who has a DEA number and then identify who has not registered.

Mr. Law asked about efforts to inform physicians of disciplinary cases. Ms. Kirchmeyer replied that the Medical Board publicizes disciplinary cases through its quarterly newsletter and subscriber alerts.

Mr. Law complimented Ms. Kirchmeyer on the Medical Board's efforts to discipline physicians. Dr. Wong thanked Ms. Kirchmeyer for her report, and he expressed support for collaboration among the medical, pharmacy and other healing arts boards.

VII. Licensing Committee (continued)

c. Consideration of Possible Revisions to Pharmacist Renewal Requirements and Content-Specific Continuing Education (Title 16 CCR §1732.5)

Ms. Veale offered a motion to bifurcate the proposed CE regulations and send the required CE provisions to the Licensing Committee for a fuller review. She said she still was undecided whether the specified CE subjects should be mandated. The motion was seconded by President Gutierrez, who said that she also supported more discussion by the Licensing Committee.

Other board members opposed the motion. Mr. Lippe pointed out that the board had already decided to make it mandatory, and Mr. Law said more discussion would only further delay the process.

Motion: Send the proposed changes to Section 1732.5 for dedicated CE to the Licensing Committee.

M/S: Veale/Gutierrez

Support: 3 Oppose: 6 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		x

d. Consideration of Ownership Structures for Pharmacies, Including a Summary of a Presentation by the Office of the Attorney General Regarding Trusts and Possible Next Steps

Chairperson Weisser noted that the board tracks the beneficial interest of business owners for pharmacies, whether they are natural persons or entities. Board regulation specifies the reporting of a transfer in the beneficial interest in the business and specifies the threshold as to when a change of ownership must be submitted to the board.

Business and Professions Code section 4035 defines a "person" as follows:

"Person" includes firm, association, partnership, corporation, limited liability company, state governmental agency, or political subdivision.

Chairperson Weisser explained that when processing a pharmacy application, the board identifies

and records all levels of ownership of the applicant business. This is done through a careful analysis of all information submitted in support of the application, and oftentimes identifies inconsistencies with respect to the ownership reported. For some, what is initially reported as (what appears to be) a simple, two- or three-level ownership structure, when staff uncovers details, it often turns out to be multiple levels of ownership with multiple stakeholders. He noted that it is common for applicants with complex ownership structures to argue that the board doesn't need to know all of the information related to a pharmacy's ownership.

Chairperson Weisser reported that board staff has identified where (revocable or irrevocable) trust(s) is/are reported as owners of the applicant business. Pharmacy Law does not currently recognize a "trust" as a person to which the board is authorized to issue a license; however, in researching older licensing records, some trusts have been found to be on record as "shareholders" of existing licensees.

During the board meeting, the board was advised by legal DCA counsel that as with other ownership structures trusts can be used as a legitimate form or ownership. However, they can be manipulated to hide ownership.

Chairperson Weisser reported that the committee heard a presentation from Matthew Heyn, Deputy Attorney General. Mr. Heyn discussed that one of the challenges currently facing the board is hidden ownership of applicant business. Mr. Heyn referenced the Panama Papers that detailed two foreign-owned pharmacies held by trusts that ultimately allowed them to exert monopoly control using their hidden ownership. Mr. Heyn confirmed his belief that the board does not currently have the authority to issue a license to a trust owner and indicated that the board will need to identify what information should be collected as part of the application if it chooses to allow such ownership.

Chairperson Weiser stated that the committee heard information from the public that offered different opinions on what the law currently provides. The committee noted the important role a trust plays in estate planning.

Committee Recommendation: Ask legal counsel to review statutes and regulations to propose a fix to resolve the trust issue and how to regulate the entities within the board's regulatory framework.

During the board meeting, Ms. Herold told the board that trust ownership presents a very serious issue for the licensing unit staff. Mr. Law asked if pending applications involving trusts can be processed while the legal issues are being resolved. Ms. Freedman said the board does not have statutory authority to issue licenses to trusts, despite the fact that the board has done so in the past. Ms. Herold said the board has about 75 licensees that have been identified as having trusts that are as part owners of pharmacies, but she noted that there could be additional cases because it is difficult to find them without pulling and reviewing individual files by hand. In addition, she said the board has about 15 to 20 pending applications with reported trust ownership.

Chairperson Weisser said that discussion at the committee meeting made it clear that there is a need to amend California Code of Regulations section 1709 to requires trusts to disclose the identity of all trustees, beneficiaries and grantors, etc. Ms. Freedman said that the problem has a

statutory element as well.

Ms. Herold said the intent is to bring a proposed legal solution to the Licensing Committee in September. She added that in the meantime, the board must decide what to do with pending trust applications. She said that time is critical, because a statutory solution could mean 18 months before the board could license a trust, assuming a bill could be passed and signed into law next year. Ms. Sodergren said staff's intent is to present a regulatory framework to the Licensing Committee in September so that the board can take action in October. She added that the board could seek an urgency designation in the legislation that would allow a statutory solution to take effect sooner.

Mr. Sanchez noted that, because applications are completed under penalty of perjury, the board has a means to prosecute licensees who are not truthful about trust ownership.

Peter Speranza, general counsel for One Point Patient Care LLC, argued that the board already has the statutory authority that it needs to issue a license to a trust. in Business and Professions Code sections 4035 and 4112 He said One Point applied for a license in March and fully disclosed additional information requested by the board about the trusts in the company's ownership structure, including grantor, trustee and beneficiaries. He said section 4207(d) authorizes the board to request any ownership information it needs to complete an application request.

Ms. Freedman said other presenters have made the same argument as Mr. Speranza, but the position of DCA and the Attorney General is that if trusts are prohibited at one level of ownership, then they are prohibited at all levels. She explained that a trust is not one of the enumerated entities described as a "person" in section 4035. She said that she and the AG's lawyers are not persuaded by the counter-arguments.

Brian Warren of the California Pharmacists Association told the board that observers on all sides of the issue agree that trusts should be allowed to be licensed, whether they are in the statute or not, as long as the board has the correct information. He said the board should amend currently pending SB 1193 to allow trusts to be licensed, and then the board could pursue any needed additional regulations. He said this could be completed by January 2017 and would provide a quick resolution for pharmacies that are affected by this issue but have complied with all board regulations.

Ms. Herold said that, if the board followed Mr. Warren's suggestion, she would like the board to build in a two-year period during which staff could work with the already identified trusts to have them provide the appropriate information and a tracking mechanism. She agreed that an amendment to SB 1193 could be a possible solution, but she added that the board should ensure that legal counsel is prepared to amend section 4035 and any other code sections needed, as well as build in a period to allow staff to review licensing records, so that the board has the same information from already licensed trusts and from future licensed trusts.

Ms. Freedman said that legal counsel might be able to draft proposed language and asked the board to table the discussion to allow her time to research the issue and report back after lunch.

Ms. Jarvis urged the board to first decide from a policy standpoint if it wants to change the law to

allow trusts to be licensed. She noted that it's harder to identify who is a beneficiary of a trust, and it would take more staff time to investigate applications. She said the beneficiaries of a trust can be difficult to discern, because they can be dependent on other factors, and the board may not want to do background checks on some people identified as beneficiaries – particularly minors.

Chairperson Weisser said the Licensing Committee believed from a policy standpoint that trusts should be allowed to own pharmacies. Other board members agreed that trusts should be allowed to own pharmacies.

Ms. Herold said the board should consider whether a trust should be in allowed to be the first-line ownership position over any pharmacy..

The board asked for additional public comment.

Peter Gregorovic of FMG Pharmacy Law in San Diego told the board that he represents pharmacies with applications that are being held up because of the trust issue. He said that lawyers drafting legislation should keep in mind important distinctions between revocable and irrevocable trusts in terms of who actually owns the property in the trust. Among other things, he said that tracking ownership is easier in revocable trusts.

Tony Park, a lawyer and pharmacist, said that there are ways to change ownership without disclosing it to the board. He said that some pharmacy owners are using these strategies to circumvent the trust ownership issue.

Jon Roth of the California Pharmacists Association said he was contacted by a Redding pharmacy whose application is in limbo because of this issue and the result is that patients in that community cannot get their pharmacy services met because the license can't be transferred. He urged the board to consider interim solutions to help communities.

Steve Gray of Kaiser Permanente, speaking as an individual, said the board also should consider legal issues related to disclosure of people involved in a nonprofit corporation.

Dr. Castellblanch asked about the purpose of knowing ownership besides knowing who is accountable if any problems arise. Ms. Herold said reasons include needing to know who benefits from ownership, and not wanting some individuals to be owners because of their criminal backgrounds.

President Gutierrez asked Chairperson Weisser to continue with the Licensing Committee's report to allow legal counsel time to draft proposed language on trust ownership.

e. <u>Licensing Statistics</u>

Chairperson Weisser said that the board received 16,423 applications last fiscal year, including:

- 6,257 pharmacy technician applications
- 1,959 pharmacist license applications

- 754 pharmacy applications.

Chairperson Weisser reported that the board issued almost 12,000 licenses, including

- 5,851 pharmacy technician licenses
- 1,978 pharmacist licenses
- 671 pharmacy licenses

Chairperson Weisser stated that the board renewed over 64,000 licenses and as of June 30, 2016 had 6,097 applications pending. In addition to the annual licensing statistics, a three-year comparison revealed the following overall trends:

- 5 percent decrease in the number of applications received.
- No significant change in the number of licenses issued.
- 4 percent increase in the number of applications pending.
- 4 percent increase in the number of licenses renewed.
- 2 percent growth in the overall licensing population of the board.

f. Future Committee Meeting Dates for 2016

Chairperson Weisser reported that the Licensing Committee meeting scheduled for this fall has changed to September 27, 2016. He added that the location for the meeting was still being determined.

The board recessed for lunch at 12:55 p.m.

The meeting reconvened at 1:33 p.m. Mr. Weisser and Mr. Sanchez were absent.

VIII. Legislation and Regulation Committee

Part 1: Legislation for Discussion and Consideration

a. Board-Sunset Legislation

1. SB 1193 (Hill) California State Board of Pharmacy
   Version: June 21, 2016 Amended
   Location: Assembly Appropriations
   Position: Support

   Chairperson Lippe said this measure would extend the operations of the California Board of Pharmacy and the board's authority to appoint an executive officer until January 1, 2021; would establish the framework for the licensure of outsourcing facilities; would authorize the board to synchronize license renewal dates and aggregate fees for clinics, as specified; would authorize the board to issue a temporary permit for specified licenses; would repeal obsolete provisions related electronic data transmission prescriptions in the Health and Safety Code, and makes other technical changes. Staff attended the June 28th hearing and was available for questions. The bill passed out of Assembly Business and Professions 13-0 and was re-referred to Appropriations.

Chairperson Lippe reported that the committee discussed this measure and was advised that the application and renewal fees for outsourcing facilities will be amended during the Assembly Appropriation Committee hearing to align with the fees for resident and nonresident sterile compounding facilities respectively. He noted that the committee did not recommend a change in the board's current support position.

There were no comments from the board or the public.

2. SB 1039 (Hill) Professions and Vocations
Version: June 21, 2016 Amended
Location: Assembly Appropriations
Position: Support

Chairperson Lippe said Senate Bill 1039 would set forth a new fee schedule, which is needed to sustain board operations. The bill amends numerous provisions related to various professions and vocations, to include the Board of Podiatric Medicine, Dental Hygiene Committee, and others.

Chairperson Lippe reported that the committee discussed this measure and did not recommend a change in the board's support position.

There were no comments from the board or the public.

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

1. AB 45 (Mullin) Household Hazardous Waste
Version: January 21, 2016 Amended
Location: Senate Environmental Quality Committee
Position: Oppose Unless Amended

Chairperson Lippe said this measure would have established a process for model guidelines to be created for the disposal of household hazardous waste, include prescription drugs**.**

Chairperson Lippe stated that the committee was advised that the measure is died as it did not meet the July 1, 2016 policy deadline.

There were no comments from the board or the public.

2. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
Version: July 1, 2015 Amended
Location: Senate Appropriations Committee (7/7/2015)
Position: Oppose Unless Amended

Chairperson Lippe explained that AB 1069 would expand the provisions under which a county-established repository and distribution program allows the transfer of drugs to other

counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

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

Chairperson Lippe stated that the committee was advised that amendments are expected as part of the hearing during the Senate Appropriations Committee and if the amendments are available they will be brought to the July Board Meeting for consideration. He added that the committee did not recommend any change to the board's current position.

Ms. Sodergren informed the board that there will be amendments that will significantly change the legislation to allow repackaging of medications in advance of the patient presenting at the pharmacy if it is a pharmacy within the county that specifically only deals with these types of medication serving this specific population.

Mr. Lippe asked if the board might change its position, based on the amendments. Ms. Sodergren said she could not say until she had a chance to look at the language. She said staff can work with the board president and the Legislation and Regulation Committee chairman on the issue.

There were no comments from the public.

3. AB 1386 (Low) Emergency Medical Care: Epinephrine Auto-Injectors
   Version: June 28, 2016 Amended
   Location: Hearing in Senate Appropriations Scheduled for August 1, 2016
   Position: Support

Chairperson Lippe said this measure would amend Pharmacy Law and other provisions of the Civil Code and Health and Safety Code to authorize a health care provider to issue a prescription, and a pharmacy to furnish, epinephrine auto-injectors to an authorized entity, as defined. The bill calls for specific labeling on any epinephrine auto-injectors dispensed pursuant to the bill's provisions. Authorized entities include any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course, as defined. As is with current law, authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors shall be established and approved by the California Emergency Medical Services Authority.

Chairperson Lippe reported that the committee discussed this measure and did not recommend a change to the board's support position. The committee asked staff to reach out to the author's office to determine if the author would consider allowing a pharmacist to provide the auto-injectors without a prescription. Chairperson Lippe added that the committee noted that the board may want to consider pursuing legislation to allow a pharmacist to do this without a prescriber order if the current measure is not amended to incorporate this.

There were no comments from the board or the public.

4. AB 1748 (Mayes) Emergency Medical Care: Naloxone Hydrochloride or other Opioid Antagonist

Version: June 20, 2016 Amendment
Location: Senate Appropriations – Hearing set for August 1, 2016
Position: None

Chairman Lippe said this bill would authorize specified educational agencies to provide an emergency opioid antagonist to school nurses or trained personnel and would authorize a school nurse or trained individual (volunteer) to administer an opioid antagonist to a person who is believed to be suffering from an opioid overdose, as specified. The bill contains provisions that authorize the writing of a prescription by a physician and surgeon, and a pharmacist's authority to dispense naloxone hydrochloride or other opioid antagonist pursuant to that prescription.

Chairperson Lippe explained that the author's office indicated this measure is modeled after provisions that allow a pharmacist to dispense emergency epinephrine auto-injectors to authorized entities for the purpose of providing emergency medical assistance. The board has not considered this measure previously.

Chairperson Lippe reported that the committee discussed this measure and is recommending a support position. Further, the committee suggests that given the ability of a pharmacist to provide naloxone under protocol, ask the author if they are interested in amending the measure to allow a pharmacist to provide it without a prescription to an authorized entity.

Steve Gray of Kaiser Permanente spoke in support of amending the bill to allow pharmacists to be allowed to provide naloxone without a prescription. He said that some doctors are reluctant to write a prescription for schools because they do not want to have a relationship with the school.

Committee Recommendation: Support AB 1748 and ask the author to amend it to allow a pharmacist to provide an opioid antagonist without a prescription to an authorized entity.

Support: 8 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. SB 482 (Lara) Controlled Substances: CURES database
Version: June 21, 2016
Location: Appropriations (Suspense File)
Position: Support

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

Chairperson Lippe reported that the committee briefly discussed this measure and did not recommend a change in in the board's current support position.

President Gutierrez asked about the "specified settings" and noted that the bill does not include any mention of physicians being unable to look up prescriptions in CURES by provider – only by patient. Ms. Sodergren said the seven-day supply limit applies to the emergency room of a general acute-care hospital when ordered or dispensed for a patient as part of his or her treatment for a surgical procedure, and she noted that a prescriber could order more than seven days of supply if the prescriber checks CURES. She added that the bill does not include any provision regarding looking up prescriptions by physician name.

There was no public comment.

6. SB 999 (Pavley) Health Insurance: Contraceptives: Annual Supply
Version: June 20, 2016, Amended
Location: Assembly Appropriations
Position: None

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

amended, the bill incorporates reference to Section 733 of the Business and Professions Code (conscience clause). The board does not have a position on Senate Bill 999.

Chairperson Lippe said the committee briefly discussed this measure but did not take action nor make a recommendation.

Mr. Law asked why the committee did not want to support the bill. Mr. Lippe replied that the committee did not feel comfortable in dispensing a 12-month supply without the patient being checked. Ms. Veale said the committee felt the measure was not really focused on patient safety.

There was no public comment.

7. SB 1229 (Jackson) Pharmacies: Secure Drug Take-Back Bins
Version: June 27, 2016 as Amended
Location:Assembly Floor
Position: Support

Chairperson Lippe said that Senate Bill 1229, as amended, states the Legislature's intent to encourage good faith participation of federally authorized entities to maintain secure drug take-back bins for the convenience and public health and safety of prescription drug consumers, and for the proper disposal in the waste stream of pharmaceutical waste contained in the bins.

Chairperson Lippe explained that the bill incorporates the Secure and Responsible Drug Disposal Act of 2010 (Public Law 111-273) and states that the provisions of the bill shall be construed in a manner that is consistent with the requirements imposed by the DEA's final rule and any regulations promulgated by the state.

Chairperson Lippe said the committee discussed this measure and how it relates to the board's pending drug take back regulations. He added that the committee did not recommend a change to the board's current support position.

Chairperson Lippe told the board that Dr. Gray, Kaiser, stated to the committee that this bill may discourage participation and added that members of community have reached out to the author's office to express concern.

There were no comments by the board or the public.

c. Legislation Impacting Board Operations

1. AB 12 (Cooley) State Government: Administrative Regulations: Review
Version: August 19, 2015
Location: Last location was Senate Appropriations / Held under submission
Position: Oppose (4/22/15 text version)

Chairperson Lippe said that AB 12 would require state agencies to review, adopt, amend or repeal any regulations that are duplicative, overlapping, and inconsistent or out-of-date by January 1, 2018, and establish reporting requirements. The bill was amended on August 19, 2015, but there are no substantive differences from the prior version.
The bill has not moved since August 2015.

Chairperson Lippe reported that the committee discussed this measure and did not recommend a change to the board's current oppose position.

There were no board or public comments.

2. SB 952 (Anderson) Pharmacy Technicians: Licensure Requirements
Version: As Introduced February 4, 2016
Location: Consent Calendar, Assembly Appropriation
Position: Support

Chairperson Lippe said SB 952 would modify the pharmacy technician licensure requirement to replace the current certification by the Pharmacy Technician Certification Board (PTCB) pathway with a pharmacy technician certification program that is accredited by the National Commission for Certifying Agencies that is approved by the board.

Chairperson Lippe explained that as indicated in the bill analysis provided as an attachment, the fiscal estimate previously provided to the board has doubled based on information received from the department's Office of Professional Examination Services. Further, staff notes that the board will need to develop a regulation to identify which certification programs it wishes to approve.

Mr. Lippe noted that the fiscal estimate was only $75,000 at the time that the board voted to support the bill, and that it has since increased to $150,000. Ms. Sodergren said that staff has notified DCA and does not believe the increased amount can be absorbed in the board's current budget – so staff will pursue a budget change proposal if the legislation passes.

Ms. Herold acknowledged that the fiscal is high and the funding cannot be redirected, so staff will have to secure a budget change proposal. She added that staff would push back on the amount.

There was no public comment.

Mr. Sanchez returned to the meeting at 2:00 p.m.

3. SB 1155 (Morrell) Professions and Vocations: Licenses: Military Service
Version: June 23, 2016 - Amended
Location: Assembly Appropriations
Position: None

Chairperson Lippe said this measure would allow a veteran who is honorably discharged who served as an active duty member of the California National Guard or the United States Armed

Forces to have one fee waiver for the application for an issuance of one license by one of the boards within the Department of Consumer Affairs. The provisions would go into effect on January 1, 2018. The most recent amendment specifies information that would constitute "satisfactory evidence" of being honorably discharged.

Committee Recommendation: Support this SB 1155.

Support: 8 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			

d. Legislative Items for Future Meeting

Note: The board may discuss other items of legislation in sufficient detail to determine whether such items should be on a future board meeting agenda and/or whether to hold a special meeting of the board to discuss such items pursuant to Government Code section 11125.4.

Steve Gray of Kaiser Permanente advised the board that the Legislature is considering a bill, AB 1306, supported by certified nurse midwives to be independent of physician supervision. He noted he was not speaking for or against it. He said that the bill would allow certified nurse midwives – who currently can furnish prescription drugs but cannot buy their own supply of prescription drugs – to buy, hold and store their own supply of prescription drugs. He stated that certified nurse midwives are not included in sections in the Business and Professions Code and the Health and Safety Code that list to whom prescription drugs can be sold to or ordered by.

Board members said that a discussion of the bill could be added to any upcoming emergency board meetings that might happen. There was no public comment.

Part 2: Regulations for Discussion and Consideration

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

1. <u>Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists</u>

Chairperson Lippe reported that in July 2015, staff initiated a formal rulemaking to add Title 16

CCR sections 1730, 1730.1, and amend section 1749 related to the licensing requirements for advanced practice pharmacist. At the February 2016 board meeting, the board adopted the final regulation text. He noted that the final rulemaking file was submitted to the Office of Administrative Law for final review on June 3, 2016.

Laura Freedman, DCA Staff Counsel, explained that when OAL reviewed the regulation package they found problems and disapproved the regulation due to a lack of clarity and ambiguity in the language as well as a lack of explanation of necessity in the file itself.

Ms. Freedman stated that OAL's clarity issue was with the language that prohibits experiential hours earned under a collaborative practice agreement from also being used to fulfill the criteria for the residency program. She explained that OAL found the language in this section to be ambiguous. Ms. Freedman reported that she drafted modified language to address the clarity issue raised by OAL.

Note: The revised language was provided to the board and the public at the meeting and has been provided immediately following these minutes. The language is titled "Draft Third Modified Text."

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210, subdivision (a)(2)(A).

Note: Authority cited: Sections 4005 and, 4210 ~~and 4400~~, Business and Professions Code. Reference: Sections ~~4052.6,~~ 4210 ~~and 4400~~, Business and Professions Code.

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of Business and Professions Code section 4210, an applicant for advanced practice pharmacist licensure must satisfy two of the following subsectionsdivisions.

> ~~(a)~~ (1) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, subdivision (a)(2)(A), ~~an applicant shall~~ by providinge either:

~~(1)~~ (A) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

~~(2)~~ (B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

~~(b)~~ (2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, subdivision (a)(2)(B)~~, an applicant shall by~~ providinge either:

~~(1)~~ (A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

~~(2)~~ (B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, the area of specialty, and the dates of participation and completion~~, and area(s) of specialty~~. For an applicant whothat cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection ~~(2)~~.

~~(c)~~ (3) Demonstrate that experience earned under a collaborative practice agreement or protocol, as required by Business and Professions Code section 4210, subdivision (a)(2)(C), has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must ~~be composed of~~ include no fewer than 1,500 hours of experience providing clinical services to patients~~, and must be earned within four consecutive years~~. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or ~~and~~ discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

~~(1)~~ (A) A written statement from the applicant attesting under penalty of perjury that he or she has:

~~(A)~~ (i) Earned the clinical experience within the required time frame; and

~~(B)~~ (ii) Completed the required number of hours of experience providing clinical services to patients, as specified in ~~this subdivision~~ subsection (a)(3), ~~and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, modifying or and discontinuing drug therapy of patients; and~~

~~(i)~~ (I)The applicant shall provide a copy of the collaborative practice agreement or protocol.

~~(ii)~~(II)If a copy of the collaborative practice agreement or

protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

~~(2)~~ (B) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least ~~one year~~ 1,500 hours of experience providing clinical services to patients. For an applicant who~~that~~ cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection~~(2)~~.

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.

Note: Authority cited: Sections 4005~~,~~ and 4210 ~~and 4400~~, Business and Professions Code. Reference: Sections 4052.1, 4052.2~~,~~ and ~~4052.6,~~ 4210 ~~and 4400~~, Business and Professions Code.

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4210, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars ($520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars ($325). The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars ($325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260).

(e) The fee for regrading an examination is one hundred fifteen dollars ($115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300*). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.*

(g)(1) The fee for the biennial renewal of a pharmacist's license is **one hundred ninety-five dollars ($195)** ~~two hundred seven dollars ($207)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents ($97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars

($150). *The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.*

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars ($165). The penalty for failure to renew is eighty two dollars fifty cents ($82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars ($195). The penalty for failure to renew is ninety seven dollars and fifty cents ($97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).

(*l*) The fee for an intern pharmacist license is one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars ($520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325) . The penalty for failure to renew is one hundred fifty dollars ($150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars ($195). The penalty for failure to renew is ninety-seven dollars and fifty cents ($97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars ($325). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred twenty-five dollars ($125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be $800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be $800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

Ms. Freedman reviewed the changes in the draft modified text. She explained

that the following text was added specifically to address OAL's concerns.

> **(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subdivision (a) above may not also be used to satisfy another of the criteria.**

Ms. Freedman stated that the attorney at OAL reviewing the regulation package indicated that the newly modified text addressed their concerns and would likely be approved by OAL or resubmitted.

Ms. Freedman noted that there were two other issues raised by OAL. The first issue was the board's requirement that the application be submitted under penalty of perjury. The second issue OAL raised was the board defining one-year as 1,500 hours. Ms. Freedman explained that each of the requirements were easily explained to OAL, but needed to be remedied by modifying the Initial Statement of Reasons (ISR) to explain the board's rationale behind each of the two requirements. She noted that the board did not need to take action in order for staff to update the ISR.

Ms. Freedman recommended that the board approve the "Draft Third Modified Text" (as provided at the meeting and following these minutes) and initiate a 15-day comment period.

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

Motion: Approve the modified language as provided at the July 27-28 meeting titled "Draft Third Modified Text." Assuming no negative comments are received during the 15-day comment period, adopt the regulation. Delegate the authority to the executive officer to make any non-substantive or technical changes as may be required to complete the rulemaking file.

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210**, subdivision** (a)(2)(A).

Note: Authority cited: Section**s** 4005 **and**~~**,**~~ 4210 ~~**and 4400**~~, Business and Professions Code. Reference: Section~~**s 4052.6,**~~ 4210~~**and 4400**~~, Business and Professions Code.

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of Business and Professions Code section 4210, an applicant for advanced practice pharmacist licensure must satisfy two of the following subsectiondivisions.

(a) (1) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, subdivision (a)(2)(A), ~~an applicant shall~~ by providinge either:

(1) (A) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) (B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) (2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, subdivision (a)(2)(B), ~~an applicant shall~~ by providinge either:

(1) (A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) (B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, the area of specialty, and the dates of participation and completion, ~~and area(s) of specialty~~. For an applicant whothat cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection (2).

(c) (3) Demonstrate that experience earned under a collaborative practice agreement or protocol, as required by Business and Professions Code section 4210, subdivision (a)(2)(C), has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must ~~be composed of~~ include no fewer than 1,500 hours of experience providing clinical services to patients, ~~and must be earned within four consecutive years~~. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or ~~and~~ discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(1) (A) A written statement from the applicant attesting under penalty of perjury that he or she has:

~~(A)~~ (i) Earned the clinical experience within the required time frame; and

~~(B)~~ (ii) Completed the required number of hours of experience providing clinical services to patients, as specified in ~~this subdivision~~ subsection (a)(3). ~~and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, modifying or and discontinuing drug therapy of patients; and~~

~~(i)~~ (I)The applicant shall provide a copy of the collaborative practice agreement or protocol.

~~(ii)~~(II)If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

~~(2)~~ (B) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least ~~one year~~ 1,500 hours of experience providing clinical services to patients. For an applicant who~~that~~ cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection~~(2)~~.

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.

Note: Authority cited: Sections 4005~~,~~ and 4210 ~~and 4400~~, Business and Professions Code. Reference: Sections 4052.1, 4052.2~~,~~ and ~~4052.6,~~ 4210 ~~and 4400~~, Business and Professions Code.

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4210, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars ($520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars ($325). The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars ($325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260).

(e) The fee for regrading an examination is one hundred fifteen dollars ($115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195).
(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300*). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.*
(g)(1) The fee for the biennial renewal of a pharmacist's license is **one hundred ninety-five dollars ($195)** ~~two hundred seven dollars ($207)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents ($97.50).
(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). *The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.*
(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars ($165). The penalty for failure to renew is eighty two dollars fifty cents ($82.50).
(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars ($195). The penalty for failure to renew is ninety seven dollars and fifty cents ($97.50).
(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(*l*) The fee for an intern pharmacist license is one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).
(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).
(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
(o) The fee for the issuance of a clinic license is five hundred twenty dollars ($520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325) . The penalty for failure to renew is one hundred fifty dollars ($150).
(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars ($195). The penalty for failure to renew is ninety-seven dollars and fifty cents ($97.50).
(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars ($325). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred twenty-five dollars ($125).
(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be $800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be $800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

M/S: Lippe/Gutierrez

Support: 8 Oppose: 0 Abstain: 0

Board Member	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 section 1730.2 related to Advanced Practice Pharmacists – Certification Programs

Chairperson Lippe said that at the November 2015 Board Meeting, the board approved proposed text to add Title 16 CCR section 1730.2, establishing the certification program criteria for advanced practice pharmacist. At the February 2016 Board Meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law for final review on June 29, 2016.

The board was advised that OAL has until August 11, 2016 to complete its review of this rulemaking file.

There were no comments from the board or the public.

3. Proposed Regulations to Add Title 16 CCR section 1746.4 related to Immunization (Vaccinations)

Chairperson Lippe said that in July 2015, the board initiated a formal rulemaking to add Title 16 CCR section 1746.4 to specify the requirements for a pharmacist to administer vaccinations. On January 19, 2016, following the completion of a 45-day comment period and two 15-day comment periods, the board adopted the final regulation text. In June 2016, the board clarified that the protocol should apply to all pharmacist-provided immunizations. The board voted to amend the protocol language for clarity and released the amended text for a

15-day comment period. The 15-day comment period ended on June 25, 2016 and the board adopted the final regulation text at the July 1, 2016 Board Meeting.

Ms. Martinez informed the board that the rulemaking was provided to OAL on July 14, and OAL has until Aug. 25 to complete its review. There were no comments from the board or the public.

4. Proposed Regulations to Amend Title 16 CCR section 1735 and 1751 et seq. related to Compounding

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

The committee was advised that the rulemaking was referred to Agency for review and that the review by Agency must be completed and forwarded to OAL by August 3, 2016.

Ms. Martinez informed the board the rulemaking was still being reviewed by Agency. There were no comments from the board or the public.

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

Chairperson Lippe said that at the June 2015 Board Meeting, the board approved proposed text to add Title 16 CCR section 1746.5, related to the furnishing of travel medications. At the April 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the Department of Consumer Affairs for final review on May 9, 2016.

The board asked if there was anything holding up this regulation. Ms. Freedman said she had the file under review. Ms. Martinez said the file has to be at OAL by September 24.

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

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

Chairperson Lippe said that in September 2015, the board initiated a formal rulemaking to amend Title 16 CCR section 1760 related to the board's disciplinary guidelines. Following the initial comment periods, the board, at the April 2016 board meeting, adopted the final regulation text.

Ms. Sodergren explained that staff discovered an error regarding the cross-referenced sections in the regulation. She added that, although staff believed that this was a non-substantive change that the board's executive officer could handle, staff decided out of caution to bring the measure back to the board for approval.

Note: Copies of the language showing changes made to the reference language were provided to the board and the public.

Motion: In the event OAL determines that the deletion of the cross-references to the specific uniform standard is a substantive change, the board adopts such change and, assuming no negative comments are received, authorizes the executive officer to make any non-substantive changes as may be required to complete the rulemaking file.

There was no public comment.

M/S: Lippe/Gutierrez

Support: 8 Oppose: 0 Abstain: 0

Board Member	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			

c. Board Action to Initiate Rulemaking – Awaiting Notice

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

   Chairperson Lippe said that at the July 2013 Board Meeting, the board approved proposed text to amend and/or add Title 16 CCR sections 1702, 1702.1, 1702.2, and 1702.5 related to standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as require nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal.

   Ms. Martinez informed the board that the rulemaking file was expected to be filed by the week after the board meeting. There were no comments from the board or the public.

2. Proposed Regulations to Amend Title 16 CCR sections 1780 – 1785, et seq., related to Third Party Logistics Providers

Chairperson Lippe said that at the July 2015 Board Meeting, the board approved proposed text to amend Title 16 CCR sections 1780 et seq. to establish regulatory requirements for third-party logistics providers. During the preparation of the required notice documents, board staff determined that additional modifications to the proposed text may be necessary.

Chairperson Lippe reported that the Legislation and Regulation Committee recommended returning this proposal to the Licensing Committee for review and to identify a solution to update the reference to a prior version of USP 797 that is contained in Section 1780 of the proposal.

Committee recommendation: Return this proposal to the Licensing Committee for review and to identify a solution to update the reference to a prior version of USP 797 that is contained in Section 1780 of the proposal.

Support: 8 Oppose: 0 Abstain: 0

Board Member	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			

d. Board Action to Initiate Rulemaking – Comment Period Closed; Awaiting Further Action by Board/Licensing Committee

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

Chairperson Lippe stated that the board had already taken action on this item during the Licensing Committee report.

IX. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR section 1703 related to Delegation of Certain Functions

President Gutierrez reported that at the October 2013 Board Meeting, the board approved proposed text delegate to the executive officer the authority to adopt regulation changes that are deemed to be “without regulatory effect” in accordance with Title 1 CCR Section 100.

President Gutierrez stated that at the February 2016 Board Meeting, the board approved proposed text to delegate to the executive officer the authority to approve prescription label waivers in accordance with Business and Professions Code section 4076.5(d).

President Gutierrez explained that the 45-day comment period began on April 22, 2016 and ended June 6, 2016. She noted that the Board received one comment during the 45-day comment period.

The board reviewed the comment submitted by Dr. Abrams which pointed out grammatical changes needed in the language. Ms. Freedman explained that the grammatical changes provided by the commenter were actually suggestions to change the language the Initial Statement of Reasons; therefore the board did not need to take action to address the comments.

There were no comments from the public.

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

M/S: Veale/Butler

Support: 8 Oppose: 0 Abstain: 0

Board Member	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			

X. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR section 1744 related to Drug Warnings

President Gutierrez reported that at the April 2015 Board Meeting, the board approved proposed text to amend Section 1744 of Title 16 CCR, related to Drug Warnings. The 45 day comment period began on September 25, 2015 and ended November 9, 2015.

President Gutierrez explained that at the April 2016 Board Meeting, the board approved a modified text to address concerns expressed during the 45-day comment period and initiated a 15-day comment period. She noted that the 15-day comment period began on May 11, 2016 and ended on May 26, 2016.

President Gutierrez reported that the Board received one comment during the 15-day comment period from Rayburn Vrabel.

Note: The comment was provided in the board meeting materials.

The board reviewed the comment submitted by Mr. Vrabel which asked the board to further define the term "to inform." The board did not change the language to specify how a pharmacist must inform the patient, because they wanted to allow the pharmacist to use his or her professional judgment to determine the best way to communicate with the patient.

The board noted that Mr. Vrabel's second comment which pointed out a discrepancy in the wording in various sections of the language was moot, as the language had already been corrected during a prior comment period.

After reviewing Mr. Vrabel's comments the board elected not to amend the language and to adopt the text.

Ms. Freedman clarified that the language the board would be adopting was provided in the meeting materials and was titled "Title 16. Board of Pharmacy, Modified Language" and had a modification date of May 9, 2016, at the bottom of the document.

Motion: Adopt the regulation as approved at the April 2016 Board Meeting and noticed for 15-day comment period on May 11, 2016. Delegate the authority to the Executive Officer to make any non-substantive or technical changes as may be required to complete the rulemaking file.

M/S: Law/Veale

Support: 8 Oppose: 0 Abstain: 0

Board Member	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			

XI. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR section 1707.5 related to Patient Centered Labels

President Gutierrez reported that at the January 2015 Board Meeting, the board approved proposed text to amend Section 1707.5 of Title 16 CCR, related to patient-centered labels. The 45-day comment period began on October 23, 2015 and ended December 7, 2015.

President Gutierrez explained that at the April 2016 Board Meeting, the board approved modified text to address concerns expressed during the 45-day comment period and initiated a 15-day comment period. She noted that the 15-day comment period began on May 11, 2016 and ended on May 26, 2016.

President Gutierrez reported that the board received several comments during the 15-day comment period which were provided in the board meeting materials for review by the board and the public.

Ms. Herold stated that she believed that board's intent was to put the manufacturer name outside of the patient centered portion of the label and suggested changing 1707.5 (a)(1)(B) to reflect this.

The board discussed if the manufacturer's name should be provided in the patient-centered section of the label if the brand name is no longer widely used.

Mr. Law and Ms. Veale suggested allowing the pharmacist to use his or her professional judgment to determine if the manufacturer's name should be provided in the patient-centered portion of the label. The board agreed and modified the language as provided below.

> (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted ~~into the parentheses~~. If~~, it has been at least five years since the expiration of the brand name's patent or, if~~ in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, **may list** the name of the manufacturer.

Ms. Freedman noted that this change may be considered non-substantive by the Office of Administrative Law (OAL) and recommended that the board ask OAL if an additional 15-day comment period would be required.

The board discussed the comments received regarding the requirement to list "generic for" in addition to the brand name of the drug whether or not the prescriber prescribed a brand name or a generic. The board elected not to change the language as the pharmacist can use their professional judgment to determine if listing both the generic and brand name will help the patient avoid medication errors.

There were not comments from the public.

Motion: Adopt the regulatory language as noticed on May 11, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of

Administrative Law or the Department of Consumer Affairs to complete the rulemaking file. However, if the Office of Administrative Law deems the proposed change to the language to be substantive, notice the text for 15-day comment period.

M/S: Veale/Gutierrez

Support: 8 Oppose: 0 Abstain: 0

Board Member	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			

XII. Discussion and Consideration of Proposed Regulations to Add Title 16 California Code of Regulations (CCR) sections 1776 et seq., Related to Prescription Drug Take-Back

President Gutierrez reported that at the January 2016 Board Meeting, the board approved proposed text to add Sections 1776 et seq of Title 16 CCR, related to prescription drug take-back programs. The 45-day comment period began on February 12, 2016 and ended March 28, 2016. Two regulation hearings were held on April 13, 2016 (one in Northern California and one in Southern California).

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

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

President Gutierrez reported that the meeting materials contained:

1. The modified text with the changes approved at the June 2016 Board Meeting, dated June 8, 2016.
2. Staff-recommended modified text, dated July 1, 2016.
3. Clean version of the staff recommended modified text (this is provided for clarity).

President Gutierrez explained that the recommendation from staff was to adopt the staff recommended version, dated July 1, 2016, of the regulatory language and notice the language for a 15-day comment period.

The board reviewed the language dated July 1, 2016.

During the discussion, board members changed wording in sections 1776.1(e)(3) and 1774.4(i)(3) from “Schedule II-IV” to “Schedule II-V.” Ms. Veale said that she, President Gutierrez and board staff worked to make language consistent throughout the regulations.

President Gutierrez recommended changing wording in section 1776 from “collection receptacles and mail envelopes back packages” to “collection receptacles and/or mail back envelopes packages” to indicate that licensees are not required to provide both options.

President Gutierrez noted that wording in section 1776.3(c) requires monitoring by a “pharmacy” employee. She asked if the employee had to be an employee of the pharmacy, since the take-back bin likely would not be located near the pharmacy, or whether a registrant employee could be allowed to monitor the bin and report any problems to the pharmacy.

Ms. Freedman said that if the employee has a reporting relationship to the pharmacy staff – even if that person worked mostly for another hospital department – then that employee could be considered a pharmacy employee. In addition, she said the pharmacy is responsible for closing a bin when the pharmacy is closed as required by section 1776.3(d) – even if the bin is located four floors away from the pharmacy, and the hospital itself never closes – because it is the presence of the pharmacy on site that allows the hospital to have a take-back bin in the first place.

Note: Mr. Sanchez stepped out of the meeting at 3:19 p.m.

Jim Walsh, a board member of CSHP and pharmacy director of San Juan Medical Center, noted that section 1776.3(b) requires that a receptacle be located where it is “visible to pharmacy employees.” He said that would require that the bin be placed in the pharmacy pick-up room at Mercy San Juan, which is a small area the size of a table. He stated that this requirement would deter many hospitals from participating.

At Ms. Freedman’s suggestion, the board agreed to strike “where the receptacle is visible to pharmacy employees” and to add a separate sentence saying, “Except as where provided by (c), the receptacle must be visible to pharmacy employees.” Board members also agreed that providing security cameras could satisfy the requirement in 1776.3(c) that the receptacle be “regularly monitored.”

Thomas Hare, representing the City of Santa Rosa, stated that it is overly restrictive to require that a pharmacy employee monitor the bin when the DEA only requires that the bin be monitored by a hospital employee. Ms. Freedman said that DEA regulations say that a DEA registrant is responsible for installing, managing and operating a take-back receptacle – but as a practical matter, the pharmacy will be involved. She added that the board cannot regulate the pharmacy unless the employee has some reporting relationship with the pharmacy. She said that the pharmacy is the body that is responsible for making sure that the DEA regulations are met.

Note: Mr. Sanchez returned to the meeting at 3:35 p.m.

A speaker from Alameda County told the board that the DEA understands that in a hospital with an on-site, inpatient pharmacy the receptacle could be located outside the pharmacy depending on security, convenience and accessibility.

President Gutierrez called for a break to allow counsel to review the DEA rules. The board recessed for a break at 3:37 p.m.

The meeting resumed at 4:03 p.m.

Ms. Freedman reported that DEA regulations requires that the receptacle be closed when an employee is not present – such as when the pharmacy is closed – or the receptacle is not being regularly monitored by long-term care employees. So it leaves open whether, when the pharmacy is closed, the receptacle also must be locked. She added that the monitoring employee must be an employee of the hospital and the pharmacy.

Board members expressed concern that if the restrictions on hospitals are too strict, hospitals won't offer the take-back programs. The board agreed to a recommendation by Ms. Freedman to change the wording in section 1776.3(c) from "pharmacy employees" to "registrant employees."

Megan Harwood of the Orange County Prescription Abuse Prevention Coalition urged the board to encourage pharmacists to educate parents on how to safely destroy prescription drugs at home.

Mary Staples of the National Association of Chain Drug Stores appeared with Angie Manetti of the California Retailers Association. Ms. Manetti expressed concern about the requirement for signage on the bins containing contact information for responsible pharmacies and information about sharps and needles as it could make it difficult for chains to use mass-produced universal signage. She also asked that the board drop the word "moved" from section 1776.3(b) so that it would be clear that pharmacies could move a receptacle and re-bolt it to the floor. She also noted that the DEA does not require any record keeping in their regulation. Ms. Herold explained that three years is the board's typical requirement for keeping records regarding acquisition or disposition.

Bill Worrel of the San Luis Obispo County Integrated Waste Management Authority thanked the board for changes made to the proposed regulations since January. He urged the board to clarify in section 1776.1(k) that pharmacies still may provide mail-back envelopes even if they do not provide a take-back receptacle. He also expressed concern that the regulations would drive kiosks to close because they do not accept controlled substances and are not registered with the DEA. He said that pharmacists in San Luis Obispo County with take-back receptacles that do not accept controlled substances provide the option of mail-back envelopes for customers.

Some board members said that, in the interest of public safety, a pharmacist-in-charge should be allowed to decide whether to have a take-back bin but should not be allowed to decide about providing mail-back envelopes. Other board members said that providing mail-back envelopes is a business issue for pharmacies and they should be allowed to use their professional judgment about providing both types of take-back options.

Brian Warren of the California Pharmacists Association told the board that secure envelopes to mail back controlled substances cost $5 each. Meanwhile, he said, the retail cost and the profit that

pharmacies make off drugs is often less than $5. Angie Manetti of the California Retailers Association said retailers do not know how often they will have to provide envelopes, so they would prefer that pharmacists have discretion in deciding whether to have an envelope program.

Steve Gray of Kaiser Permanente said a pharmacy should be able decide that it wants to participate in an envelope program, regardless of what a pharmacist-in-charge thinks. He said Kaiser would object to any regulation that allows a pharmacist-in-charge to decide the matter.

Board members reviewed the following proposed changes:

- change "and mail back envelopes" to "and/or mail back envelopes" in section 1776
- replace "Schedule II-IV" to "Schedule II-V'' in section 1776.1 on page 2 and 9
- add "pharmacy or registrant" on page 5
- remove "moved" in all places that say "move or removed"
- change "collector pharmacy" to "responsible pharmacy" in section 1776.1(e)(1)
- change "No medical sharps and needles" to "Medical sharps and needles shall not be deposited" in section 1776.1(e)(2)
- strike "where the receptacle is visible to pharmacy employees" and add a separate sentence saying, "Except as where provided by (c), the receptacle must be visible to pharmacy employees" in section 1776.3(b)

Motion: Adopt the staff recommended changes, edit in changes discussed by the board and notice the modified language for a 15-day comment period.

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

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

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

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

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

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

~~inhalers).~~

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

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

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

Section 1776.1 Pharmacies

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

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

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

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

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

(e) ~~(d) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's prescription drug take-back collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage informing the public that medical sharps and needles (e.g., insulin syringes) are of the items prohibited from being deposited shall be placed posted on collection receptacles as referenced in section 1776.3.~~
The collection receptacle shall contain signage that includes:
(1) The name and phone number of the responsible pharmacy;
(2) Medical sharps and needles (e.g., insulin syringes) shall not be deposited; and
(3) Consumers may deposit prescription drugs including Schedule II-V controlled substances.

(f) ~~(e)~~ Prescription drugs that are eligible for collection ~~in~~ as part of drug take-back ~~programs operated~~ services maintained by pharmacies are only those prescription drugs that have been dispensed by any pharmacy or practitioner to a ~~patient or patient's agent~~ consumer. Dangerous drugs that have

not been dispensed to ~~patients~~ consumers for use (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected ~~in~~ as part of a pharmacy's drug take-back service ~~programs~~.

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

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

(2) ~~A pharmacy shall not a~~ Accept or possess prescription drugs returned to the pharmacy ~~by~~ from skilled nursing ~~homes~~ facilities, residential care homes, ~~other facilities,~~ health care practitioners or any other entity ~~entities in a collection receptacle~~.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1776.3 Collection Receptacles in Pharmacies

(a) A pharmacy ~~Pharmacies~~ may ~~that provide prescription drug take-back services to the public may do so by establish~~ing maintain a collection receptacle ~~in the pharmacy~~ whereby for the public to ~~may~~ deposit their unwanted prescription drugs for destruction. The pharmacy is responsible for the management and maintenance of the receptacle. The receptacle shall be ~~securely locked and~~ substantially constructed, with a permanent outer container and a removable inner liner. The collection receptacle shall be locked at all times to prevent access to the inner liner. ~~In During~~

~~hours when the pharmacy is closed, the collection receptacle shall not be accessible to the public for deposit of drugs. The pharmacy shall lock the deposit slot on the collection receptacle and physically block the public patients from access to the collection receptacle by some means.~~

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

(c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When the ~~supervising~~ responsible pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. ~~When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from public patient access by some means.~~

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

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

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

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

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

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

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

shall be capable of being sealed and be kept clean and in good repair.

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

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

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

~~(1) The unique identification numbers of all unused liners in possession of the pharmacy,~~

~~(2) The unique identification number and dates a liner is placed in the collection receptacle,~~

~~(3) The date the liner is removed from the collection receptacle,~~

~~(4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and~~

~~(5) The date the liner was provided to a licensed DEA registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.~~

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

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

The collection receptacle shall contain signage that includes:

(1) The name and phone number of the responsible pharmacy;

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

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

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

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

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

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

as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(g)~~ (f) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be ~~moved or~~ removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents.

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

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

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

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

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

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

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

(1) The name and phone number of the responsible pharmacy;

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

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

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

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

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

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

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

~~(n)~~ (m) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction

by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

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

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

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

1776.5 Reverse Distributors

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

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

(c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.

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

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

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

(1) Date of acquisition;
(2) Number and the size (e.g., five 10-gallon liners, etc.);
(3) Inventory Unique Identification number of each liner or envelope/package;
(4) The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the

sealed liner;
(5) The date, place and method of destruction;
(6) Number of packages and inner liners received;
(7) Number of packages and inner liners destroyed;
(8) The ~~number~~ name and signature of the two employees of the registrant that witnessed the destruction.

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

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

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

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

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

~~(a) When obtaining unused mail-back packages and envelopes for future distribution:~~
~~(1) The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.~~
~~(2) For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.~~
~~(b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.~~
~~(c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,~~
~~(d) For sealed mail back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.~~

~~(e)~~ (a) For pharmacies ~~using~~ maintaining collection receptacles, the pharmacy shall ~~maintain~~ make and keep the following records for each liner:
(1) Date each unused liner is acquired, its unique identification number and size (e.g., ~~five~~ 5 gallon, 10~~-~~ gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
(2) Date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., ~~five-~~5 gallon, 10~~-~~ gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.

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

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

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

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

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

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

~~(1) The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier or pick-up by reverse distributor).~~

~~(2) For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.~~

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

M/S: Law/Butler

Support: 8 Oppose: 0 Abstain: 0

Board Member	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			

XIII. Consideration of Ownership Structures for Pharmacies, Including a Summary of a Presentation by the Office of the Attorney General Regarding Trusts and Possible Next Steps (Continued)

After researching the relevant statutes, Ms. Freedman informed the board that several statutory code sections had been identified that would have to be amended to allow trusts to be legally licensed by the board.

Note: Dr. Castellblanch and Mr. Sanchez stepped out at 5:30 p.m., depriving the board of a quorum. President Gutierrez called for a break.

The board recessed for a break at 5:32 p.m. and reconvened at 5:40 p.m. with Dr. Castellblanch and Mr. Sanchez in attendance.

Ms. Freedman discussed specific changes that would be needed in Business and Professions Code sections 4035, 4201, 4302, 4307 and 4308 in order to allow trusts to be licensed legally.

Mr. Warren of the California Pharmacists Association expressed support for the motion.

Motion: Seek changes to the code sections outlined by counsel in order to allow trusts to be licensed legally by the board.

4035. Person
"Person" includes firm, association, partnership, corporation, limited liability company, state governmental agency, trust, or political subdivision.

4201. Application Form: Required Information; Authority Granted by License; Reporting Changes in Beneficial Ownership
(a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be made on a form furnished by the board and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein or any person with management or control over the license.
(b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:
(1) If the applicant is a partnership or other unincorporated association, each partner or member.
(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation.
(3) If the applicant is a limited liability company, each officer, manager, or member.
(c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the

applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.
(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.
(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer if all of the provisions of this chapter have been complied with.
(f) Notwithstanding any other law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.
(g) Notwithstanding any other law, the wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.
(h) Notwithstanding any other law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.
(i) Notwithstanding any other law, the veterinary food-animal drug retailer license shall authorize the holder to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.
(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

4302. Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder
The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the ownership interest corporate stock of the corporation, or where conditions exist in relation to any officer or director or other person with management or control of the corporation license that would constitute grounds for disciplinary action against a licensee.

4307. Individuals with Denied, Revoked, Suspended, etc. Licenses Prohibited From Pharmacy Ownership or Association with Board Licensed Entities
(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner or in any other position with management or control of a

licensee as follows:
(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
(b) "Manager, administrator, owner, member, officer, director, associate, or partner, or any other person with management or control of a license," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that such capacity in or for a licensee.
(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

4308. Prohibited Association: Notification of Affected Licensees Known to Board
Whenever a person is prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner or in any other position with management or control of a licensee as provided by Section 4307, the board shall, in each case where it has that information, notify in writing each licensee for whom the person is a manager, administrator, owner, member, officer, director, associate, or partner or in any other position with management or control of the prohibition. The board shall send the notification to the licensee's address of record. The licensee shall have 30 days from the date that the notice is sent to remove and replace the prohibited person and, where appropriate, file a change of permit to reflect that change.

M/S: Law/Lippe

Support: 8 Oppose: 0 Abstain: 0

Board Member	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			

XIV. Closed Session

The board recessed into closed session at 5:48 p.m.

XIV. Reconvene Open Session

The board reconvened in open session at 6:12 p.m.

The board recessed for the day at 6:13 p.m.

Thursday, July 28, 2016

XV. Call to Order and Establishment of Quorum 9:11 a.m.

President Gutierrez called the meeting to order at 9:11 a.m. Board members present: Gregory Lippe, Victor Law, Ramon Castellblanch, Lavanza Butler, Deborah Veale, Amy Gutierrez, Ricardo Sanchez and Albert Wong.

XVI. Closed Session

The board went into closed session at 9:12 a.m.

XVII. Reconvene Open Session

The board reconvened to open session at 10:54 a.m.

XVIII. Enforcement Committee

Part 1: Enforcement Matters

a. Discussion and Consideration of the University of California, San Diego's Pilot Program to Permit Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy, Including Requests for Modifications to the Study Parameters

President Gutierrez reported that, at the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the University of California, San Diego (UCSD) School of Pharmacy involving use of an automated storage device for prescription medication from which staff of Sharp Hospital in San Diego and their families, who opted in, could pick up their outpatient medications. Consultation would be provided via telephone before medication could be dispensed to a patient for the initial dose.

President Gutierrez explained that the study was planned to start in June or July 2015; however, at the September 9, 2015 Enforcement Committee meeting, Dr. Jan Hirsch, BS Pharm, PhD, spoke via telephone and anticipated the pilot study would not begin until December.
President Gutierrez reported that at the March 2, 2016 Enforcement Committee meeting, Dr. Hirsch reported that the study had launched on January 20, 2016, and 120 patients had enrolled to use the automated device. The committee recommended that the board ask UCSD for the number of employees and the work hours of those who utilize the device. At the April 28, 2016 board meeting, the board approved the recommendation.

President Gutierrez explained that at the June 1 committee meeting, via telephone, Dr. Hirsch delivered a presentation on the progress of the implementation and reported that the program launched on January 20, 2016. Dr. Hirsh indicated that, because the kiosk was originally located near a fire exit, the location of the kiosk was moved from the employee entrance to an alcove on the first floor lobby on May 28, 2016. The kiosk still has 24-hour video surveillance and on-site monitoring.

President Gutierrez reported that the statistics Dr. Hirsch provided to the committee indicated there had been 534 total pickups at the kiosk, and 334 of those pickups had been during normal business hours. Additionally, 191 were identified as new prescriptions, 99 were refill prescriptions and 234 were for OTC medications.

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

President Gutierrez reported that after a discussion, the committee decided to recommend allowing more time for the collection of data and reporting of the study's findings.

At the board meeting, Dr. Wong questioned the study's usefulness, noting that the actual number of prescription pickups is only about two per day. Dr. Castellblanch noted that the study originally was intended to be for a short period of time but now is expected to be a couple of years. President Gutierrez said the study faced delays that were beyond UCSD's control, so the study did not begin until January 2016. She added that UCSD is using advertising and word of mouth to try to increase participation in the study.

Steve Gray of Kaiser Permanente said that Kaiser supports allowing the pilot program to continue. He said that whatever is learned from the UCSD study would be valuable, even if the lesson is that it wasn't the best way to set up a pilot program. He noted that UCSD and vendors have said that these types of devices already are being used in other states with no problems.

Karen Nishi of Cubex identified herself as a pharmacist with experience with automation. She noted that UCSD has been responsive to the board's requirements regarding the pilot program and she encouraged the board to let the study to continue.

Committee Recommendation:

1) allow UCSD to collect data through the first quarter of 2017;
2) allow UCSD to report the findings of the study at the April/May 2017 board meeting;
3) allow UCSD to continue operating the kiosk until a decision is made at the April/May 2017 board meeting

Support: 8 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			x

b. Discussion and Consideration of the Proposed Regulation Relating to Reconciliation and Inventory Reports of Controlled Substances (Currently, to Add Title 16 California Code of Regulations Section 1715.65)

President Gutierrez reported that at the July 2015 Board Meeting, the board approved initiation of a rulemaking to establish inventory requirements for controlled drugs for pharmacies and clinics. The regulation would require perpetual inventories of all federal Schedule II drugs, with a physical count required to be taken every 90 days. Additionally, the board would establish a list of one or several additional controlled drugs from Schedules III – V that are reported as frequently stolen to the board and/or the Drug Enforcement Agency.

President Gutierrez reported that the regulation was released for the required 45-day public comment period between October 16, 2015, and November 30, 2015. At the February 2016 board meeting, the board referred the regulation back to the Enforcement Committee for review and consideration of the comments submitted.

President Gutierrez and Ms. Herold then reviewed all the public comments and developed a new draft of the regulation. President Gutierrez stated the revised draft would require a quarterly inventory and reconciliation, not just an inventory. Hospitals would be required to complete an inventory and reconciliation every 90 days only for drugs stored in the pharmacy.

President Gutierrez explained that for drugs stored in automated delivery devices, the pharmacist-in-charge would be responsible, in part, for ensuring the drugs are accounted for and the device is secure. She noted that the draft removes any requirement to physically count drugs stored in a device, because the regulation would require an active, on-going reconciliation process.

President Gutierrez reported that the committee saw a seven-minute news report from Colorado regarding hospital drug diversion and losses, and then heard questions and comments from the public.

President Gutierrez read the proposed regulation. She added that requiring an on-going reconciliation would help identify diversions early, before the number of missing drugs mounts into the thousands of pills. She noted that most chain stores were already doing this, at least for Schedule II drugs.

Dr. Castellblanch asked about requiring security camera monitoring. President Gutierrez said that cameras might not be the best solution in every case and that requiring cameras would not be helpful if no one is monitoring them live or watching recorded video.

Ms. Herold said the proposed ordinance would apply to off-site machines, such as dispensers in skilled nursing facilities, which are stocked with drugs owned by the pharmacy. She said a proposed budget change would fund a staff position to track more reports of losses filed by pharmacies because of this proposed regulation.

A pharmacist from an independent, long-term care pharmacy told the board that doing reconciliation every three months would be very labor intensive and would require manually tracking drugs in tackle boxes at skilled nursing facilities. He told the board that he does a daily running inventory on the tackle boxes and does a reconciliation each time drugs are removed from the box. Board members explained that the proposed regulation would require reconciliation only every three months.

Ken Schell, pharmacy director of Sharp Grossmont Hospital in San Diego, spoke in support of the proposed regulation. Janice Dang, supervising inspector, told the board that the Health and Safety Code already requires long-term care facilities to have policies and procedures that address security and accountability for drugs in automated dispensing devices, and that the pharmacist is required to review those procedures monthly.

Committee recommendation: Recommend that the board withdraw the old rulemaking and initiate a new rulemaking using the revised proposed language dated May 25, 2016.

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
c) A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:
    1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
    2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;

3) A comparison of (1) and (2) to determine if there are any variances; and
4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.

d) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration. Likely causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.

e) The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge, and be readily retrievable in the pharmacy or clinic for three years.

f) A new pharmacist-in-charge of a pharmacy shall complete an inventory within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).

g) For inpatient hospital pharmacies, a separate Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:
1) All controlled substances added to an automated drug delivery system are accounted for;
2) Access to automated drug delivery systems is limited to authorized facility personnel;
3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;
4) Confirmed losses of controlled substances are reported to the board; and
5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

Support: 8 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			x

c. Discussion and Consideration of the Department of Consumer Affairs Contract and Audit of the DCA Diversion Program Provided by Maximus Health Services

President Gutierrez reported that the California Business and Professions Code provides that various healthcare licensing boards under the auspices of the Department of Consumer Affairs (DCA) may establish a program to identify and rehabilitate licensees whose competency might be impaired due to substance abuse or mental illness. The board is one of several DCA boards that have implemented such programs; however, the board's program differs from those of other DCA boards in that it does not divert licensees from discipline. It uses the program as a monitoring program for its participants before, during, and after discipline has been secured. A copy of the report was provided in the meeting materials.

President Gutierrez reported that in 2003, DCA began contracting with Maximus Health Services, Inc., to provide what DCA calls "Diversion Program Services." In October 2015, an audit of Maximus was conducted for the contract period January 1, 2010, through December 31, 2014. This report was referenced in the board's 2015 Sunset Report, but never shared with the board specifically.

President Gutierrez said that, at the June 1 committee meeting, Ms. Herold explained the program's importance and process, and Ms. Sodergren provided information about the board's costs to run the program. She stated that the participants pay $100 per month, and the board subsidizes the remaining administrative cost. The board asks the case manager to work with participants to find other sources of funding if private insurance won't cover the cost of the program. The board tries to address the participant's financial concerns to ensure the cost of the program does not prevent anyone from using the program.

Ms. Sodergren stated that the average length of time participants spend in the program is three to five years, depending on the person and the underlying issue. Further, Ms. Sodergren indicated that the board's program is in compliance with the standards set forth in SB 1441, a bill enacted years ago to standardize components for such DCA programs.

There were no board questions or public comment.

d. Discussion and Consideration of the Food and Drug Administration's Required Class-Wide Safety Labeling Changes for Opioid Pain Medications

President Gutierrez reported that on March 22, 2016, the U.S. Food and Drug Administration (FDA) announced required class-wide safety labeling changes for immediate-release opioid pain medications. Among the changes, the FDA is requiring a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The FDA is also now requiring a warning that chronic maternal use of opioids during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which can be life-threatening.

Provided below is a sample of how the new black box warning label might appear:

ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME

Addiction, Abuse, and Misuse
[TRADENAME] exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing [TRADENAME], and monitor all patients regularly for the development of these behaviors or conditions *[see Warnings and Precautions (5.X)]*.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of [TRADENAME]. Monitor for respiratory depression, especially during initiation of [TRADENAME] or following a dose increase *[see Warnings and Precautions (5.X)]*.

Accidental Ingestion
Accidental ingestion of even one dose of [TRADENAME], especially by children, can result in a fatal overdose of [active moiety] *[see Warnings and Precautions (5.X)]*.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of [TRADENAME] during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available *[see Warnings and Precautions (5.X)]*.

She noted that in addition, the FDA is requiring several safety labeling changes across all prescription opioid products to include additional information on the risks of these medications.

Dr. Castellblanch asked about where the warning is located and how it fits into the work flow of a pharmacist. Chairman Gutierrez said the black box warning typically is on the package insert for the prescriber and the dispenser. She explained that black box warnings are common.

Ken Schell of Sharp Grossmont Hospital said his hospital does provide patients with additional literature about their medications, especially the first time a medication is dispensed. He said pharmacists also are required to go over drug information with patients, especially for medications with black box warnings, and patients are asked to sign a document indicating that they received the consultation. In addition, he said, pharmacists go over all medications and warnings with inpatients at the time they are being discharged.

e. Discussion and Consideration of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain

President Gutierrez reported that on March 15, 2016, the Centers for Disease Control and Prevention (CDC) released 12 recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care and end-of-life care. President Gutierrez explained that the recommendations are grouped into three areas:

- Determining when to initiate or continue opioids for chronic pain
- Opioid selection, dosage, duration, follow-up, and discontinuation
- Assessing risk and addressing harms of opioid use

She noted that the categorization of the recommendations was based on the following:

- No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least one year later.
- Extensive evidence shows the possible harm of opioids (including opioid use disorder, overdose, and motor vehicle injury).
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.

President Gutierrez said that this guidance is in addition to guidance provided by other agencies on opioid prescribing. In November 2014, the Medical Board of California produced its *Guidelines for Prescribing Controlled Substances for Pain*. According to the Medical Board's executive director, the Medical Board is in the process of comparing its guidelines with those of the CDC. Board staff will continue to monitor this review and its outcome. The Medical Board's guidelines are available from its website at www.mbc.ca.gov.

Dr. Castellblanch said the CDC's guidelines raise concerns about opioids at lower levels than the Medical Board's guidelines. Dr. Gutierrez asked Ms. Herold to keep the board informed about the Medical Board's efforts to review and match the CDC guidelines.

There were no comments from the public.

f. Discussion and Consideration of a Proposal to Add Statutory Authority Relating to the Registration with the Board of Automated Delivery Systems for Dispensing of Medication

President Gutierrez said that at the February 2016 Board Meeting, the board considered a draft proposal to establish a registration requirement for pharmacies that operate automated delivery systems. During the meeting, the board discussed creating inventory requirements for the devices and the need to clarify some of the terminology used in the draft language. The board also heard public comment in which the board was asked to modify the requirements for hospitals that use the automated delivery systems.

President Gutierrez noted that at the February Board Meeting, the board asked staff to modify the language and bring it to the Enforcement Committee for further discussion.

President Gutierrez reported that the Enforcement Committee made several modifications to the language. She noted that board staff also worked with her and Ms. Veale to make additional modifications.

President Gutierrez reported that the language below was brought to the June 2016 Board Meeting and was approved by the board.

Proposal to Add Section 4105.5

(a) For purposes of this section, an automated drug delivery system includes a device as defined in Health and Safety Code Section 1261.6(a)(1).

(b) Every pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall provide the board in writing with the location of each device within 30 days of installation of such a device, and on an annual basis as part of the license renewal. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) Every pharmacy that uses such a system may only do so if all of the following conditions are satisfied.

1. *Use of the device is consistent with legal requirements.*
2. *Policies and procedures include appropriate security measures and monitoring of the inventory to prevent thefts and diversion.*
3. *Drug losses from the device are reported to the board as required by law.*
4. *The pharmacy license is unexpired and not subject to disciplinary conditions.*

(d) The board may prohibit a pharmacy from using a system if it determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal such a decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) A system operated by a licensed hospital pharmacy as defined in section 4029 for doses administered in a facility operated under a consolidated license under Health and Safety Code section 1250.8 shall be exempt from the registration requirements of subdivision (b).

There were no board questions or public comment.

Note: Dr. Castellblanch stepped out of the meeting at 11:58 a.m.

g. Consideration of a Proposal to Conduct Inspections of All Pharmacies Every Four Years

President Gutierrez reported that the board's charge to regulate the pharmacy profession necessitates routine inspections of licensed facilities to confirm adherence to or identify failures in adherence to the requirements of pharmacy law. Failure to perform such inspections makes the board's enforcement program reactive rather than proactive because inspections are currently done when the board is investigating potential violations of pharmacy law from a complaint or other information that would trigger an investigation.
President Gutierrez explained that for a number of years, the board's policy has sought to inspect all facilities every three or four years. The board has been unable to complete these routine inspections of all facilities with any regularity and in recent years has had to substantially reduce such inspections, because the board's first priority is investigation of complaints and performance of mandated annual sterile compounding inspections. While thousands of inspections are

completed, inspections occur generally as part of the investigative process, prior to issuance or renewal of a sterile compounding license, or as part of probation monitoring.

All Inspections FY11-12 thru FY14-15 by Visit Type

Number of Inspection Type	FY11-				
Routine	1730	1010	287	342	3369
Investigation	743	896	875	926	3440
Probation/PRP	258	228	139	227	852
Sterile Compounding	268	276	996	1067	2607
Other	34	39	32	26	131
Grand Total					**10399**

President Gutierrez stated that mandatory inspections on a routine but random basis would enable the board to perform compliance inspections to educate licensees about pharmacy law as well as identify problems early to prevent more serious consumer issues from developing. Like all inspections, such inspections would be unannounced. She added that compliance inspections provide an opportunity for board staff to answer questions about pharmacy law and complete follow up inspections to confirm compliance of facilities previously issued either citations or letters of admonishment.

President Gutierrez explained that establishing a policy of mandatory inspections of each pharmacy every four years would supplement our current practice of conducting inspections principally to investigate problems (or inspect sterile compounders).

Ms. Herold told the board that staff is in the process of hiring someone to track inspections in a manner that the board is not currently doing. She said that even though sterile compounding pharmacies will be inspected every year, and inspectors will still go into pharmacies to investigate complaints, the goal is to inspect pharmacies even if they do not have any complaints. She said staff would identify pharmacies that had not been inspected in the previous four years and would target them for inspections. She said all inspectors would do some of these inspections, but the focus would be on the compliance team to do the inspections long term.

Ms. Herold indicated the focus of the visits would be aimed at compliance and education and clarified that the board could create a policy and would not need legislation to require inspections every four years.

Ms. Herold indicated the board expects each inspector will have to complete 12 additional inspections per year if current statistics remain constant. The additional inspections would be done without additional funding.

Dr. Wong said he would like to see pharmacists receive more education during inspections. Ms. Butler asked if the board prioritizes cases that are a danger to the public. Ms. Herold said in those cases, staff will go to court to get a pharmacist out of practice.

Paige Talley of the California Council for the Advancement of Pharmacy asked about inspections for out-of-state pharmacies that are licensed for sterile compounding. Ms. Herold said that any pharmacy that has a sterile compounding license, whether in the state or out of state, is subject to annual inspections.

Part 2: Compounding Matters

a. Update on the Status of the Sterile Compounding Regulations, Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.

President Gutierrez reported that on May 8, 2015, the board initiated a formal rulemaking to update California's compounding regulations. She highlighted the he chronological timeline below:

Board approved proposed the text for rulemaking:	April 21, 2015
45-day comment period:	May 8 – June 22, 2015
Regulation Hearing:	June 25, 2015
15-day comment period:	July 31 – August 15, 2015
15-day comment period:	November 20 – December 5, 2015
Board approved the final text:	January 19, 2016
File submitted to DCA for review:	March 10, 2016

President Gutierrez stated that the board set the effective date of the regulation as January 1, 2017. She noted that the file is currently under review by DCA.

Ms. Freedman explained that the DCA review includes an agency review. After that, the file must go to the Office of Administrative Law by August 2, and OAL would have 30 business days to make a decision.

There was no public comment.

b. Summary of the Presentation by the Office of Statewide Health Planning and Development Regarding Its Process for Reviewing Structural Modifications Needed in Healthcare Facilities

President Gutierrez said that at the June 1 committee meeting, Glenn Gall, supervisor in the Facilities Development Division of the Office of Statewide Health Planning and Development (OSHPD), made a presentation on the process for reviewing structural modifications in healthcare facilities.

At the committee meeting Mr. Gall provided an overview of OSHPD's statutory authority, design process and involvement in hospital alteration projects. OSHPD's timeline for plan review tries to focus on one initial review and two subsequent follow ups with the initial review taking place within 60 days and the subsequent checks being completed within 30 days each.

President Gutierrez explained that OSHPD requires hospitals to meet the standards listed in USP 797 but doesn't need to enforce much as the pharmacy designers typically have the expertise to know how to design to meet standards. She stated that at the committee meeting Mr. Gall referred to California Building Code section 1224.19 (title 24, part 2, chapter 12) as being the specific pharmacy requirements. Other relevant codes include the California Electrical Code (Part 3), the California Mechanical Code (part 4), and the California Plumbing Code (part 5).

President Gutierrez reported that Mr. Gall indicated OSHPD would be willing to assist the board. He also stated that it would be a good idea to include the California Hospital Association in the process and solicit their input.

Ms. Herold reported that following the committee meeting, staff met with OSHPD and the California Hospital Association. Dr. Gutierrez said she would like OSHPD to review the waivers prior to the board conducting their review.

There was no public comment.

c. Discussion and Consideration of the Process for Pharmacies Seeking Waivers In Anticipation of the New Requirements in Title 16 California Code of Regulations, Sections 1735 et seq., and 1751 et seq.

President Gutierrez said that the final version of the proposed regulations contains a waiver provision for some of the structural requirements. As proposed in the regulation (as subdivision 1735.6(f) and in 1751.4(l)), the waiver request shall:

1) be made in writing;
2) identify the provision(s) requiring physical construction, alteration, or improvement; and
3) contain a timeline for any such change.

President Gutierrez reported that at the June 1 committee meetings, staff developed a proposed process for pharmacies to request waivers. The committee reviewed a proposed waiver application form and discussed the proposed process.

President Gutierrez explained that based on previous testimony from Mr. Gall from OSHPD, the committee decided to not discuss the waiver process at the meeting. President Gutierrez believed it would be good to develop a subcommittee to review waiver requests with technical assistance from OSHPD.

There was no board or public comment.

d. Discussion and Consideration of The Pew Charitable Trust Reports: "Best Practices For State Oversight of Drug Compounding" and "National Assessment of State Oversight of Sterile Drug Compounding"

President Gutierrez reported that the Pew Charitable Trust recently published reports on the best practices for drug compounding. The goal of these reports is to establish a baseline describing

state policies today and promote best practices in order to ensure that patients are safeguarded regardless of the state in which they receive treatment.

President Gutierrez explained that Ms. Herold served on this task force representing this board and California.

President Gutierrez said that at the June 1 committee meeting, Ms. Herold stated the process for the reports began in 2014 before there was much direction on outsourcing.

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

e. Discussion and Consideration of the Food and Drug Administration's Guidance Documents on Standards for Compounding Drugs Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

President Gutierrez reported that in April 2016, the FDA released three draft guidance documents for public comment involving compounding or outsourcing of human drugs. She noted that each of the documents listed below was discussed at the committee meeting.

President Gutierrez explained that the board may choose to submit comments, which would be due by mid-July, on some or all of these guidance documents as the FDA develops policy for compounding and outsourcing facilities in the USA.

1) Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

President Gutierrez explained that according to this guidance document, the guidance in this document addresses:

- Compounding AFTER the receipt of a prescription for an identified, individual patient,
- Compounding BEFORE the receipt of a prescription for an identified individual patient (anticipatory compounding), and
- Compounding for office use.

President Gutierrez reported that this guidance document states the value of compounding for individual patients by pharmacies, outsourcing facilities and physician offices when clinically necessary for a patient. Ms. Herold told the board that the FDA will allow 503As (pharmacies) to conduct limited compounding for future use, but wants 503Bs (outsourcing facilities) to be responsible for non-patient specific compounding. Dr. Gutierrez added that 503As are regulated by the states, while 503Bs are governed by the FDA.

President Gutierrez explained that the FDA states that when a product is compounded by a pharmacy or physician for an individual patient, the compounding entity is usually not registered with the FDA, and that the FDA is not usually aware of problems with compounded drug products unless it receives a report of a serious adverse event or visible contamination.

President Gutierrez explained that the guidance draws a distinction in the activities performed by an outsourcer versus a pharmacy in that because the outsourcer is held to a higher standard of facility requirements and reporting obligations for adverse events and other factors, "outsourcing facilities can compound and distribute sterile and non-sterile non-patient-specific drug products to hospitals, clinics, and health care practitioners for office use."

President Gutierrez noted that at the June 1 committee meeting, it was observed that the FDA guidance looked similar to the board's office compounding guidelines. Ms. Herold commented that the 30-day limit is more restrictive than California's which is more open-ended. She stressed that the guidance leans towards not dispensing without a prescription in hand for 503As.

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

2) Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act

President Gutierrez explained that this guidance document was developed for entities registered or considering registering as outsourcing facilities, and whether the "at one address means" whether multiple suites used for compounding constitute separate locations.

President Gutierrez reported that according to the guidance, outsourcing facilities may or may not receive a prescription for a compounded drug product, and are not subject to interstate distribution restrictions as are 503A facilities, but are required to compound all products under Current Good Manufacturing Practices (CGMPs), label all products as compounded, and be subject to adverse event reporting.

President Gutierrez explained that if implemented, this policy would require California licensed sterile compounding pharmacies that produce large quantities of non-patient specific compounded product to be generally regulated as outsourcers, not as pharmacies. As such, the guidance supports enactment of the board's SB 1193 provisions to permit separate regulation of outsourcers and pharmacies.

President Gutierrez noted that the guidance states that approved drug products manufactured by a manufacturer would be easily differentiated from the outsourcing-produced products due to the differing labeling requirements between outsourcing facility-produced drugs and manufactured drugs.

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

3) Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

President Gutierrez explained that this guidance states that outsourcing facilities are not required to be licensed as pharmacies, they may compound products in large quantities, they will be inspected by the FDA on a risk-based assessment, and they may compound with or without having a patient-specific prescription.

President Gutierrez reported that the FDA notes that compounding in hospitals can occur under various forms: some hospitals compound only those products the hospital needs for its patients (e.g., inpatients and emergency department), while other hospitals compound for other facilities within their health system (clinics, infusion centers, long-term care) for administration or dispensing.

President Gutierrez stated that according to this guidance document, hospitals can compound pursuant to a patient-specific prescription as well perform anticipatory compounding for future use. Hospitals can also buy compounded products from outsourcers for use within their facilities. Additionally, some hospitals have registered as outsourcing facilities.

President Gutierrez reported that the FDA indicates that it does not intend to take action when a hospital pharmacy distributes compounded drug products without first receiving a patient-specified drug order if:

1) The drug products are distributed only to healthcare facilities that are under common ownership of the hospital pharmacy and that are located within a 1-mile radius of the compounding pharmacy;
2) The drug products are only administered within healthcare facilities to patients within the healthcare facilities, pursuant to a patient specific prescription or order; and
3) The drug products are compounded in accordance with all other provisions of section 503A, and any other applicable requirements of the FD&C Act and FDA regulations (e.g., the drug products are not made under insanitary conditions or misbranded).

President Gutierrez explained that the FDA states that the 1-mile radius is necessary because a health system pharmacy that compounds drug products without patient-specific prescriptions for facilities within its health system across a broader geographic area could function as a large manufacturing operation, but without the necessary standards to assure drug quality. If such a pharmacy contaminates or otherwise adulterates or misbrands a compounded drug, the drug has the potential to harm many patients.

President Gutierrez explained that this guidance conflicts with the regulatory provisions enacted under Business and Professions Code section 4128 et seq. under which the board licenses centralized hospital packaging pharmacies. Centralized packaging pharmacies allow hospitals under common ownership to secure unit-dose packaged medications from a centralized pharmacy if the pharmacies are located within 75 miles of the licensed packaging pharmacies.

President Gutierrez reported that at the June 1 committee meeting, she asked whether the guidance affects all packaging. Ms. Herold responded that the guidance is silent on the repackaging piece.

President Gutierrez stated that according to the guidance, the hospital pharmacy will need to become licensed as an outsourcing facility. Under the FDA's construct, the pharmacy won't be able to serve the hospital. Ms. Herold said she that believed California hospitals will need to push back strongly against the FDA regardless of what the board decides.

President Gutierrez highlighted the conflict between the FDA guidance and California. She noted that the hospital association is raising the issue with the FDA, saying the guidance creates issues because they do have locations that are over a mile away.

Page Talley of the California Council for the Advancement of Pharmacy said the FDA announced that it is no longer inspecting 503A pharmacies under CGMP rules.

Ken Schell of Sharp Grossmont Hospital said that a one-mile limitation would cost consumers millions of dollars as the hospital redid every facility in its system to become a repacking pharmacy. He urged the board to continue to express to the FDA its concerns over the one-mile limit and said it does not protect the public.

Bill McGuire of Omnicell pharmacy automation indicated the FDA also looked at the long-term care process as well as the acute care process. He said the FDA did not understand E-kits, remote dispensing of first doses and closed-door pharmacies.

Note: Dr. Castellblanch returned to the meeting at 12:27 p.m.

The board took no action.

f. Overview of Compounding Inspections Performed and Violations Noted

President Gutierrez reported that at the June 1 committee meetings, Supervising Inspector Christine Acosta presented data compiled from board inspections of licensed (sterile and non-sterile) compounding pharmacies from July 1, 2015, through May 13, 2016.
A copy of the presentation was provided in the meeting materials.

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

Part 3: Administrative Matters

a. Future Committee Meeting Dates

President Gutierrez reported that the Enforcement Committee will meet on August 31, 2016

b. Enforcement Statistics

Note: At the meeting the board and the public received an updated copy of Attachment 15 with the fourth quarter report of the enforcement statistics, SB 1441 program statistics, and citation and fine statistics.

Dr. Castellblanch asked about trends in corresponding responsibility violations and complaints about pharmacies refusing to dispense opioids. Ms. Herold said that it appears that there are more corresponding responsibility cases than previously, in part because staff is focusing on corresponding responsibility as a primary drug diversion component. She said complaints about refusals to dispense opioids have increased as well.

There was no public comment.

XIX. Communication and Public Education Committee

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

Chairperson Veale reported at the October 2015 Board Meeting, President Gutierrez asked the committee to develop a broader survey for licensees about patient consultation. At the May 2016 Communication and Public Education Committee Meeting, Division of Program & Policy Review Chief Tracy Montez, Ph.D., of the Department of Consumer Affairs addressed the committee and her office's ability to develop the patient consultation survey for the board's licensees. During the meeting, the committee provided basic parameters to Dr. Montez regarding the survey including: intent, privacy for participants, and addressing various practice settings that must be addressed.

Chairperson Lippe stated that the committee directed board staff to work with Dr. Montez's team and develop the agreement for the completion of the survey. The committee directed Dr. Castellblanch and board staff to work with Dr. Montez's team on the development, administration and completion of the survey. The committee agreed to a target date of September 2016 for the committee to review the survey at the next Communication and Public Education Committee meeting.

Chairperson Veale reported that staff recently met with Dr. Montez's team to develop the agreement deliverables for the completion of the study. Dr. Montez's team will develop the agreement deliverables and a timeline for board staff to review.

The board discussed the possible costs of the survey provided by Dr. Montez's team. The board expressed diverging views on what the board's next step should be ranging from using the previous survey anticipating no change in answers, to implementing a new survey that would be defendable in the event that future board policies are made using the data.

Ms. Veale indicated she would like the committee to do two things at their next meeting:

1.) Look at other consultation surveys done in the past; and
2.) Hear the proposal from Dr. Montez's team

There were no comments from the public.

b. Discussion on Current Patient Consultation Practices and Actions the Board Can Take to Educate Consumers and Licensees on Appropriate Patient Consultations

Chairperson Veale reported the committee discussed the importance of educating consumers and licensees on appropriate patient consultations. The committee agreed in waiting for the results of the upcoming patient consultation survey and board strategic planning sessions before moving forward.

Ms. Herold suggested the possibility of developing a video demonstrating what a good consultation looks like and perhaps what a bad consultation looks like as a tool for consumers and pharmacists. Chairperson Veale suggested a university competition to develop such a video.

Chairperson Veale reported that both the English and Spanish versions of the Notice to Consumers (NTC) posters are now available for ordering on the board's website in addition to NTC available for download in full color in six languages on legal-size paper.

Dr. Castellblanch commented that he hoped the committee would reconsider the content of the NTC to ensure people can read the information from 10 feet away. Chairperson Veale reminded the board that the content on the NTC is language required in regulation.

c. Update and Discussion on Prescription Label Translation of Directions for Use

1. Update on the Communication Plan

Chairperson Veale reported Assembly Bill (AB) 1073 (Ting) was signed by the Governor on October 11, 2015, and the provisions went into effect on January 1, 2016. The law requires a pharmacist to use professional judgment to provide a patient with appropriately worded directions for use on a prescription label consistent with the prescriber's instructions.

Ms. Veale explained that the bill also requires a prescriber to provide existing translated directions for use on a label when appropriate, if requested. Dispensers are not required to provide translated directions for use beyond what the board has made available. However, the bill does authorize a dispenser to provide his or her own translated directions for use to comply with the requirement. Veterinarians are exempt from the requirement to provide translated directions for use.

Chairperson Veale reported at the January 2016 Communication and Public Education Committee Meeting, the committee directed board staff to develop a communication plan and provide an update to the committee. The committee directed board staff to release a public service announcement about the change in law immediately. Board staff released the public service announcement on February 10, 2016. The release was translated into Chinese, Korean, Vietnamese, Russian and Spanish. Overall, the release was sent to over 800 media outlets.

Chairperson Veale explained that as part of the Communication Plan – Phase I, the information from the public service announcement was added to the board's website on the homepage. Additionally, board staff contacted the Department of Consumer Affairs' (DCA) Public Affairs Office for assistance in disseminating the message through DCA's website, Facebook and Twitter accounts. The board's Spring 2016 edition of The Script also included an article on this topic. A copy of these items was provided in the meeting materials.

Ms. Veale reported as part of the Communication Plan – Phase II, the board staff recommended and the committee directed board staff to disseminate information regarding the availability of written translations as part of a specific ***Did You Know?*** Campaign, to be implemented as follows:

- Flyer/Fact Sheet Development – Develop in concert with the DCA Office of Publications, Design and Editing. Identify fact sheet and tag line materials translated into the five languages and post these on the board's website.
- Follow Up Press Release – Reiterate the message through a follow-up Press Release with Flyer/Fact Sheet directed to audiences of the five languages identified in the law.

Chairperson Veale informed the board that staff is working with California Pan-Ethnic Health Network (CPEHN) as a collaborative partner for Phase II of the Communication Plan. Board and CPEHN staffs have had two telephone conferences to develop the flyer/fact sheet. Once the flyer/fact sheet has been developed, the two organizations will work together to increase distribution and consumer awareness.

Board Member Wong inquired if the board has received any consumer complaints since the implementation of AB 1073. Ms. Herold indicated that she knew of no consumer complaints specific to the translations received by the board.

There were no comments from the public.

2. Proposed Draft Regulation Language for Board Consideration

Chairperson Veale reported that at the January 2016 meeting, the committee discussed developing draft regulation language requiring pharmacies to post information for consumers regarding the availability of written translations. She added that at the May 2016 meeting, the committee reviewed language to require the Point to Your Language notice to include a translated direction for the consumer to ask about translations available.

Committee Recommendation (Motion): Direct board staff to provide draft language for 16 CCR 1707.6(c) as discussed in the committee to reflect the addition of translations of prescription labels being available in Spanish, Chinese, Korean, Vietnamese and Russian and provide prescription labels may be available for other languages referenced in 16 CCR 1707.6(c) and recommend draft to the board for consideration.

Draft Proposal to Amend Subsection (c) of Section 1707.6 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:
"*Point* to your language."

1. Interpreter services will be provided to you upon request at no cost. Ask the pharmacist what translations may be available for prescription labels." This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, and Tagalog, and Vietnamese.
2. *" Written translations may be available for your prescription's directions. Ask the*

pharmacist what translations are available." This text shall be repeated in at least the following languages: Chinese, Korean, Russian, Spanish, and Vietnamese.

Rebecca Cupp from Ralphs brought to the attention of the board a new OCR Anti-Discrimination Rule which does require tag lines in the top 15 languages per state.

Upon hearing the public comment the board decided to withdraw the motion and send it back to the committee for further discussion and review.

d. Update on Development of FAQs Received From ask.inspector@dca.ca.gov

Chairperson Veale reported that licensees are now able to call and ask general questions of pharmacy inspectors on Tuesdays and Thursdays from 8:00 am to 4:30 pm. In addition, licensees may submit an email inquiry to an inspector at ask.inspector@dca.ca.gov. She added that the board is developing an FAQ to be posted on the board's website concerning the most frequent questions and issues.

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

Chairperson Veale reported that board staff has been drafting FAQs to add to the board's website as a reference for licensees. She noted that the challenge with many of the drafted FAQs is that it is difficult to create a full response as a written response has implications in what is said and what is not said too.

Chairperson Veale asked about a timeline for posting FAQs. Ms. Herold said posting was delayed during the website redesign. She added that FAQs must be written carefully to avoid giving wrong or incomplete answers, so they must be reviewed by legal counsel before posting.

There were no public comments.

e. Discussion and Consideration of Naloxone Related Matters

1. Sample Naloxone Labels

Chairperson Veale said that pursuant to title 16 CCR section 1743.6 (c)(5), the board is required to provide on the board's website sample naloxone labels. The committee reviewed the sample naloxone labels at the meeting. At the committee's request, board staff updated the sample naloxone labels to reflect both a specific patient's name and an unknown patient's name as recipient.

There were no board or public comments.

2. Communication to the California Healing Art Boards Regarding Naloxone

Chairperson Veale said the committee discussed reaching to out to California healing arts boards regarding naloxone access, regulation and protocol. This would proactively inform physicians, nurses, physician assistants, and others about naloxone access, the existing protocol and the pharmacist's role in dispensing naloxone.

Chairperson Veale reported that executive Officer Virginia Herold has shared this information with the Medical Board of California, and has talked to the Dental Board and their association. She noted that Ms. Herold also spoke on May 20, 2016, about the naloxone protocol at an opioid abuse event sponsored by the Sacramento County Medical Association.

Chairperson Veale stated that the Summer 2016 edition of *The Script* is scheduled to include an article that can be shared with other healing arts boards for their respective newsletters.

Chairperson Veale reported that the committee discussed the roadblocks to the furnishing and dispensing of naloxone including insurance billing with anonymous patient names, time required for protocol completion and anonymous patient medication records.

Chairperson Veale explained that the committee also discussed the status of the updated naloxone fact sheet which is under development. Board staff reported the San Francisco Department of Public Health was working in concert with the California Department of Public Health to update the information. The San Francisco Department of Public Health anticipates the updated naloxone fact sheet be available by the end of July 2016.

Ms. Herold informed the board that the updated fact sheet with a nasal form of naloxone was released recently and will be will be posted on the website.

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

3. Need for Naloxone FAQs

Chairperson Veale reported that at the request of the committee staff has added information on insurance and billing to the naloxone FAQs.

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

f. Update and Discussion on SB 493 Implementation

1. Immunization Protocol: Sample Administration Records for Immunizations

Chairperson Veale said the board initiated a formal rulemaking in July 2015 to add Title16 CCR section 1746.4 to specify the requirements for a pharmacist to administer vaccinations. In June 2016, near the end of the rulemaking process, the board modified the protocol to ensure all pharmacist-provided immunizations were subject to a single set of requirements. The 15-day comment period ended on June 25, 2016, and the board adopted the final regulation text at the July 1, 2016, Board Meeting

Chairperson Veale explained that pursuant to the board-adopted final text, the board is required to maintain on the board's website an example of an appropriate vaccine administration record once the regulation is approved by the Office of Administrative Law.

Chairperson Veale explained that the committee reviewed multiple samples of immunization records including: The California Immunization Record (yellow card) - California Department of Public Health; The California School Immunization Record - California Department of Public Health; and Immunization and Development Milestones for Your Child from Birth Through 6 Years Old - Centers for Disease Control and Prevention.

Chairperson Veale reported that at the committee meeting staff reviewed the sample immunization record formats and recommended using the California Department of Public Health's yellow card. The yellow card is a widely recognized immunization record used in California and has space to write in immunizations given beyond school age (e.g., HPV, shingles, etc.). Chairperson Veale noted that staff felt the other two formats presented limitations.

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

Committee Recommendation (Motion): Recommend that the board post on the board's website The California Immunization Record (yellow card) developed by the California Department of Public Health as the board recommended vaccine record upon approval of pending adoption of regulation 16 CCR 1746.4.

Support: 7 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. Self-Administered Hormonal Contraception Matters: Documents Available to Memorialize Prescriptions Furnished by a Pharmacist as a Drug Order

Chairperson Veale explained that, pursuant to 16 CCR 1746.1 (b)(11), the protocol for pharmacists furnishing self-administered hormonal contraception requires that each hormonal contraception furnished by a pharmacist in accordance with the protocol shall be documented in a patient medication record as required by 16 CCR 1717 and 1707.1. These records are required to be maintained for a period of at least three years from the date of dispense.

Chairperson Veale reported that the committee considered developing a referral list in cases where a pharmacist declines to provide contraception. She said the committee decided that a referral list was not necessary, because of unintended consequences of having a referral list in the pharmacy.

In addition, Chairperson Veale said, the committee reviewed a sample document that records hormonal contraception furnished by a pharmacist along with a copy of a self-screening questionnaire.

Note: the sample document was provided in the board meeting materials.

Ms. Veale reported that the committee asked counsel to review the document and report back to the committee at their next meeting.

Ms. Freedman said that, before being posted on the website, the document should include a space to add the patient's name on the second page. In addition, Ms. Freedman said, the website should make clear that the posted document is a sample and is not required.

Lori Hensic of Kaiser Permanente asked if a pharmacy already has a form in place, is there an expectation that it will use the format on the sample document. Ms. Veale said pharmacies must collect and record the information required by regulation, but the form used does not have to look like the board sample.

3. Nicotine Replacement Therapy Matters: Discussion of The DCA Page: News from the Department of Consumer Affairs Blog Article – Pharmacists Can Help You Quit Smoking

Chairperson Veale reported that on March 29, 2016, an article about the nicotine replacement therapy regulation was featured on *The DCA Page*, which is the department's blog page.

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

g. Discussion on the Development of FAQs for SB 493-Related Items

Chairperson Veale reported that, at the April 2016 Board Meeting, the board requested that the Communication and Public Education Committee coordinate the development of FAQs for SB 493-related items. Chairperson Veale explained that the committee determined to hold the discussion at the September 2016 Communication and Public Education Committee meeting.

There were no comments from the board or the public.

h. Update and Discussion on CURES 2.0 and Communication to Licensees

Chairperson Veale reported that the committee reviewed and discussed the board's outreach to licensees regarding the requirement for pharmacists to be registered for CURES 2.0 by July 1, 2016.

- In February 2016, the board mailed a reminder postcard to pharmacists to register for CURES 2.0 by July 1, 2016.
- In April 2016, the board issued a subscriber alert announcing a DOJ tip sheet as well as a reminder that all pharmacists with active California licenses need to be registered to access CURES 2.0 by July 1, 2016.

Chairperson Veale explained that additionally, the Department of Justice (DOJ) has published on its website publications and training videos to assist in the registration process: http://oag.ca.gov/cures/publications. She added that at the end of May 2016, the board mailed letters to licensed pharmacists who were not registered in CURES according to DOJ records.

There were no board or public comments.

i. Update and Discussion on Resources Available on the Board's Website

Chairperson Veale reported that, at prior meetings, the committee reviewed multiple items for posting on the board's website as a resource for consumers and licensees during the meeting. The committee directed the board to post on the board's website Drug Diversion Toolkit: Patient Counseling – A Pharmacist's Responsibility to Ensure Compliance by Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain. The committee directed staff to continue to reach out to Consumer Reports for approval to post their article on the board's website. The committee directed board staff to develop a draft policy for posting resources on the board's website and bring back to the committee.

Chairperson Veale said the board's website has been updated to include links for the Drug Diversion Toolkit: Patient Counseling – A Pharmacist's Responsibility to Ensure Compliance by CMS and the CDC Guideline for Prescribing Opioids for Chronic Pain at: http://www.pharmacy.ca.gov/publications/pubs_for_licensees.shtml. She added that staff has drafted guidelines for posting information to the board's website for consideration at the September 2016 Communication and Public Education Committee Meeting.

Dr. Wong asked if the inspectors' Q&A is on the website. Ms. Herold said the Q&As have to be cleared with Ms. Freedman and maybe reviewed by inspectors as well before they can be posted on the website. Ms. Butler said she liked the draft Q&A.

Ms. Jarvis requested that the DOJ also be allowed to review Q&As.

There were no public comments.

j. Discussion and Consideration of the United States Access Board's Recommendation Related to Prescription Labels for Visually-Impaired and Elderly Patients

Chairperson Veale reported that as part of the FDA's Safety and Innovation Act signed by President Obama on July 9, 2012, an "Access Board" was authorized to convene a stakeholder working group to develop best practices for making information on prescription drug container

labels accessible to people who are blind, visually impaired or who are elderly. Guidelines were developed and are posted on the board's website where prescription label samples are provided.

Chairperson Veale noted that the guidelines were provided in the board meeting materials.

There were no board or public comments.

k. Proposal to Develop a Consolidated List of Drug Take Back Locations for the Board's Website

Chairperson Veale reported that since the committee meeting the board's website has been updated to include a link entitled "DEA Drug Takeback Program" and can be found at the board's website: http://www.pharmacy.ca.gov/consumers/information.shtml. This link makes available a list o fdrugs list of
list of drug take-back locations for consumers.

Megan Harwood of Orange County Prescription Abuse Prevention Council said that she submitted a list of Orange County sites and asked that it be included on the website. Chairwoman Veale said the new link on the website should link to the Orange County sites as well.

l. Discussion on a Possible Regulatory Change to Require the Collection of Pharmacists' Email Addresses

Chairperson Veale said that at the April 2016 Board Meeting the board asked the Communication and Public Education Committee to discuss a possible requirement to collect pharmacists' email addresses.

Chairperson Veale reported that the committee discussed the options of (1) requiring a pharmacist to maintain an email address on file with the board and (2) requiring pharmacists to sign up for email notification with the board's subscriber list. She stated that the committee made the following recommendation

Committee Recommendation (Motion): Recommend that the board pursue a requirement as a condition of license renewal that a pharmacist with an email address shall sign up for the board's email alert system and self-certify on the renewal form that he or she has met this requirement.

Chairperson Veale explained that after the committee meeting board staff drafted the language below:

Draft Proposal to Amend Section 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.
(c) All pharmacists with an email address shall subscribe to the board's email notification system and shall self-certify enrollment to the board in writing at the time of license renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Chairperson Veale emphasized that the requirement would apply to pharmacists who actually have an email address.

President Gutierrez said that anyone can get a free email address to meet the requirement. Ms. Freedman advised the board that laws under laws governing electronic communications, people cannot be compelled to communicate with the board electronically.

Ms. Herold informed the board that she had worked with the California Pharmacists Association to add collection of email addresses for all individual licensees as a component of the Sunset Review bill. In addition to pharmacists, the bill would allow the board to collect emails for pharmacy technicians and designated representatives. She said the board still could vote on the committee recommendation in concept.

There were no public comments.

Chairperson Veale repeated the committee motion:

Committee Recommendation (Motion): Recommend that the board pursue a requirement as a condition of license renewal that a pharmacist with an email address shall sign up for the board's email alert system and self-certify on the renewal form that he or she has met this requirement.

Support: 7 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			

m. Update on The Script Newsletter

Chairperson Veale reported that board staff was continuing to work on articles for the Summer 2016 issue of *The Script*.

There were no board or public comments.

n. Update on Media Activity

Chairperson Veale reported that the board's Executive Officer (unless otherwise noted) participated in the following media interviews and requests for information.

- **Ventura County Star,** April 13, 2016: Tom Kisken, Hormonal contraception regulation
- **The Verge,** April 13, 2016: Lindsey Smith, Prescription writing and filling by doctors and pharmacists using smart phone applications
- **HECHO EN CALIFORNIA on KIQI 1010 am/San Francisco & KATD 990 am/Sacramento,** April 15, 2016: Isabel Gutierrez, interview for radio program: Hormonal contraception regulation
- **One Medical Group,** May 6, 2016: Maria Hunt, Hormonal contraception regulation
- **San Jose Mercury News,** May 11, 2016: Tracy Seipel, End of Life Option
- **KQED,** May 13, 2016: Kelly Dunleavy O'Mara, Self-Administered Hormonal Contraception
- **San Francisco Examiner,** June 16, 2016: Robyn Purchia, pending drug take-back regulations.
- **Redding Searchlight Record**, June 28, 2016: Amber Sandhu, pharmacist training for dispensing self-administered hormonal contraception.

There were no board or public comments.

o. Update on Public Outreach Activities Conducted by the Board

Chairperson Veale directed the board to a list of major public outreach activities provided by the board's staff:

- April 29-30: Executive Officer Virginia Herold spoke at the CPhA Annual Meeting.
- May 15: Executive Officer Herold provided a CE presentation to 500 individuals on regulation of wholesalers and third-party logistics providers by the states under federal provisions of the federal Drug Quality Security Act at the National Association of Boards of Pharmacy annual meeting in San Diego.
- May 20: Executive Officer Herold provided a presentation on CURES at an annual prescription drug abuse symposium at California State University Sacramento sponsored by the Sacramento Medical Association.
- June 21: Executive Officer Herold provided training to new or newly reappointed board members on board member/executive officer working relationships as part of DCA's required board member orientation training.
- June 28: Executive Officer Herold and Supervising Inspector Michael Ignacio provided a presentation on sterile compounding via webinar for the California Hospital Association.

- June 29: Executive Officer Herold provided information on the Board of Pharmacy's role in regulating the profession to UOP second-year pharmacy school students.

Ms. Herold introduced Mr. Dávila as the board's new public information officer. Chairperson Veale welcomed him to the board staff.

There was no public comment.

p. Review and Discussion of News or Journal Articles

Chairperson Veale reported that the committee reviewed news or journal articles on medication-related topics. She noted that the articles were available in the committee packet for the May 2016 Communication and Public Education Committee Meeting.

There were no board or public comments.

q. Future Meeting Dates

Chairperson Veale announced meetings for the Communication and Public Education Committee on September 8, 2016, and December 1, 2016.

There were no board or public comments.

The board recessed for lunch at 1:45 p.m and reconvened at 2:21 p.m.

XX. Executive Officer's Report

a. Demonstration of the Board's New Website

Ms. Herold reported that on June 22, 2016, the board launched its newly re-designed website. Board IT specialist and Webmaster Victor Perez gave a demonstration of the new website, including the location of key information and new website features.

Ms. Herold also informed the board of plans to add a QR code to the board's letterhead to enable cell phones to scan the barcode and be taken directly to the board's website.

b. Report of the Board's Efforts to Assist Pharmacists in Meeting the CURES Registration Deadline as Required in SB 809, and Possible Next Steps

Ms. Herold explained that on July 1, California licensed prescribers and dispensers were required to have applied to the Department of Justice for access to CURES.

Ms. Herold reported that the board reached out in various forums for 18 months to advise licensees of the requirement to apply to the Department of Justice for access to CURES by July 1. In addition, the board did specific mailings to California- licensed pharmacists:

- Postcards sent to all pharmacists: 2/8/16
- Letters sent to pharmacists the board identified as potentially not registered in CURES: 5/25/16
    - 8,143 with California addresses
    - 5,985 with out-of-state addresses
    - 202 with out of country addresses

      Total: 14,330

Ms. Herold reported that of these 14,330, staff later determined 2,113 were inactive licenses, so the total unregistered pharmacist count on June 1 was approximately: 12,217

Ms. Herold stated that both mailings generated a number of calls, but the May letter resulted in a large number of calls to the board. By early July, 2,017, calls were received. Board of Pharmacy staff and staff of the Department of Justice responded to these callers to assist them in getting registered.

Ms. Herold reported that the Department of Justice noted that as of May 31, 2016 (the last date it provided statistics); it had received 7,080 calls and emails asking for assistance.

Ms. Herold provided the following statistics (according to June 22 data from the Department of Justice):

- There are 35,702 dispensers registered in CURES (both 1.0 and 2.0)
- There are 25,275 dispensers registered in CURES 2.0
- CURES reports run on patients 5/15/16 - 6/15/16: 683,371
- Prescribers have run 268,306 of these reports
- Dispensers have run 414,258 of these reports

Ms. Herold said updated figures showed that the number of dispensers registered for CURES had grown to about 38,000. In addition, the number of reports run by dispensers increased to about 448,000 between June 25 and July 25.

Ms. Herold said that once the backlog of calls and emails have been resolved, the board will seek a final count of the number of pharmacists who are registered in CURES. Meanwhile, new pharmacists are being advised of their requirement to apply for registration in CURES at the time they are notified that they are ready for pharmacist licensure.

c. Discussion and Consideration of Cooperating with Other Public Agencies in Issuing a CURES Survey

Ms. Herold reported that the Board of Pharmacy and Medical Board of California have been approached by researchers at the University of California, Davis, in partnership with the California Department of Public Health, to assist them in contacting licensees to participate in a survey regarding the CURES program.

Ms. Herold explained that the surveyors want to contact all pharmacists and physicians who renew their professional licenses in November and ask them to participate in a voluntary survey

available through a link on our respective boards' websites. The request and link to the survey would be included in the boards' renewal notices.

President Gutierrez and Ms. Veale recommended that the number of survey questions be reduced to help increase participation.

Ms. Herold noted that the Medical Board has agreed to assist with contacting their licensees for this survey. She asked for the board's authorization to assist in contacting pharmacists for the survey.

Motion: Support the board's participation in the CURES Survey.

M/S: Gutierrez/Veale

Support: 7 Oppose: 0 Abstain: 0

Board Member	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			

d. Review of the NABP's .PHARMACY Program, Including its July 7, 2016, Executive Board Meeting

Ms. Herold reported that the National Association of Boards of Pharmacy has been working for several years to establish a program, which it administers, that issues ".pharmacy" (stated as "dot pharmacy") domain names. Any website offering services using .pharmacy would be allowed to do so only if they have been registered with NABP and meet the requirements for registration. This is similar to website domains being established for .bank and .realtor in other professions.

Ms. Herold explained that in order to secure a .pharmacy suffix, an entity must agree to comply with various requirements, including being licensed in all appropriate jurisdictions, selling medication allowed in the jurisdiction and pursuant to local requirements (e.g., have a written prescription in hand).

Ms. Herold reported that the NABP is now focusing on increasing recognition of the .pharmacy suffix and moving to add legitimate entities to its membership worldwide. National regulators have begun to take notice of the program.

Ms. Herold stated that the California State Board of Pharmacy has a .pharmacy presence as well, which if accessed at www.caboard.pharmacy will direct the individual to the board's website (www.pharmacy.ca.gov).

Ms. Herold reported that currently, there are more than 230 entities with domain name registrations, which include 12,000 pharmacies and 26 US boards of pharmacy.

e. Review of Demographic Data Available Describing California Licensed Pharmacists

Ms. Herold presented a demographic report on California pharmacists. The report contained charts and graphs with a variety statistics about the state's 41,586 licensed pharmacists, including gender, age, education, country of origin. The report also included a county-by-county breakdown of pharmacists-to-pharmacies ratios.

Note: A copy of this report has been provided immediately following these minutes.

XXI. Organizational Development Committee

a. Budget Update/Report

1. Fiscal Year/16 Budget Report

President Gutierrez reported that fiscal year 2015/16 ended on June 30, 2016, but the final FY 2015/16 numbers will not be available until the beginning of August. A final budget report will be provided during the October Board Meeting.

President Gutierrez noted that the board has expended $20,917,300 and taken in $20,290,400 in FY 2015/16. Ms. Sodergren explained that when the board spends more than is taken in, the board spends from its fund condition.

President Gutierrez noted that personnel services account for 59 percent of expenditures, and prorate expenses make up 16 percent. Ms. Herold pointed out that both costs are mostly fixed, which makes it difficult to cut spending when budget cuts are needed.

Dr. Wong asked if all licensees who are disciplined also receive a citation and fine. Ms. Sodergren said that some cases are resolved with a citation and fine, while others are resolved by securing discipline.

President Gutierrez asked staff to provide the Enforcement Committee with a report on citations and fines showing how many citations were issued by disciplinary category and the total amount received by disciplinary category for the fiscal year.

There were no comments from the public.

2. Fund Condition Report

President Gutierrez presented information showing the fund condition with and without

additional revenue from approved fee increases.

Fund Condition: With Fee Increase		
Fiscal Year	**Fund Balance**	**Months in Reserve**
2014/2015	$11,742,000	6.9
2015/2016	$9,923,000	5.8
2016/2017	$5,525,000	3.1
2017/2018	$7,829,000	4.4

Fund Condition: Without Fee Increase		
Fiscal Year	**Fund Balance**	**Months in Reserve**
2014/2015	$11,742,000	6.9
2015/2016	$9,923,000	5.8
2016/2017	$5,525,000	3.1
2017/2018	$822,000	0.5

President Gutierrez noted that even with a fee increase, the board would have fewer months in reserve in 2017-2018 – 4.4 months – than it does now. Ms. Herold said that 2017/2018 is when the board would begin building its fund condition back up.

3. Governor's Budget for FY 2016/2017

President Gutierrez reported that on June 27, 2016, the Governor signed the budget for FY 2016/17. The new budget year began July 1, 2016. The board's spending authorization for the year is $20,652,000, which is a 2.9 percent increase from the prior year.

There were no comments from the board or the public.

b. Board Member Reimbursement Information

President Gutierrez referred board members to date provided regarding board reimbursement. She reported that board members may seek reimbursement for expenses and per diem payments. These are hours and expenses claimed by board members during the indicated. Board members are paid for each day of a board meeting but, in accordance with board policy, may also submit hours for work performed doing additional board business. It is important to note that these figures only represent hours where reimbursement was sought. It is not uncommon for board members to waive their per diem payments.
There were no comments from the board or the public.

Note: Ms. Butler and Ms. Veale left the meeting at 3:24 p.m.

c. Personnel Update

1. Board Member Updates

President Gutierrez reported that Dr. Castellblanch's term will end with the board on July 28, 2016. Dr. Castellblanch was appointed to the board by the Senate Rules Committee on June 1, 2009. During his tenure on the board he served as public member on several of the board's strategic committees, including serving as the chairperson of the Board's Prescription Drug Abuse Subcommittee. President Gutierrez publicly thanked Dr. Castellblanch for his services.

President Gutierrez also reported that Valerie Muñoz is appointed to the board effective July 29, 2016, as the new Senate Rules Committee appointment. Ms. Munoz has served on the La Puente City Council as Mayor since 2014. She is also a member of the San Gabriel Valley Regional Chamber of Commerce, Kiwanis Club of la Puente, California Cities Association and an alternate on the Foothill Transit Executive Board.

Dr. Wong suggested that new public members of the board should be offered an orientation visit to a pharmacy to learn how pharmacies operate.

President Gutierrez reported that the board currently has one board member position vacant. This position was formerly held by Rosalyn Hackworth. This position is designed for a public member who will be appointed by the Speaker of the Assembly.

2. Staff Updates

Ms. Herold reviewed the board's recent hires and departures.

Note: This information can be found in the board meeting materials.

d. Discussion and Consideration of the 2017-2021 Strategic Plan

President Gutierrez reported that the final draft of the plan will be provided at the October Board Meeting for review and approval by the board.

There was no board or public comment.

e. Fiscal Year 2016/17 Committee Rosters

President Gutierrez announced the new committee roster. She thanked board members for providing input on which committees they serve best. She also thanked board members for serving in committee leadership positions.

Note: the new committee roster was provided in the board meeting materials.

f. Future Board Meeting Dates

1. Remaining Dates Established for 2016

President Gutierrez announced that the board will meet on October 26-27, 2016, at the Holiday Inn San Jose.

2. Proposed Dates for 2017

President Gutierrez announced proposed meeting dates for 2017 as follows:

- January 24-25, 2017
- May 3-4, 2017
- July 25-26, 2017
- November 7-8, 2017

Note: The location for all 2017 meetings will be announced via the board's website.

President Gutierrez adjourned the meeting at 3:27 p.m.

All Pharmacists Licensed in California as of 6-15-16	
# of Pharmacists Licensed in CA	
Address of Record	Total
California	35,526
Out of Country	113
Out of State	5,947
Grand Total	**41,586**

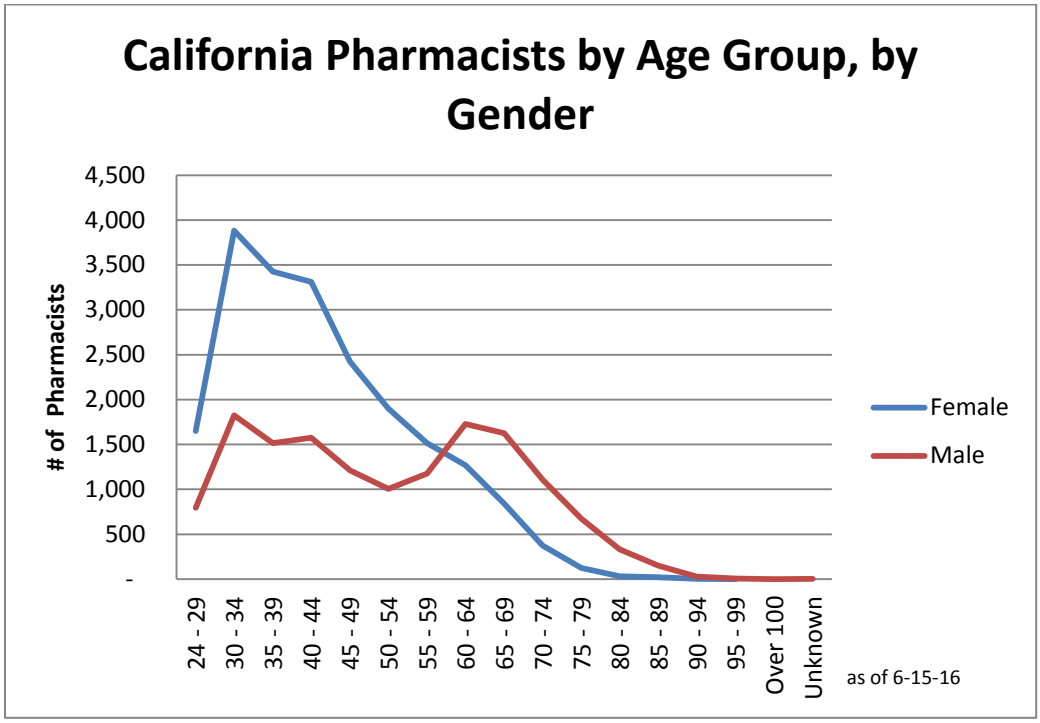
California State Board of Pharmacy Licensed Pharmacist Demographics

as of 6/15/2016

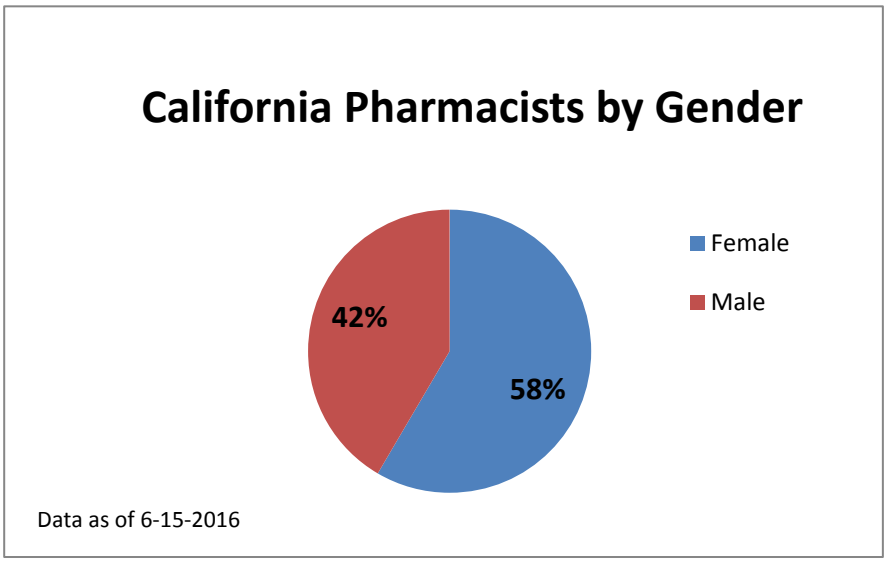
California Resident Pharmacists to Pharmacy/Hospital Ratio by County			
County	**# of Pharmacists**	**# of PHY/HSP**	**Pharmacist to Pharmacy**
ALAMEDA	1,610	244	7:1
AMADOR	19	8	2:1
BUTTE	178	46	4:1
CALAVERAS	33	9	4:1
COLUSA	8	4	2:1
CONTRA COSTA	1,130	168	7:1
DEL NORTE	19	5	4:1
EL DORADO	190	32	6:1
FRESNO	797	183	4:1
GLENN	9	6	2:1
HUMBOLDT	93	33	3:1
IMPERIAL	55	28	2:1
INYO	14	6	2:1
KERN	439	155	3:1
KINGS	40	18	2:1
LAKE	28	16	2:1
LASSEN	13	6	2:1
LOS ANGELES	9,050	2,047	4:1
MADERA	65	25	3:1
MARIN	233	47	5:1
MARIPOSA	5	2	3:1
MENDOCINO	66	22	3:1
MERCED	85	38	2:1
MODOC	4	2	2:1
MONO	9	3	3:1
MONTEREY	228	56	4:1
NAPA	100	26	4:1
NEVADA	67	18	4:1
ORANGE	5,302	694	8:1
PLACER	465	82	6:1
PLUMAS	12	4	3:1
RIVERSIDE	1,295	390	3:1
SACRAMENTO	1,629	255	6:1
SAN BENITO	20	8	3:1
SAN BERNARDINO	1,286	352	4:1
SAN DIEGO	3,059	489	6:1

SAN FRANCISCO	1,210	162	7:1
SAN JOAQUIN	616	113	5:1
SAN LUIS OBISPO	265	57	5:1
SAN MATEO	881	110	8:1
SANTA BARBARA	243	73	3:1
SANTA CLARA	2,146	284	8:1
SANTA CRUZ	149	43	3:1
SHASTA	171	43	4:1
SIERRA	1	1	1:1
SISKIYOU	35	10	4:1
SOLANO	281	65	4:1
SONOMA	339	87	4:1
STANISLAUS	301	90	3:1
SUTTER	81	20	4:1
TEHAMA	15	13	1:1
TRINITY	6	3	2:1
TULARE	250	76	3:1
TUOLUMNE	39	13	3:1
VENTURA	680	162	4:1
YOLO	147	32	5:1
YUBA	15	12	1:1
Grand Total	**35,526**	**6,996**	**5:1**

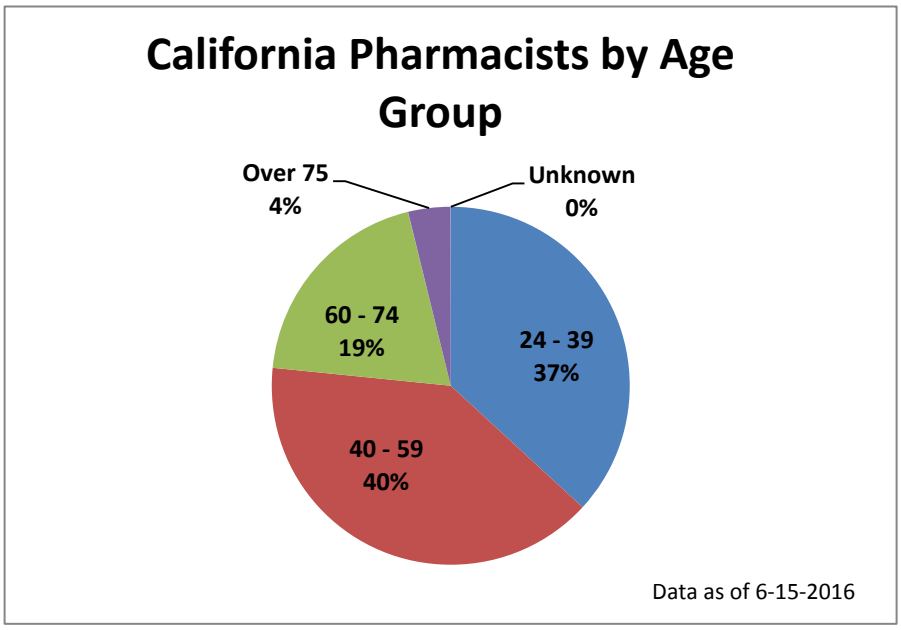
CA Pharmacists by Age Group, By Gender			
# of Pharmacists	Gender		
Age Group	Female	Male	Grand Total
24 - 29	1,649	796	2,445
30 - 34	3,883	1,826	5,709
35 - 39	3,425	1,514	4,939
40 - 44	3,311	1,574	4,885
45 - 49	2,425	1,213	3,638
50 - 54	1,900	1,006	2,906
55 - 59	1,515	1,176	2,691
60 - 64	1,268	1,727	2,995
65 - 69	842	1,626	2,468
70 - 74	375	1,108	1,483
75 - 79	125	673	798
80 - 84	31	331	362
85 - 89	20	148	168
90 - 94	2	28	30
95 - 99	1	5	6
Over 100		1	1
Unknown		2	2
Grand Total	20,772	14,754	35,526



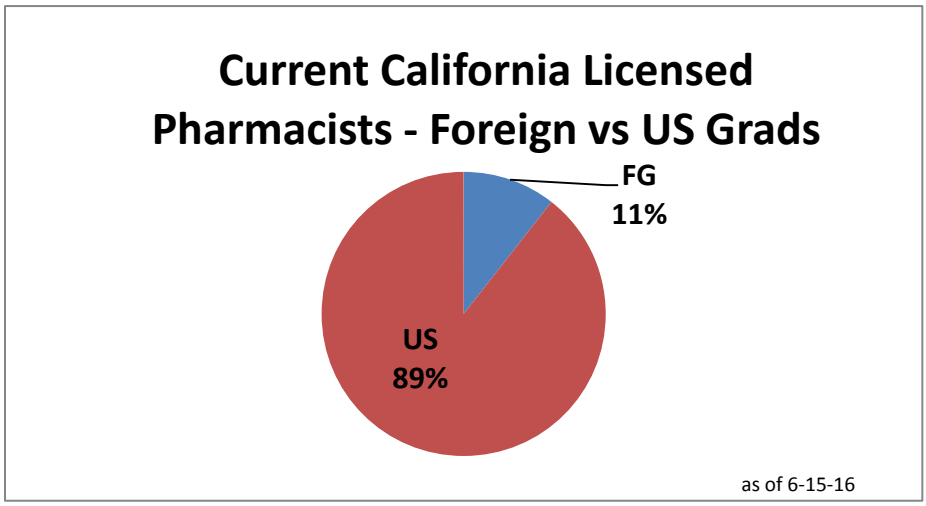
# of Pharmacists Gender	Total
Female	20,772
Male	14,754
Grand Total	**35,526**



# of Pharmacists Age Grp	Total
24 - 39	13,093
40 - 59	14,120
60 - 74	6,946
Over 75	1,365
Unknown	2
Grand Total	**35,526**



Current California Licensed Pharmacists - Foreign Grads vs US Grads		
	Values	
US vs FG	# of Pharmacists	%
FG	3,760	10.85%
US	31,766	89.15%
Grand Total	35,526	100.00%



Top 25 Pharmacy US Pharmacist Graduate Schools as of 6-15-16 (descending order by total graduates)

Count of Lic. Country Gradua	School	Total
United States	UNIVERSITY OF THE PACIFIC (CALIF)	6,358
	UNIVERSITY OF SOUTHERN CALIFORNIA	6,206
	UNIVERSITY OF CALIFORNIA-S.F.	4,066
	WESTERN UNIV. HEALTH SCIENSES COLL. OF PHY (CA)	1,697
	MASSACHUSETTS SCHOOL OF PHARMACY - BOSTON	851
	TOURO UNIVERSITY - CALIFORNIA COLLEGE OF PHARMACY	595
	NEVADA COLLEGE OF PHARMACY	567
	LOMA LINDA UNIVERSITY	516
	UNIVERSITY OF ARIZONA	433
	OREGON STATE UNIVERSITY	425
	CREIGHTON UNIVERSITY (NEBRASKA)	418
	UNIVERSITY OF CALIFORNIA, SAN DIEGO	415
	IDAHO STATE UNIVERSITY	385
	CALIFORNIA NORTHSTATE COLLEGE OF PHARMACY	323
	UNIVERSITY OF COLORADO	322
	A & M SCHWARTZ(LI UNIV)(C/PH N Y)	298
	MIDWESTERN UNIVERSITY COLLEGE OF PHARMACY - ARIZONA	277
	UNIV OF ILLINOIS AT CHICAGO	263
	UNIVERSITY OF UTAH	244
	UNIVERSITY OF NEW MEXICO	238
	TEMPLE UNIVERSITY (PENNSYLVANIA)	222
	NORTHEASTERN UNIV (MASSACHUSETTS)	208
	UNIVERSITY OF MARYLAND	207
	PURDUE UNIVERSITY (INDIANA)	194
	UNIVERSITY OF WASHINGTON	194
Grand Total		**25,922**

Top 25 Foreign Graduate School Countries for Licensed Pharmacists as of 6-15-16 (descending order by total graduates)	
Count of Lic. Country Graduated	Total
Philippines	588
India	560
Egypt	469
Vietnam	275
Korea South	261
South Africa	207
Iran	139
Taiwan	116
United Kingdom	113
Canada	108
Nigeria	90
China	74
Jordan	68
Lebanon	43
Syrian Arab Republic	41
Iraq	40
Russia	39
Philappines	33
Pakistan	33
France	32
Thailand	30
Germany	26
Armenia	26
Switzerland	24
Brazil	19

August 31, 2016
Draft Board
Meeting Minutes

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

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

DATE: August 31, 2016

LOCATION:

Staff Location
Department of Consumer Affairs
1625 North Market Blvd., First Floor Hearing Room
Sacramento, CA 92834

Additional Teleconference Locations
4040 Palos Verdes Drive North, Suite 206
Rolling Hills Estates, CA 90274

1418 S. San Gabriel Blvd., Suite A
San Gabriel, CA 91776

BOARD MEMBERS PRESENT:
Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Greg Lippe, Public Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member
Allan Schaad, RPh
Stanley Weiser, RPh

BOARD MEMBERS NOT PRESENT:
Ryan Brooks, Public Member
Lavanza Butler, RPh
Albert Wong, PharmD

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Lori Martinez, Staff Manager
Debbie Damoth, Staff Manager
Laura Hendricks, Staff Analyst
Bob Dávila, Public Information Officer

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

Wednesday, August 31, 2016

Call to Order 9:02 a.m.

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

President Gutierrez called the meeting to order at 9:02 a.m. Board members present: Greg Lippe, Valerie Muñoz, Ricardo Sanchez, Allan Schaad, Amy Gutierrez, Stanley Weisser, Debbie Veale and Victor Law.

President Gutierrez asked if there were any members of the public at the teleconference locations. Ms. Veale said no members of the public were at her location in Palos Verdes Estates. Mr. Law said two members of the public were at his location in San Gabriel.

Note: This meeting was not webcast.

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

President Gutierrez asked if there were any comments from the public at any of the meeting locations. There were no comments from the public at any of the meeting locations.

III. Discussion and Consideration of AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

President Gutierrez reported that AB 1069 originally would have expanded the provisions under which a county-established repository and distribution program allows the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription. However, at the July 2016 Board Meeting, the board was advised that AB 1069 was being amended to significantly change the legislation to allow repackaging of medications in advance of the patient presenting at the pharmacy if it is a pharmacy within the county that only deals with these types of medications serving this specific population. She noted that as the amended language was not available at the July meeting, the board did not change its Oppose Unless Amended position.

President Gutierrez said that the measure has been amended twice since the July Board Meeting. In its current form, the bill will allow a pharmacy that solely operates a redistribution program to repackage a reasonable quantity of donated medication in advance of a prescription. The pharmacy must have policies and procedures in place to identify and recall medications, and the medication label must include the earliest expiration date of the medications are commingled into a single bottle.

President Gutierrez said that, as established by board policy, staff worked with the board's president and the chairperson of the Legislation and Regulation Committee to discuss the amendments and determine what (if any) changes should be made to the board's position on the measure. President Gutierrez explained that as part of the discussion, it was determined that the bill now encourages the use of a pharmacy to operate the redistribution program

which provides better safeguards for patients. As such, the position on this measure was changed to support.

President Gutierrez reported that the bill was enrolled on August 23, 2016, and is currently awaiting action by the governor.

President Gutierrez explained that at this meeting, the board would have the opportunity to discuss the amendments to AB 1069 and ratify the position taken by the board president and the chair of the Legislation and Regulation Committee. She noted that the board meeting materials included a copy of the measure as it will amend the law as well as copy of the support letter that was provided to the author's office.

Mr. Weisser noted that the bill would allow a pharmacy to repackage a "reasonable" quantity of donated medicine. He asked if this wording would pose a problem because it is not exact enough.

Ms. Freedman said the wording would be problematic for OAL – but AB 1069 is legislation, not a regulation, and the Legislature can make its own rules on wording. She also explained that if the board was charged with enforcing the statute, the board would be able to call for expert opinion from pharmacists in order to determine what would constitute a "reasonable" quantity.

President Gutierrez added that another way to determine a "reasonable" quantity of a drug would be to consider how much of that drug a pharmacy typically would have on its shelf and would dispense in a given time period. Mr. Lippe added that the term "reasonable" was not an issue for him or President Gutierrez in their discussion of AB 1069.

Mr. Schaad asked for a history of the bill to understand the type of program addressed by AB 1069. He asked how this program is currently being handled and where the dispensing it taking place.

Ms. Sodergren explained that existing provisions in the Health and Safety Code allow a county to establish a program by which it can accept donated medications from various facilities for redistribution to indigent patients. Under current law, there are various locations in the county that can provide these medications. According to the author's office, Santa Clara County is currently operating this type of program. The county receives donated medications from various sources, with skilled-nursing facilities being one of the largest donors. The current law requires the donated medication to be in a tamper-evident package, typically a bubble pack, and it must have specific information.

Ms. Sodergren explained that AB 1069 would allow a pharmacist to punch out the medication from the medication bubble cards in advance of the patient presenting. Currently, when a patient presents, the medications are stored in the bubble cards – one card may have 10 dosage units, one may have 5, another may have 12 – and the dispenser has to identify the medication prescribed, punch them out of the cards, put them in a vial and label them. This bill would allow a stand-alone pharmacy whose sole purpose is to redistribute these donated medications to repackage the medication in advance. The author's office said that patients

getting these medications at the pharmacy in Santa Clara face long waits because the repackaging is labor intensive and presents work-flow issues for the pharmacy.

Ms. Sodergren added that, besides allowing medications to be repackaged in advance, the bill would provide better patient protections because the work would be done in a pharmacy, by a pharmacist with better controls in place than.

Ms. Veale asked if counties would be controlling the program, including the pharmacist component, and whether that board would have to adopt regulations telling pharmacists what they need to do in order to participate.

Ms. Sodergren explained that current law allows redistribution to be done in various locations (i.e., clinics, doctors' offices, etc.). AB 1069 would centralize the distribution to a pharmacy, which has better controls in place. Since the pharmacy would be mixing medications with various lot numbers and expiration dates, it would be better to have this done in a pharmacy with specific policies and procedures in place for handling recalls. The bill also would ensure that the medication is repackaged with the earliest expiration date on it so that a patient does not take medication that has expires.

President Gutierrez and Ms. Sodergren noted that current law permitted someone under a physician's oversight to handle repackaging, such as in a clinic. Ms. Sodergren said that the key change in the bill would be the repackaging component and the requirement that it be done in a pharmacy.

Steve Gray of Kaiser Permanente asked if the bill would require creation of a new pharmacy license category and whether repackaging pharmacies could accept partially opened bottles of medications from pharmacies or wholesalers. Ms. Herold replied that no new license is needed. Ms. Sodergren said that a pharmacy redistributing medications would be no different from any pharmacy that specializes in an area, such as a closed-door pharmacy that focuses on skilled-nursing facilities. She added that current law requires counties to notify the board if they are operating this type of pharmacy. If a pharmacy is not handling repackaging, it is free to serve other types of patients.

Ms. Herold added that counties are required to notify the board if they are operating a repackaging pharmacy. Ms. Sodergren said repackaging pharmacies cannot accept partially opened bottles, because the law requires the medications to be in tamper-evident packaging.

Bill McGuire asked if bubble packs contain all the same drug or multiple drugs. He said that accepting bubble packs containing multiple medications, even in tamper-proof bubble packs, might conflict with USP 681. President Gutierrez said the board would review USP 681.

Motion: Affirm the decision by the board president and the chair of the Legislation and Regulation Committee to change the board's position on AB 1069 from oppose unless amended to support.

M/S: Weisser/Sanchez

Support: 8 Oppose: 0 Abstain 0

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

IV. Consideration and Possible Adoption of Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists

President Gutierrez said that, in July 2015, staff initiated a formal rulemaking to add Title 16 CCR sections 1730, 1730.1, and amend section 1749 related to the licensing requirements for advanced practice pharmacist. At the February 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law (OAL) for final review on June 3, 2016.

President Gutierrez said that at the July 2016 Board Meeting, DCA Staff Counsel Laura Freedman explained OAL found problems and disapproved the regulation due to a lack of clarity and ambiguity in the language. OAL's clarity issue was with the language that prohibits experiential hours earned under a collaborative practice agreement to also be used to fulfill the criteria for the residency program, an action prohibited by the underlying statute. Ms. Freedman said that OAL wanted that provision to be memorialized in the text of the regulation itself.

President Gutierrez reported that OAL also raised two other "necessity" concerns regarding the rulemaking file. The first issue was the board's requirement that the application be submitted under penalty of perjury. The second was the explanation of how the board chose the 1500 hours as the equivalent of one year.

President Gutierrez explained that Ms. Freedman drafted modified language to address the issue raised by OAL and reviewed the text with the board at its July 2016 meeting. The board approved the "Draft Third Modified Text" as provided at the July 2016 board meeting. The board approved board staff to initiate a 15-day comment period. The board initiated a 15-day comment period for the addition of documents to the rulemaking file and third modified text. President Gutierrez reported that the 15-day comment period began August 12, 2016, and ended on August 27, 2016.

President Gutierrez stated that, at this meeting, the board would have the opportunity to discuss the regulation and the comment(s) received and to determine what course of action it wishes to pursue. The options include:

1. Adopt the regulation as approved at the July 2016 Board Meeting after reviewing the public comments.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

President Gutierrez noted that Attachment 2 of the board meeting materials contained the Draft Third Modified Text that was noticed on August 12, 2016.

Ms. Damoth reviewed the public comments that were received by the board during the most recent comment period. One comment would add "or graduate clinical emphasis degree" into subsection (b)(2) and as well as subsection (c) and in (1)(A). President Gutierrez characterized his comment as asking that the board allow an advanced degree such as an MS or Ph.D. in clinical pharmacy in lieu of pharmacy. Ms. Freedman stated that these changes were contrary to the requirements in the statute. The board did not amend the language.

Ms. Damoth reported that a comment asking how the board can justify a regulation that asks that pharmacists with a residency have better memory than pharmacists who have not completed the residency. Ms. Freedman said the comment does not appear to be related to the 15-day changes but the board could still respond.

President Gutierrez explained that the issue of requiring 1,500 hours of experience involved a desire by the board to ensure that the one year of experience was meaningful – not just doing one hour a week and for a year as a year's worth of experience. Ms. Freedman said OAL's issue with the 1,500 hours was that the board didn't specifically say why that figure was chosen in the rulemaking file itself. President Gutierrez said the number of hours was based on the requirements for intern pharmacists that equate 1,500 hours to a year's worth of experience.

The board elected not to modify the language in response to the comments received during the comment period.

There were no comments from the public.

Motion: Adopt the regulations as approved at the July 2016 Board Meeting.

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210, subdivision (a)(2)(A).

Note: Authority cited: Sections 4005 and, 4210 ~~and 4400~~, Business and Professions Code. Reference: Sections ~~4052.6,~~ 4210 ~~and 4400~~, Business and Professions Code.

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of Business and Professions Code section 4210, an applicant for advanced practice pharmacist licensure must satisfy two of the following subsectiondivisions.

~~(a)~~ (1) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, subdivision (a)(2)(A), ~~an applicant shall~~ by providinge either:

~~(1)~~ (A) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

~~(2)~~ (B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

~~(b)~~ (2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, subdivision (a)(2)(B) ~~, an applicant shall~~ by providinge either:

~~(1)~~ (A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

~~(2)~~ (B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, the area of specialty, and the dates of participation and completion ~~, and area(s) of specialty~~. For an applicant whothat cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection ~~(2)~~.

~~(c)~~ (3) Demonstrate that experience earned under a collaborative practice agreement or protocol, as required by Business and Professions Code section 4210, subdivision (a)(2)(C), has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must ~~be composed of~~ include no fewer than 1,500 hours of experience providing clinical services to patients ~~and~~

~~must be earned within four consecutive years~~. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, **modifying or** ~~and~~ discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

~~(1)~~ **(A)** A written statement from the applicant attesting under penalty of perjury that he or she has:

~~(A)~~ **(i)** Earned the clinical experience within the required time frame; **and**

~~(B)~~ **(ii)** Completed the required number of hours of **experience providing** clinical services to patients, as specified in ~~**this subdivision**~~ **subsection (a)(3), and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, modifying or and discontinuing drug therapy of patients; and**

~~(i)~~ **(I)** The applicant shall provide a copy of the collaborative practice agreement or protocol.

~~(ii)~~**(II)** If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

~~(2)~~ **(B)** A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least ~~**one year**~~ **1,500 hours** of experience providing clinical services to patients. **For an applicant who~~that~~ cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection~~(2)~~.**

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.

Note: Authority cited: Section**s** 4005**,** ~~**,**~~ **and** 4210 ~~**and 4400**~~, Business and Professions Code. Reference: Section**s** 4052.1, 4052.2**,** ~~**,**~~ **and** ~~**4052.6,**~~ 4210 ~~**and 4400**~~, Business and Professions Code.

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, **4210,** 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars ($520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars ($325). The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars ($325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars ($105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars ($130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars ($65).
(d) The fee for application and examination as a pharmacist is two hundred sixty dollars ($260).
(e) The fee for regrading an examination is one hundred fifteen dollars ($115).
(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195).
(2) The fee for application of an advanced practice pharmacist license is three hundred dollars ($300*). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.*
(g)(1) The fee for the biennial renewal of a pharmacist's license is **one hundred ninety-five dollars ($195)** ~~two hundred seven dollars ($207)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents ($97.50).
(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). *The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.*
(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars ($165). The penalty for failure to renew is eighty two dollars fifty cents ($82.50).
(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars ($195). The penalty for failure to renew is ninety seven dollars and fifty cents ($97.50).
(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(*l*) The fee for an intern pharmacist license is one hundred fifteen dollars ($115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars ($30).
(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars ($100).
(n) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.
(o) The fee for the issuance of a clinic license is five hundred twenty dollars ($520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars ($325) . The penalty for failure to renew is one hundred fifty dollars ($150).
(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars ($780). The penalty for failure to renew is one hundred fifty dollars ($150).
(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars ($330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars ($195). The penalty for failure to renew is ninety-seven dollars and fifty cents ($97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars ($425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars ($325). The fee for the issuance of a temporary license is two hundred and fifty dollars ($250). The penalty for failure to renew is one hundred twenty-five dollars ($125).
(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars ($45).
(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be $800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be $800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 0

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

Motion: Delegate authority to executive officer to any make non-substantive or technical changes as may be required by the OAL to complete the rule-making.

There were no board comments or public comments on the motion.

M/S: Weisser/Sanchez

Support: 8 Oppose: 0 Abstain: 0

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

Schaad	x			
Veale	x			
Weisser	x			
Wong				x

V. Consideration and Possible Adoption of Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) section 1707.5, Related to Patient-Centered Labels

President Gutierrez said that at the January 2015 Board Meeting, the board approved proposed text to amend Section 1707.5 of Title 16 CCR related to Patient-Centered Labels. The 45-day comment period began on October 23, 2015, and ended December 7, 2015.

President Gutierrez said that at the April 2016 Board Meeting, the board approved modified text to address concerns expressed during the 45-day comment period and initiated a 15-day comment period. The 15-day comment period began on May 11, 2016, and ended on May 26, 2016.

President Gutierrez reported that at the July 2016 Board Meeting, the board approved a modified text to address concerns expressed during the 15-day comment period and initiated a second 15-day comment period. The second 15-day comment period began on August 3, 2016, and ended on August 18, 2016.

President Gutierrez said the board received several comments during the 15-day comment period.

President Gutierrez explained that at this meeting, the board would have the opportunity to discuss the regulation and the comments received and to determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the July 2016 Board Meeting and noticed for 15-day comment on August 3, 2016.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a third 15-day comment period.

Ms. Martinez said that four comments were received, which she reviewed for the board at the meeting. One comment stated that the regulation does not appear to require the drug manufacturer's name, which could pose a conflict with statute. Ms. Herold noted that Business and Professions Code section 4076 already requires the manufacturer's name be placed on the label, whether or not it is in the patient-centered area of the label.

Ms. Martinez said that a second comment recommended that the wording "may list the name of the manufacturer" be changed to "shall list …" so that it is required. President Gutierrez said she believed that that the manufacturer's name is not as important from a patient perspective.

Ms. Herold said that the board's intention was to give pharmacists some discretion about where to place the manufacturer's name while still meeting the statutory requirement that that the manufacturer's name be provided somewhere on the container.

Ms. Martinez said that another comment asked that "equivalent to" be used in the wording instead of "generic for" on the label because some patients do not believe that generic drugs are as good as brand drugs. Ms. Martinez said the comment reflected an issue of patient education and was outside the scope of the 15-day comment period. President Gutierrez said patients should be informed that their medication is generic.

Ms. Martinez said that the final comment was also outside the scope and requested that the board change 1707.5(a)(1)(B) to allow the purpose of the medication to be added to the label at the pharmacist's discretion.

Mr. Weisser made a motion to adopt the regulation as approved at the July 2016 Board Meeting and delegate to the executive officer the authority to make technical and non-substantive changes as may be required by OAL and DCA to complete this rule-making file. The motion was seconded by Mr. Schaad.

Mr. Law said he agreed with the two comments from the public. He said that putting the manufacturer's name in the patient-centered area is beneficial to the public, because generic companies make drugs in different sizes, shapes and colors. He said that having the abbreviation of the manufacturer's name on the label would enable patients to know the product's color, shape and size. He said putting the manufacturer's name outside the patient-centered area makes it difficult for patients to find.

In addition, Mr. Law said the board should allow pharmacists to exercise their discretion to put in parenthesis the general purpose of the drug even though the prescriber does not specify. He said that many senior citizens and others receive prescriptions for multiple medications. If the label includes in parenthesis what the medication is being prescribed for in easy-to-understand terms, which would be helpful to those patients. He recommended that these items be incorporated in the labels.

Ms. Veale said she agreed with Mr. Law that having the manufacturer's name on the label in the patient-centered area is beneficial to consumers. But she noted that the name can be either inside or outside the patient-centered portion, so as long as it is on the label as required by law, that would be acceptable. Regarding suggestions that a patient diagnosis be included on the label, Ms. Veale said that issue might be outside the scope of the rulemaking. She said the board had considered that issue previously and perhaps should revisit it, but it was beyond the current rulemaking.

President Gutierrez said that she agreed with Ms. Veale. She added that one of the issues with including a diagnosis on the label is that so many drugs are used for many different indications – so it would be difficult for pharmacists to include that information on the label unless the provider provides that information on the prescription.

Mr. Law said that he disagreed with President Gutierrez. He said that many patients complain that they have too many medications at home and that they do not know what they are for. He said that, most of the time, prescribers do not put down the purpose of the medication on the prescription. He said the board should give pharmacists, at the patient's request, to put the condition on the label so that the patient would not be confused about what the medication's purpose.

President Gutierrez said that the rulemaking is concerned with the requirements for the label – not optional items that a pharmacist, in his or her discretion, can add. Ms. Herold said that if a patient requests that the purpose be included on the label, the pharmacist could use his or her professional judgment to provide that information to the patient. She added that the issue of putting the medication purpose on the label is beyond the intended scope of the regulation and could trigger notice requirements if the board decided to address the issue here. She suggested that the board discuss the drug purpose issue at another time.

President Gutierrez suggested the Communication and Public Education committee consider the issue at its next meeting.

Mr. Law asked for clarification if pharmacists can put the drug's purpose on a label at a patient's request. Ms. Herold indicated that a pharmacist may do so at the patient's request.

Mr. Law reiterated his belief that the manufacturer's name should go in the patient-centered area. It was clarified that the word "may" in the regulation would allow a pharmacist to put it inside or outside the patient-centered area, as long as it is somewhere on the label. Ms. Veale also noted that the wording of the regulation would give the pharmacist discretion on whether to put the manufacturer's name inside or outside the patient-centered area.

Ms. Muñoz asked if including the medication purpose on the label could violate HIPAA requirements for patients who do not want their health history on the label. President Gutierrez said Ms. Muñoz raised a very good point and said the medication purpose issue raises many concerns – which is why the board should refer the matter to the Communication and Public Education Committee.

Ms. Herold noted that the drug purpose information is intended for the patient and the patient's caregiver to know how to take the medication, so it should be up to the patient to decide what information goes on the label.

Robert Stein of KGI School of Pharmacy said that the purpose of the rulemaking is to reduce public confusion – but requiring both the brand and generic name in the patient-centered portion of the label may actually cause confusion. President Gutierrez replied that one of the reasons for the requirement is situations where a patient is also taking the brand-name drug, and he or she would not understand that they are duplicating therapy by taking the brand-name and the generic drug.

Steve Gray of Kaiser Permanente expressed support for the regulation and support for Mr. Law's concerns about putting the medication's purpose on the label. He said that the issue has been pursued for 10 or 12 years and said that there was a bill to do it in the current legislative

session, but the bill died. He spoke in support of the Communication and Public Education Committee holding an in-depth discussion on providing purpose on the label.

Motion: Adopt the regulation as approved at the July 2016 Board Meeting and delegate to the executive officer the authority to make technical and non-substantive changes as may be required by OAL and DCA to complete this rule-making file.

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted ~~into the parentheses~~. If, ~~it has been at least five years since the expiration of the brand name's patent or, if~~ in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, may list the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

~~(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.~~

~~(f)~~ (e) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

M/S: Weisser/Schaad

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x

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

President Gutierrez adjourned the meeting at 9:59 a.m.

September 22, 2016 Draft Board Meeting Minutes

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

DATE:	September 22, 2016
LOCATION:	Embassy Suites Anaheim Orange 400 N. State College Blvd. Orange, CA 92868
BOARD MEMBERS PRESENT:	Amy Gutierrez, PharmD, President Deborah Veale, RPh, Vice President Victor Law, RPh, Treasurer Lavanza Butler, RPh Greg Lippe, Public Member Valerie Muñoz, Public Member Ricardo Sanchez, Public Member Allan Schaad, RPh Stanley Weiser, RPh
BOARD MEMBERS NOT PRESENT:	Ryan Brooks, Public Member Albert Wong, RPh
STAFF PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Counsel Desiree Icaza Kellogg, Deputy Attorney General Christine Acosta, Supervising Inspector Joan Coyne, Supervising Inspector Janice Dang, Supervising Inspector Debbie Damoth, Staff Manager Lori Martinez, Staff Manager

Call to Order **8:01 a.m.**

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

President Gutierrez called the meeting to order at 8:01 a.m. Board members present: Greg Lippe, Lavanza Butler, Stanley Weisser, Victor Law, Amy Gutierrez, Debbie Veale and Allan Schaad.

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

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

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

a. Mumbert, William; RPH 48782
b. Avalos, Albert; TCH 69538

Administrative Law Judge Debbie Ney-Perkins presided over the petition for reinstatement of licensure for William Mumbert, RPH 48782.

Note: Mr. Sanchez arrived at 8:04 a.m. and Ms. Muñoz arrived at 8:17 a.m.

The board recessed for a break at 9:06 a.m. and reconvened at 9:17 a.m.

Administrative Law Judge Debbie Ney-Perkins presided over the petition for reinstatement of licensure for Albert Avalos, TCH 69538.

IV. Closed Session

The board went into closed session at 9:54 a.m.

The board reconvened in open session at 10:33 a.m. to announce a case title and resumed closed session at 10:35 a.m.

The boarded went into closed session at 10:36 a.m. and ended closed session and recessed for a break at 11:41 a.m.

V. Reconvene Open Session

The board reconvened in open session at 12:02 p.m.

VI. Planning Discussion for Future Stakeholders' Meeting Regarding the Final Rule Implementing Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities, Specifically Including its Impact on Pharmacy Translations and Interpretations

Communication and Public Education Committee Chairperson Law reported that at the September 2016 Communication and Public Education Committee meeting, members discussed a new rule issued by the U.S. Department of Health and Human Services that requires pharmacies to provide "meaningful access" to customers with limited English proficiency. This rule includes posting taglines written in at least 15 languages advising the public that interpreter and translation services are available free of charge. Further,

Chairperson Law noted that the regulation implements Section 1557 of the Affordable Care Act, which forbids discrimination in health care on the basis of race, color, national origin, age, disability and sex. The rule went into effect on July 18, 2016. He said that a copy of the board's draft newsletter article on this requirement, the APHA summary documents and Federal Rule itself are included in the meeting materials.

Chairperson Law said that committee members discussed this new rule and how it impacts California law. He told the board that the committee contemplated if a meeting focused on this topic would be appropriate. Chairperson Law said that the meeting would provide stakeholders with the opportunity to discuss efforts to implement the provisions, an opportunity to discuss changes that may be necessary to California Law, and provide the board an opportunity to help facilitate implementation through information sharing and education.

Chairperson Law told the board that the committee is seeking guidance from the board about this issue, including if a dedicated meeting is appropriate and, if so, preferences for how and when such a meeting should be convened. He noted that the new rule would pre-empt many California laws that the board has implemented for label translations.

Board member Stan Weisser noted that the new federal rule pre-empts California Code of Regulations section 1707.6. Ms. Veale said that Communication and Public Education committee members felt it would be helpful to have stakeholders meet and present their solutions to complying with the federal rule, rather than board members trying to develop solutions without the necessary expertise. She said committee members wanted feedback from the board on whether to host a forum for stakeholders as part of the October board meeting and whether to do it as part of the two-day meeting or to add an extra day to the meeting.

President Gutierrez asked if APHA had offered any recommendations on compliance. Ms. Herold said she did not know. Ms. Herold said she was aware of one pharmacy chain that would be ready by the implementation date of the rule on Oct. 18. She said that because of the current California law has been on the books for some time, the California Pharmacists Association (CPhA) told her going from 10 to 15 languages would be straightforward with interpreter services. She said that identifying the top 15 languages would require a process but would be readily achievable.

Ms. Herold said providing translations for prescription labels raises concerns about pharmacists relying on a Google translation app, which she said could be unreliable. She said the board could use certified DCA translators for assistance once the board has determined what is needed.

Brian Warren of the CPhA said CPhA was beginning to look into compliance issues and would be checking with APHA for guidelines.

Ms. Veale said the committee noted that the board might not able to provide 15 language translations on its website and the board would need to consider the impact on its current regulations. Ms. Herold said a statutory provision and some regulations would have to be amended to comply with the federal rule. President Gutierrez asked what health plans, PBMs or other large organizations that follow federal rules were doing. Ms. Veale said that the committee was told that the new rule had been imposed very quickly and that organizations were not prepared.

Mr. Weisser noted that the federal rule requires more notice to be posted in pharmacies and suggested asking the Communication and Public Education Committee to consider how pharmacies already are impacted by all of the posting requirements already established by the board. Ms. Veale said that already was a goal of the committee.

President Gutierrez noted that the board would not have to duplicate the federal rule, since pharmacies must comply with federal requirements. Ms. Herold said the board has some regulations that are outdated and must be brought into compliance with federal law or eliminated. In addition, she noted that changes also would be required in statutory provisions, including the bill that established label translations.

Ms. Herold suggested scheduling a stakeholder forum in mid-November in Southern California, to accommodate most of the board members. Ms. Herold stated the board could invite national stakeholders, insurance providers and other experts in addition to the public. She said that other boards of pharmacy have not acted yet and that many said they did not know about the new federal requirements.

DCA Counsel Laura Freedman noted the federal rule technically applies only to pharmacies that receive federal funding, and not to all pharmacies. Ms. Herold said the board does not want to provide different standards of care in California based upon whether consumers use pharmacies that receive federal funding or pharmacies that are reimbursed by other sources. President Gutierrez said most retail pharmacies would be covered by the new role because most do in some way deal with Medicaid.

Ms. Veale suggested that the board not set a specific meeting date and instead direct that the forum be held within six to eight weeks. Chairperson Law noted that the federal rule was effective in July and it requires pharmacies to post taglines in at least two languages within 90 days. President Gutierrez noted that, because the rule is a federal requirement, pharmacies will have to comply regardless whether the board acts or not. She added that the board should focus only on areas where the federal rule impacts state regulations.

Ms. Herold suggested that the forum be organized as a board meeting but if a quorum is not available, then hold it as a committee meeting or a hearing of the board.

Steve Gray of Kaiser Permanente told the board that the new federal rule caught a lot of people throughout the health-care industry by surprise. He suggested that the board check with the Medical Board, other licensing boards and the Department of Health Plans on what they plan to do regarding compliance. He also informed the board that the American Society of Pharmacy Law will discuss the new federal rule during its national meeting Nov. 8-14 and suggested that the board not schedule its stakeholder forum during that period.

Paige Talley of the California Council for the Advancement of Pharmacy asked if the stakeholder forum would be webcast if it held as a committee meeting instead of a full board meeting. Ms. Herold said webcasting depends generally on availability and what other DCA board meetings are happening. She said the board would explore webcasting after a date is selected.

Motion: Set up a board meeting to occur preferably before the end of the year to address the implementation of the final rule regarding section 1557 of the Affordable Care Act regarding nondiscrimination in health programs and activities, specifically including its impact on pharmacy translations and interpretations and other regulations and activities that are applicable.

M/S: Veale/Butler

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x
Butler	x			

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

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

President Gutierrez noted that this item has been a longstanding issue at board meetings. Dr. Gutierrez noted the history of this rulemaking described in the board meeting materials. At the January 2016 meeting, the board approved proposed text to add Sections 1776 et seq. of Title 16 CCR, related to Prescription Drug Take-Back Programs. The 45-day comment period began on Feb. 12, 2016, and ended March 28, 2016. In addition, two regulation hearings were held on April 13, 2016 (one in Northern California and one in Southern California).

At the April 2016 Meeting, the board approved modified text to address concerns expressed during the 45-day comment period and at the regulation hearing. The 15-day comment period began on May 3, 2016, and ended May 18, 2016.

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

At the July 2016 meeting, the board reviewed and approved the modified language as recommended by staff. A 15-day comment period was initiated on Aug. 4, 2016 and ended Aug. 19, 2016. The board received numerous comments.

President Gutierrez reported during the board meeting that members would have the opportunity to discuss the future of the regulation and determine what course of action to pursue. She noted that the meeting packet included an attachment with two drafts of the language – the modified text approved at the July 2016 meeting, and a clean version of the modified text approved at the July 2016 meeting – a compilation documents of the comments received during the 15-day comment period, and the comments themselves.

Ms. Martinez reviewed the comments with the board. She said the certain comments mainly focused on whether sharps would be allowed in take-back programs, which she noted was a policy decision by the board. President Gutierrez asked that the board review each comment by regulation section.

Regarding section 1776, President Gutierrez noted that Douglas Barcon recommended adding “mail-back” to the second paragraph so that they are not excluded from a take-back program. Ms. Herold noted that the board had removed “mail-back” from a prior version because a business does not have to be registered as a collector to distribute mail-back envelopes. President Gutierrez said the board would accept staff recommendation to reject the comment.

Regarding section 1776.1(c), President Gutierrez said Douglas Barcon noted a spelling correction, which the board accepted.

Regarding section 1776.1(e)(2), Ms. Martinez said the San Francisco Department of Environment noted that Department of Transportation does not require that Sharps be removed and added that it was mainly related to EpiPens. She said that the commenter suggested removing the reference to Sharps or else add an exemption for EpiPens. Ms. Freedman advised the board that a statute, section 4146, says that a pharmacist may accept needles from the public if contained in a Sharps container as defined in section 117750 of the Health and Safety Code, so allowing it in the regulation could create a conflict with the statute. Board members agreed to reject the comment.

Ms. Herold advised the board that she had been informed by CDPH that EpiPens disposed in locations to be incinerated pose an explosion risk.

President Gutierrez noted that the next three comments – from Douglas Barcon, about sections 1776.1(h), 1776.1(i) and 1776.1(i)(1) – were related to the previous mail-back comment that the board had rejected.

Ms. Herold asked Ms. Freedman about recent legislation dealing with sharps that the board had supported. Ms. Freedman advised the board that SB 1229 (Jackson) creates minimum standards for pharmacies that operate collection bins and gives them a degree of immunity from civil and criminal liability if they meet those standards.

Another comment regarding section 1776.1(i), from city of Santa Rosa, identified the wrong section. Ms. Martinez said the commenter appeared to be saying that a pharmacy in a skilled-nursing facility should be able to work with any agency, such as law-enforcement, to distribute mail-back envelopes in the facility. Ms. Herold said there is nothing in the pharmacy regulations that forbids skilled-nursing facilities from providing mail-back envelopes on their own. President Gutierrez said the board would reject the comment.

President Gutierrez said the next comment, regarding 1776.1(i) from Douglas Barcon, was about "mail-back," which the board had previously decided to reject.

The next two comments, regarding section 1776.1(k) from San Francisco Department of Environment and from city of Santa Rosa, asked that the section be removed because a pharmacy that cannot comply with DEA rules cannot collect controlled substances. President Gutierrez said that the board had previously discussed that section and would leave it as it is.

Ms. Martinez said that the next comment, regarding section 1776.1(k) from Kaiser, asked that the language be changed to "collection receptacles" only. President Gutierrez said that the comment was the same as Santa Rosa's comment, which the board had rejected.

Ms. Martinez said that a comment regarding section 1776.2(c) from Gordon Miller requested that language regarding postage-paid envelopes be added back into the section that is, in fact, already in the section. The board rejected the comment.

Regarding section 1776.3, Ms. Martinez said city of Santa Rosa expressed concern that the language could be misunderstood to mean that the deposit-opening to the receptacle must be locked at all times, not the receptacle itself. Board members expressed satisfaction with the existing language and rejected the comment.

Regarding section 1776.3(b), President Gutierrez said the comment from Fred Mayer was actually a question. The board rejected the comment. Board members also rejected the comments about this section from city of Santa Rosa and San Francisco Department of the Environment, because pharmacies may have an emergency exit door with the location.

Regarding section 1776.3(c) and comment from city of Santa Rosa, Ms. Freedman said that sentence in the regulation should have been deleted. She said the regulation requires that the collection box be closed if the employees of the registrant are not present – but the registrant in a hospital pharmacy setting is the hospital, not the pharmacy. She suggested that the language be changed to mirror the federal regulation.

Ms. Herold crafted new language: "When there is no pharmacy or DEA registrant employee available, the collection receptacle shall be locked so that drugs may not be deposited." Board members approved the change.

Regarding section 1776.3(d), board members rejected the comments by city of Santa Rosa, Alameda County Hazardous Waste and San Francisco Department of Environment. Ms. Freedman explained that the comments were rejected because in the case of a retail pharmacy, the pharmacy itself is the licensee, not the entire store – so the employee has to be an employee of the pharmacy.

Regarding section 1776.3(d) and comment from Kaiser recommending against use of the term "slot," board members agreed to change the wording to "opening."

Regarding section 1776.3(f), board members rejected comment by Douglas Barcon about ASTM bag requirements. Ms. Herold said the board heard much discussion of bag standards before choosing the standards in the regulation.

Regarding section 1776.3(g), board members rejected the comment by Kaiser. Ms. Herold said the regulation could be amended later if it becomes a problem.

Regarding section 1776.3(h), on the advice of Ms. Freedman, board members agreed to add "sealable" to describe covers in the third sentence, and to delete the final sentence.

Regarding section 1776.3(i), board members rejected the comments by Alameda County Hazardous Waste and Douglas Barcon.

Regarding section 1776.3(j), board members rejected the comment by San Francisco Department of Environment recommending the wording "promptly."

Regarding section 1776.3(m), board members rejected the comment from San Francisco Department of Environment about Sharps for reasons discussed earlier in the meeting.

Regarding section 1776.4(a), board members agreed to remove the sentence cited in the comments from San Francisco Department of Environment and city of Santa Rosa. President Gutierrez said the sentence implies that the pharmacy has to permit a skilled nursing facility to hand out envelopes.

Regarding section 1776.4(c), board members agreed with staff rejection of the comment.

Regarding section 1776.4(g)(2), board members rejected the comment by Kaiser for reasons discussed earlier in the meeting. The board also rejected the comment from Douglas Barcon, noting that pharmacy staff may wear gloves but do not have to wear gloves. The board also rejected the comment from city of

Santa Rosa for reasons discussed earlier in the meeting. The board also agreed to add “sealable” third sentence, as previously discussed in the meeting.

Regarding section 1776.4(h), the board agreed to remove “established by the pharmacy” from the third sentence. Ms. Herold said the board does not want to prohibit the reverse distributor from handing the liner to the pharmacy. She said there is no reason that a reverse distributor that is providing a bag to a pharmacy could not also serialize it.

Regarding section 1776.5(e), the board agreed with staff recommendation to modify the language as recommended by commenter Sharps.

Regarding section 1776.5(e)-(f), board members agreed with staff rejection of comment by city of Santa Rosa and comment by San Francisco Department of Environment.

Regarding section 1776.6, the board rejected the comment by city of Santa Rosa. Ms. Martinez said staff would go through the final language to make sure all the authority and reference citations are correct.

Regarding section 1776.6(a)(1), the board rejected comment by Alameda County Hazardous Waste. Staff noted that this is a DEA requirement.

The board rejected a general comment from San Luis Obispo stating that creating the regulations exceeds the scope of the board’s authority. Ms. Freedman said that the board has authority to regulate what happens in pharmacies; how pharmacists behave and what is professional conduct and what is not; and to enforce federal law. Based on all that authority, she said, the board also has authority to create take-back regulations. Ms. Herold added that the End of Life Option Act also specifically directed the board to develop a process.

The board rejected a comment by San Luis Obispo stating that the regulations would have a negative impact on the environment by forcing kiosks to close. Ms. Freedman said the comment indicated that the board was required to do an EIR under CEQA. She advised the board that the take-back regulations do not qualify as a “project” under CEQA – and even if it did, there are exemptions that would apply in this case.

Regarding a general comment from San Francisco Department of Environment that the board regulations mirror the DEA regulations, President Gutierrez said that has been the intent of the board.

The board rejected a comment about section 1776 from Gordon Miller, who said localities should be allowed to use DEA regulations to administer drug take-back programs. President Gutierrez said that was the board’s intent when the take-back regulations were created. She also noted that pharmacies do have to follow DEA regulations.

The board agreed to adopt three grammatical changes recommended by County of Los Angeles for sections 1776.6(a)(2), 1776.6(a)(4) and 1776.6(a)(5).

Ms. Freedman called the board’s attention to comments regarding section 1776.5(c), which requires two employees of the reverse distributor to pick up or receive inner liners from DEA registrants. She said the language should be amended to match the DEA requirement that only one employee is required to accept delivery. She recommended breaking the sentence into two sentences, with one stating that two employees are required to pick up inner liners and one employee may accept deliveries of inner liners. The board agreed.

Ms. Freedman and the board also clarified that, in section 1776.4, the board's intent is to remove the sentence: "The pharmacy may allow skilled nursing facility employees to distribute mail back envelopes or packages to consumers."

Patrick Holland from County of Los Angeles Department of Public Works expressed several concerns about the regulations. He said that putting EpiPens in a sharps container to be processed in an autoclave would not destroy the medication. Mr. Schaad and Mr. Weisser replied that an autoclave would destroy the drug. Mr. Holland cited an email from the Chief of the Medical Waste Management program of the California Department of Public Health advising that the medication would not be destroyed in an autoclave.

Mr. Holland also disagreed about language permitting a pharmacist to use professional judgment to decide not to host a collection bin. He said the language could cause conflicts in areas like Santa Cruz, which mandates pharmacy participation in take-back programs. President Gutierrez said legal counsel has advised the board that any such conflict would have to be decided by courts.

President Gutierrez read aloud the CDPH email regarding EpiPens, which advised against putting EpiPens in a Sharps container and suggested adding labels to take-back kiosks advising consumers what items should not be placed in them. Ms. Herold said the board chose to restrict labeling on take-back containers to a minimum. President Gutierrez said the board did not want people to simply dump all their syringes and needles in take-back bins.

Mr. Holland suggested an exception to allow Sharps with a self-injected drug attached to them to be deposited in take-back bins. Ms. Herold pointed out that such an exception would allow syringes that have residual medication in them to be deposited as well, which would pose a risk to anyone who handles the collection bin liner.

President Gutierrez asked if "medical Sharps and needles" is the same as a drug product that has a needle attached. Mr. Weisser said that if the board's intent is to protect anybody handling the liners from needle sticks, then the ban on Sharps and needles should remain in the regulation. Ms. Herold noted that the liner standards adopted by the board are not tough enough to prevent a needle stick.

Ms. Herold acknowledged that EpiPens and bronchial inhalers pose an issue. President Gutierrez said that, after the regulations are adopted, the board should issue some guidance and clear instructions to deal with the issue.

Stan Goldberg asked about drug destruction in lower-level care facilities such as assisted-living facilities and board-and-care facilities. He asked if those types of facilities could use products such as Rx Destroyer to render drugs unusable, or a mail-back bag to be sent to a DEA-approved reverse distributor, to destroy medications, including controlled medications. He said the facility would keep a log signed by two facility employees, and when the bag is full, it would be sent to the reverse distributor and properly destroyed.

Ms. Herold said that DEA regulations are for skilled-nursing facilities only. She said the care facilities described by Mr. Goldenberg would be under the auspices of a Department of Social Services licensed-care provider. Ms. Herold stated the facilities can go to law enforcement, use mail-back envelopes and drug destroyer products, but DEA regulations prohibit returning the drugs to the pharmacy.

Mr. Goldenberg asked about pharmacies taking an Rx Destroyer container from these facilities and placing it into a biohazard-waste receptacle. Ms. Herold said products like Rx Destroyer are outside the scope of the board's regulations.

Steve Gray of Kaiser Permanente advised the board that needles used in EpiPens retract after the medication is injected, but the needles do not retract in the generic version of the drug. He also said that many Sharps containers have syringes that still have drugs in them because not all of the drug is used.

Dr. Gray also said that some pilot take-back programs have collection bins with slots or small openings that require users to take pills out of the bottles and containers and put them directly into the bin without the bottle or container. He said the result is often that pills are left on the floor around the bin. He added that some slot openings are not secure mechanisms like mailboxes that prevent users from reaching inside. In other states, he said, thieves have used a vacuum tube to suck the loose pills out of the bins.

Robert Stein, speaking as an individual, pointed out that all the responsibility and liability for drug take-back falls on the pharmacists and not on consumers.

Paige Talley of the California Council for the Advancement of Pharmacy warned that the board's regulations could conflict with existing rules by CDPH and Department of Waste Management on destroying medications in care facilities. Board members said any conflict could be raised during the next comment period.

Ms. Freedman told the board that section 1776.4(c) regarding removal, transfer or storage of inner liners from a collection bin in a skilled-nursing facility conflicts with section 1776.4(k), which also addresses the removal, collection or storage of liners. Section 1776.4(c) says only the pharmacy shall remove, seal, transfer, store or supervise those actions, but section 1776.4(k) says those actions shall be performed only by one collector-pharmacy employee and one supervisory level employee of the long-term care facility, or by or under the supervision of two employees of the collector pharmacy.

Ms. Freedman recommended deleting section 1776.4(c) entirely. Ms. Herold agreed that section 1776.4(c) was not necessary because it has little impact. The board agreed.

Motion: Notice the regulations for a 15-day comment period.

M/S: Weisser/Law

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

The board recessed for a lunch break at 1:44 p.m. and reconvened at 2:04 p.m.

VIII. Discussion and Consideration of Proposed Regulations to Amend Title 16 CCR sections 1732.05, 1732.2

and 1732.5 related to Continuing Education

President Gutierrez reported that the board had reviewed this item before and noted that in July, the board discussed and recommended consolidating the six specific subject areas into a board-provided CE course in law and ethics. She said the board approved a modified text and initiated a 15-day comment period that began on Aug. 3, 2016, and ended on Aug. 18, 2016.

President Gutierrez reported that the board received one comment during the 15-day comment period. She noted that the comment was anonymous and read: "There should be no Board provided CE requirement at all. All CE should be ACPE accredited and the pharmacist be allowed flexibility to choose among any general CE's that would meet the requirement for license renewal. This is an outrage to mandate pharmacists to take board provided CE's when pharmacists are licensed in multiple states."

Mr. Lippe asked whether there would be a charge for board-provided CE, and President Gutierrez asked about what happens to pharmacists who reside outside California. Ms. Herold said the CE would be available at least in video form and possibly also in webinar form, as well as perhaps a CE form in the newsletter. She noted that the board already provides CE this way, and the only difference is that this CE will be focused on a single topic. She added that the board currently provides CE at no charge.

President Gutierrez said that she was concerned that pharmacists have sufficient access to the CE course. Ms. Herold said the webinar format would be "on demand" and that staff could explore other methods of access, including a YouTube video. She said this would be a new opportunity for the board to explore and use different types of technology to provide CE training.

Brian Warren of the California Pharmacists Association told the board that pharmacists should not have to take board-provided law and ethics CE. He noted that pharmacists already take law and ethics CE courses in various venues throughout the state. He said that they should be able to apply that course to satisfy this CE requirement, unless the board believes there are certain law and ethics areas that are not being provided and that the board wants to provide. In addition, he asked CE provided by the board in person would be accredited by ACPE.

President Gutierrez replied that, based on previous board discussions, the board believes that there sometimes pharmacists do not understand or have trouble complying with new regulations issued by the board. She said that board-provided CE would provide an opportunity for the board to educate pharmacists on those targeted areas.

President Gutierrez also suggested asking the License Committee to look at how the board-provided CE could be done, how it could be accessed by pharmacist and other details about how it would work. Mr. Weisser said the Licensing Committee would be willing to do that.

Ms. Freedman added that board-provided CE does not need to be accredited by ACPE. She explained that the board has authority to approve its own CE course.

Steve Gray of Kaiser Permanente, speaking on his own behalf, expressed support for the board's decision to require two hours of CE on law and ethics rather than six hours on various subjects. He encouraged the Licensing Committee to consider what standards would be used to measure whether pharmacists are actively learning from the board-provided CE course.

Mr. Weisser noted that many educational institutions, including universities and accrediting bodies, struggle with how to measure learning outcomes. President Gutierrez suggested that pharmacy schools

could be invited to advise the Licensing Committee on this issue.

Motion: Adopt the regulatory language as approved on July 27, 2016, and delegate authority to the executive officer to make technical and non-substantive changes as may be required by the Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

M/S: Veale/Sanchez

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

IX. Pending Compounding Regulations, Title 16 California Code of Regulations, 1735 et seq., and 1751 et seq.; Status Update and Discussion and Consideration of Next Steps, If Necessary

President Gutierrez reported that on Sept. 14, 2016, the Office of Administrative Law approved the board's compounding regulations, which go into effect Jan. 1, 2017.

President Gutierrez noted that the compounding regulations contain provisions that will require construction be undertaken in some pharmacies. She said that such construction may require a temporary time waiver to permit a pharmacy to do the structural modifications required. She noted that a process to do this will be completed shortly.

The board meeting materials included slides by Ms. Herold of draft procedures for requesting a waiver. Ms. Herold said that she and Supervising Inspector Christine Acosta also developed a standard form package for waiver requests that Ms. Herold planned to discuss with Ms. Freedman the next day.

President Gutierrez suggested developing a standardized waiver request form that would be available to pharmacies that want to use it and would everyone know what information is required for a request.

Ms. Acosta told the board that she has been collecting questions, license numbers and other information from pharmacists seeking information about the waiver process. She advised that pharmacies perform a gap analysis to determine what changes need to be made to comply with the compounding regulations. She added that the board currently is not accepting waiver requests.

President Gutierrez and Dr. Acosta clarified that waivers would be available only for physical changes in facilities that need to be done to comply with the new regulations, not for other matters such as training. Ms. Acosta added that the waiver allows only a delay in compliance.

Mr. Lippe asked if there could be anything else besides construction that would be a legitimate reason for seeking a waiver for time. Dr. Acosta said the law is written in a way that does not allow the board to approve a waiver for any reason that is not construction. President Gutierrez noted that the draft regulations had been public for a year, affording plenty of time for pharmacies to know what would be required by the new regulations.

Ms. Herold said that typically there is a period of educational compliance when the board issues major new regulations. She said that for the past year, inspectors have been training pharmacists about the new regulations during annual inspections of sterile compounding pharmacies. President Gutierrez noted an earlier question about what happens if a pharmacy cannot escape a lease in time to comply with the new regulations; Dr. Acosta said the new law would not allow a delay in compliance if there were no construction or alteration to the physical environment.

Mr. Law asked if a hospital currently is doing sterile compounding, and some construction changes are needed, could the hospital continue compounding at the current site while construction is being done at a new facility. Supervising Inspector Acosta said it is not clear if the regulation allows for a waiver for construction being done at a new facility, so the board would have to decide. President Gutierrez said board members would gain a better understanding of issues once it begins receiving waiver requests. She added that OSHPD also would be involved in waiver issues.

Supervising Inspector Acosta said many licensees are ready to begin submitted documentation. Ms. Herold said a form for waivers has been developed and that she would review it the next day with Ms. Freedman. President Gutierrez asked that the form be brought to the October board meeting and suggested that the board reconvene its compounding group – including Mr. Schaad, Ms. Freedman and Ms. Herold – to work on the form and bring it to the October meeting.

Supervising Inspector Acosta said she expects to receive 800 waiver requests. She also asked if the waiver process would apply to NSE, who must meet the same requirements and are also asking about the process. She said that if board review of each waiver request would take a lot of time, so she hopes to move forward as quickly as possible. Ms. Herold noted that the board would be asking licensees what they intend to do about compounding while the waiver process is pending.

Ms. Freedman noted that licensees would not be required to use the waiver form developed by the board because it is not part of the regulations. She asked if the form should go to the full board before it is released to the public and noted that it could change over time. Ms. Herold said the board would not be asking to see construction plans. Mr. Weiser noted that construction necessary for some pharmacies to comply with the new regulations could take years. Ms. Herold said that the board would work on those types of issues with OSHPD in the review process. President Gutierrez said that having OSHPD involved in the review group would help minimize delays.

Brian Warren of California Pharmacists Association asked about a time frame for releasing a recommended form. Ms. Herold said it would depend on how quickly a team to review the process could be assembled. She added that the general parameters of what information pharmacies will be required to submit were outlined in a power point presentation at an Enforcement Committee meeting last month. She said the form would be straightforward and easy to complete and would not require an architect to complete it.

Ms. Freedman added that the form also would not be required. Ms. Herold said the form would be "guidance."

Mr. Warren asked who would review the waivers. Ms. Herold said waivers would be two board members, until the board decides to give that duty to board staff. President Gutierrez said it would helpful for stakeholders on the inspectors' staff to also be involved.

Ms. Acosta suggested that she and another inspector work with the board to review five to 20 waiver forms, get a sense of what the board wants and then take over the task to keep the process moving quickly. If staff members have any questions, they can be presented to the board. President Gutierrez said she agreed with the suggestion.

Mr. Warren asked if the board would require licensees to specify a projected completion date for construction and what would happen if construction were not completed by that date. Ms. Herold said the draft waiver form includes the following questions: Is there an architect? If so, who? Is this a structural modification? Have building plans been developed – yes or no? Has a building permit been secured? What is the time frame for completion of construction. She added that, for health-care providers that would have to use OSHPD, the board also would ask for a copy of the project completion timeline and the general OSHPD project number so that board staff could track the project online.

President Gutierrez asked about the status of FAQs for sterile compounding. Ms. Freedman said she would be discussing the FAQs with Ms. Herold the next day. President Gutierrez said the FAQs would help address many questions about the new regulations. Ms. Herold added that staff is working on a self-assessment form for sterile compounding.

Mr. Warren asked about compounding of hazardous drugs. He said the definitions in the regulations of hazardous drugs specifically initially referred to antineoplastic drugs identified by NIOSH, which has three tables of hazardous drugs – one of antineoplastics and two of nonantineoplactics. He said pharmacies believed the nonantineoplastics were not going to be considered hazardous, according to the regulations. But subsequent communication that the language regarding "any other drug deemed hazardous by the PIC," and there would be an expectation that there are many drugs on those other two tables of the NIOSH list that ought to be considered hazardous. He said that this has drawn the recent attention of non-sterile compounding pharmacies, who had not expected that this would apply to them.

Mr. Warren said that USP 800 allows for pharmacies to do a risk assessment in which they look at their compounding of one of those drugs on the NIOSH list but, based on the process they are using, the PPE they are using and the engineering control they are using, there is no risk of contamination. He said USP 800, for non-sterile compounding, allows a pharmacy to deem a drug "nonhazardous" in that specific process. He asked if the board is going to take a similar view for pharmacies in terms of doing a risk assessment consistent with USP 800 so that for certain drugs, although they may appear on the NIOSH list, the full-blown USP 800 or negative-pressure room is not required for something that has controls in there.

President Gutierrez asked for the difference between doing a risk assessment and having the PIC identify what is considered hazardous. She said she saw them as similar. Supervising Inspector Acosta said USP 800 asks for an assessment but requires all drugs on all three NIOSH lists to be handled as hazardous drugs. She said that USP 800 does not allow for exclusion of any of the drugs. She said that the board's regulations allow pharmacists to do a risk assessment and use their professional judgment in determining how they handle and use a hazardous drug in their facility for nonantineoplastics. She said the board wanted to do what it could to not hinder the practice of pharmacy while still protecting patients.

Mr. Schaad said the list includes a lot of commonly dispensed drugs, such as Dilantin, Tegretol and others, that meet NIOSH criteria for hazardous drugs. He indicated the list raises concerns about regulatory compliance. Mr. Warren said that USP says that an entity must maintain a list of hazardous drugs "which

may include items on the current NIOSH list." In addition, he said, USP says that "any antineoplastic HD must follow the requirements in this chapter" and "dosage forms of other hazardous drugs on the NIOSH list the entity may perform an assessment risk to determine alternative containment strategies." He said those alternative containment strategies may be for certain drugs that are on the NIOSH list that, when treated with a certain procedure, do not need the full requirements of the chapter 800 – mainly, the negative pressure room – because the risk of exposure has been mitigated by specific procedures that the pharmacy has performed a risk assessment for and determined that the risk of contamination is low enough that they should not be deemed hazardous.

Supervising Inspector Acosta said that she and Mr. Warren agree on the issue while relying on different sections of USP 800. She said that, while NIOSH may designate a drug as a hazardous drugs, if one looks at how it is being handled – such as a commonly dispensed drug cited by Mr. Schaad – it may not need all of the protection and room requirements needed in 800.

Mr. Schaad agreed and said he wants to ensure that the public can obtain the drugs without too much regulatory, bureaucratic burden. He said he wants to make sure that the board, while in the business of public protection, uses common sense in the enforcement of it.

Mr. Warren said that pharmacists also want common-sense enforcement as well as clarity. He noted that USP 800 lays out more detail by requiring that, if there is a drug on the NIOSH list that a pharmacist is not going to deem hazardous for how it is being used, the pharmacist must perform a risk assessment. He noted that the regulations say simply "in the PIC's judgment," which is less detailed. He said the USP 800 procedure for performing a risk assessment provides greater clarity to pharmacies that are in this situation. He said that if a pharmacy does not have to construct an entire negative pressure room for certain compounding, that could make the difference between the board receiving several dozen waiver requests versus waiver requests from all 900 compounding pharmacies.

President Gutierrez said that if she were a PIC who performs a self-assessment and determines that a nonantineoplastic drug is not a hazardous agent, she would not have to include the drug on the list and would have some justification for that. Mr. Warren agreed and said he would like clarity from the board that he and the board are in agreement on this question. He said that although the agent is still hazardous, what the pharmacist is doing with it has mitigated that hazard. President Gutierrez said they were in agreement.

Supervising Inspector Acosta said the regulations could have been more clear. Instead of "the professional judgment of the pharmacist," the board could have said "after a risk assessment is performed by the PIC" or something to that effect. She said the board is allowing the PIC to use professional judgment to determine if the product and form and manipulations being performed are considered hazardous. She said the board gave California pharmacists a bit of leeway in the way the regulations are written, but it also created a gray area that raised concern among pharmacists.

Mr. Warren said his organization is trying to establish guidelines for its members so they can feel more comfortable in complying with the regulations. President Gutierrez said the board shares that goal, and she called for feedback back and forth between the board and pharmacists to ensure that understanding is there.

Ms. Freedman noted that the board had a specific motion on the floor. She recommended that the board focus on comments related to the particular motion to resolve the motion and then move on to other comments related to the agenda item so that the board could take further action if necessary, based on the comments being received. Ms. Freedman read the motion to authorize Mr. Schaad and President

Gutierrez to work with staff to help develop the waiver process and review a sample form that will be made available to the public.

President Gutierrez agreed and asked Mr. Warren if he had any comments related to the pending motion. Mr. Warren said the board has discussed that USP 800, for nonsterile hazardous drugs, allows the use of redundant HEPA filtration instead of external ventilation – but the board's regulations do not allow for that. He said that is a big difference which the board has acknowledged and has said can be cleared up with follow-up regulations.

Mr. Warren asked if there is any way to deal with this problem through the waiver process, because the regulations take effect on Jan. 1 – and even if the board were to file rulemaking immediately, pharmacists still would have an extensive period of time during which it would not be allowed. He asked if there is a way to deal with this issue so that those pharmacies are not harmed. He said that even pharmacies that have been pro-active in trying to comply with USP 800 have already purchased those redundant HEPA filtration hoods at a cost of about $20,000 each, and now the regulations might not even allow them to use that equipment.

Ms. Freedman noted that the waiver is specifically for physical alterations. Board members discussed whether the issue is one involving only equipment or physical alteration. President Gutierrez said pharmacies would not have to do physical construction because they have the possibility of redundant HEPA filters. Supervising Inspector Acosta said the board could consider a regulation that would allow pharmacies not to do physical construction. President Gutierrez said that would be appropriate as long as it is for non-sterile compounding.

Supervising Inspector Acosta said pharmacies are going to have to externally vent the rooms anyway, so they want the HEPA filters so that they do not have to vent the box or biological safety cabinet that they are compounding in. But she said pharmacies still have to vent the rooms, so the question is whether the board is going to allow a waiver process for the redundant HEPA filter and then an additional one for not externally venting the room.

Ms. Freedman said those types of questions would be presented best on a case-by-case basis which can be addressed as those requests begin coming to the board. She added that right now, the board is talking about the waiver process and form and the pending motion is about delegating authority to President Gutierrez and Mr. Schaad to work with staff to develop something that the board can use. President Gutierrez agreed and said the board would get a better feel on how to handle issues as cases arrive. Mr. Schaad agreed.

Ken Schell, PIC and director of pharmacy at Sharp Grossmont Hospital, offered his services to the board group working on the waiver form process. Paige Talley of California Council for the Advancement of Pharmacy asked if a pharmacist who is not allowed by the property owner to make alterations and is looking to get out of the lease could receive a waiver. Ms. Herold said that situation would not qualify for a construction waiver.

Motion: Authorize President Gutierrez and Board Member Schaad to work with staff to develop a recommended format that can be distributed to stakeholders so that they understand what is being requested of them in the waiver process.

M/S: Gutierrez/Sanchez

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Muñoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

President Gutierrez invited Mr. Warren for additional comments. Mr. Warren said that CPhA members want to know if the board will accept published literature for determining a BUD for specific formulations or will it require an in-house study for all BUDs.

Ms. Freedman said the question is related to enforcement. She the board meeting was an awkward forum for resolving the issue and suggested submitting questions that could be addressed with FAQs. Mr. Warren agreed and added that time is of the essence.

Mr. Schaad asked what published literature Mr. Warren was suggesting. Mr. Warren said the question is whether each pharmacy would have to do its own in-house study for establishing BUDs.

Supervising Inspector Acosta said pharmacies want to know if they can use another pharmacy's stability study in its own operations. She said the issue is specifically addressed in the new regulations, section 1735.2(i)(4), which says, that in addition to the requirements in paragraph (3), which is about the extension of the BUD, "the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews and packaging as the finished drug or compounded drug preparation." She said the regulation is alluding that if pharmacies meet that criteria, it may be possible to use somebody else's study. But she added that they have to meet that criteria – so the answer is yes and no.

Mr. Warren said another question deals with the conflict between what is in the statute for sterile compounding and what is in the regulations for hazardous compounding. He said the B&P Code requires all sterile compounding to be done in a positive air pressure differential room, and the regulations require all hazardous compounding – including hazardous sterile compounding – to be done in a negative pressure room. He said the room cannot be both positive and negative at the same time.

Mr. Warren recommended that the board enforce the regulations, which is consistent with USP 800 as far as how to deal with sterile hazardous compounding. He said the question is one where pharmacies, which may need to make a physical change, need to know what the board is going to expect to be doing on Jan. 1 and whether they need to change the air pressure differentials or make any construction changes before then, or perhaps submit a waiver.

President Gutierrez said the board needs to have these types of FAQs come up and then take a look at them. Mr. Schaad agreed. President Gutierrez said the board would be modifying and adding to the first draft of FAQs. She said the board's goal is not to play "gotcha" with pharmacies but to improve and elevate the practice of pharmacy in California.

Mr. Warren said his organization wants the pharmacies to be clear on what they are expected to do. He said they need clarity as soon as possible, because these are questions that may require physical changes to be made at the pharmacy.

Mr. Warren also said that B&P Code section 4127.7 requires that all compounding be done in an ISO class 5 hood within an ISO class 7 cleanroom – while the regulations define an ante-area which can be ISO class 8 or better, which can include staging components and other high-particulate generating activities. He said CPhA is seeking clarity from the board as to whether this allows for pre-sterilization procedures to be performed in the ante-area, which he said is a good policy and consistent with FDA guidance on insanitary conditions. He said the regulations do not make the board's intent clear regarding allowing the pre-sterilization procedures to be performed in the ante-area. He said he would submit the question to the board.

Ms. Herold asked if the B&P Code needs to be amended to remove inconsistencies and conflicts with the recently approved regulations. Board members said yes. Ms. Herold said staff could present proposed legislation at the October board meeting that could be an omnibus provision.

Supervising Inspector Acosta agreed and said the board needs to change section 4127.7 and also needs to address building code 1250.4 which conflicts with CGMPs and the board's pending regulations. Ms. Herold said that would be a three-year process, and Supervising Inspector Acosta suggested that the board and legal counsel could find a way to work around the building code.

Ms. Freedman noted that the statute will trump a regulation. She said that staff will develop ways to resolve inconsistencies.

Paige Talley of California Council for the Advancement of Pharmacy asked if section 1735.2(F), which says "30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations" in reference to BUDs, means when the compounding pharmacist is adding water to that product. She said many of the bases come with water in them that pharmacists are not adding. She asked if any water-based base that is used has to be 30 days or less.

President Gutierrez said it was a good question to submit for the FAQs. Supervising Inspector Acosta said she would refer pharmacists to section USP 795 for a clearer answer. Ms. Talley asked that the question be addressed in an FAQ.

Ms. Kellogg suggested that the regulations are sufficiently clear and said there may be a few areas where FAQs are needed. She said it is important for the board to move forward. Ms. Talley said that she had more questions. President Gutierrez asked her to submit them for consideration for FAQs. Ms. Freedman said she agreed with Ms. Kellogg and that clarification about what the regulations require would best be handled by FAQs. Ms. Talley said she would submit the questions for consideration.

X. Federal Food and Drug Administration's Draft Guidance Documents – Discussion and Consideration, Including Whether to Submit Board Comments, regarding:

1. **Insanitary Conditions at Compounding Facilities**
2. **Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug and Cosmetic Act**
3. **Compounded Drug Products That are Essentially Copies of Approved Drug Products Under Section**

503A of the Federal Food, Drug and Cosmetic Act

President Gutierrez reported that the FDA had released these documents regarding compounding and said they are still in draft form. She said that the FDA notes in each of these documents that the guidance documents "do not establish legally enforceable responsibilities. Instead, the guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited."

President Gutierrez said that at its Aug. 31 meeting, the Enforcement Committee discussed several of the guidance documents which contain proposed elements for FDA regulation. She said the committee determined that comments should be submitted on the guidance documents and asked staff to draft comments for the board to review and approve at its next meeting. Ms. Herold said comments are due within 15 to 20 days, by mid-October.

President Gutierrez noted that Ms. Herold had just attended the FDA's *50-State Meeting on Compounding* on Sept. 20-21. She asked Ms. Herold to update the board on the meeting.

Ms. Herold said the FDA is mostly emphasizing the document on insanitary conditions at this time. She said it was done in the wake of complaints by California and other states about the FDA inspecting and holding 503A compounding pharmacies to good-manufacturing practices, which is the standard for outsourcing facilities – a very high standard that few pharmacies can meet. She said this action forced the pharmacies to issue a recall, retract a lot of product and, in some cases, stop sterile compounding.

Ms. Herold reported that the insanitary guidelines list conditions under which the FDA will take action against either a compounding pharmacy or an outsourcing facility and, if a product is adulterated, will order a recall. She added that she was not aware of any outsourcer that has been required to do this.

Mr. Weisser asked if the document was pushed by the industry in an effort to limit providers who are compounding products. Ms. Herold said she believed that what is happening is that the FDA wants to get to a point where pharmacies are compounding, with rare exceptions, only patient-specific drugs with a prescription in hand. The FDA does not support pharmacies compounding for prescriber-office use unless the entity is an outsourcer, in which case the company is held to CGMPs.

Ms. Herold said she pointed out at the FDA meeting that no one regulates compounding in physicians' offices. She said that if the board – which has a statute authorizing the board to oversee compounding for future use for prescribers – stops doing that, more drugs potentially will be made in physicians' offices, because pharmacies would no longer be providing the drugs for doctors' offices.

President Gutierrez asked if USP 800 is restricted to only pharmacies. Ms. Herold said physicians can compound too, and Mr. Schaad noted that there would be no enforcement. President Gutierrez said the board should reach out to the Medical Board to take action for its licensees just as the Board of Pharmacy is doing. Ms. Herold said the discussion with the Medical Board has been about whether California law even allows physicians to compound. She said that she and the Medical Board executive officer have discussed establishing regular group meetings between board meetings to share issues of concern.

President Gutierrez noted that federal standards for compounding apply to all – not just to pharmacy preparation – and suggested that the state should be enforcing it as well in all areas where preparation takes place. Ms. Herold said the Medical Board would be responsible for enforcing compounding by physicians. Mr. Weisser noted that is not an area where the Medical Board has expertise. Ms. Herold said that some physicians' offices hire pharmacy technicians – who are simply employees in that setting, not

pharmacy technicians – to do compounding.

Ms. Herold added that the Veterinary Board is in the process of developing regulations for compounding in veterinary offices for their own patients. She added that they would not be allowing sterile compounding in veterinary offices.

Ms. Herold said it was unclear how many physicians' offices do compounding. She added that some specialties do it more than others.

Ms. Herold said the FDA would continue to use the insanitary conditions guidelines in pharmacies to force recalls and push for a higher standard. She added that one way around that would be for the board to sign an MOU. She said that without it, the FDA would limit cross-state transmission to 5 percent.

Jody Jacobson, a pharmacist, asked how a state agency charged with protecting consumers could allow the Medical Board not to put consumers at risk by not regulating compounding in physicians' office.

Ms. Herold asked the board for approval to work with President Gutierrez on comments for the FDA on the guidance documents. Mr. Weisser recommended that Mr. Schaad also be involved in drafting the comments.

Ms. Herold said that one issue being discussed regarding 503B facilities is whether they involve making a copy of a commercially available drug. She said the guidance document is clear that if duplicating a commercially available product is not permitted, unless there is a drug shortage. She said that is to protect manufacturers who have gone through ANDA and NDA testing for their drug products. She said outsourcers do not do stability studies and other necessary documentation, and that threatens the drug approval process and does not protect consumers.

Mr. Schaad said he disagreed with that argument. He said the issue is something that is being pushed by drug manufacturers and is contrary to the laws and regulations that the board enforces.

Andrew Harrison, chief counsel for Pharmedium Services, a 503B outsourcing facility, provided a statement. He said the FDA was incorrectly applying the clinical difference documentation requirement to drugs made without any bulk substance API, such as drugs that are compounded using a sterile-to-sterile process to develop the compounded drug product. He said the guidance blurs the line between 503A pharmacies and 503B outsourcing facilities. He said the FDA document fails to address the public health objective that is stated in the intent of the statute.

Grace Magedman of Children's Hospital of Orange County (CHOC) urged the board to draft comments to the FDA on the compounding of essentially copied products. She said that many commercially made drugs are intended for adults and do not have a pediatric indication. She said CHOC is required to purchase the drugs, which can be very expensive and detrimental to patient care.

Motion: Direct the executive officer to work with President Gutierrez and Mr. Schaad to draft a response to the FDA on the three guidance documents listed on the board's agenda.

M/S: Law/Weisser

Yes: 9 No: 0 Abstain: 0

Name	Yes	No	Abstain	Not Present
Brooks				x

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

The board recessed at 3:42 p.m. for closed session

The board adjourned in closed session at 5:10 p.m.