



**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
DRAFT
MINUTES**

DATE: January 24-25, 2017

LOCATION: Hilton Glendale
100 West Glenoaks Blvd.
Glendale, CA 91202

BOARD MEMBERS PRESENT: Amy Gutierrez, PharmD, President (January 24 only)
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Lavanza Butler, RPh
Greg Lippe, Public Member
Valerie Muñoz, Public Member (January 24 only)
Ricardo Sanchez, Public Member
Allen Schaad, RPh
Stanley Weiser, RPh
Albert Wong, RPh

BOARD MEMBERS NOT PRESENT: Ryan Brooks, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Counsel
Desiree Icaza Kellogg, Deputy Attorney General
Debbie Damoth, Staff Manager

Call to Order

10:01 a.m.

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

President Gutierrez called the meeting to order at 10:01 a.m. Board members present: Greg Lippe, Lavanza Butler, Valerie Munoz, Stanley Weisser, Victor Law, Amy Gutierrez, Debbie Veale, Albert Wong, Ricardo Sanchez and Allen Schaad.

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

Morgan McCloud, representing Road Runner Veterinary Compounding Pharmacy located in Phoenix, Arizona, requested the board exempt veterinary compounding from some of the

requirements in the compounding regulations.

Mr. McCloud reported to the board a colleague Jeremy Schmidt addressed the January 4, 2017, Enforcement and Compounding Committee regarding the recent adoption of new BUD dating and testing for compounding medications and the need for the veterinary community to be exempted from California Code of Regulations (CCR) section 1735.2. Method suitability tests and container closure integrity tests normally associated with sterile products are now mandated for nonsterile products if BUD dating extension is to occur. Additionally, stability studies in the same paragraph can be interpreted differently. Using stability indicators, a common process used in manufacturing could add as much as \$20,000 to the BUD analysis and would significantly raise costs to pet owners, of which most have no insurance dramatically decreasing pet patient care. Due to differences in the practice of veterinary medicine versus human medicine, the Enforcement and Compounding Committee agreed to add the topic to their agenda at the next committee meeting.

Mr. McCloud explained to the board the importance of the request for exemption and to ensure the board is aware of the impact of compounding medications within the veterinary community. He explained in the veterinary practice, it is expected for the veterinarian to have the appropriate medication for the pets. Due to the wide range of patients seen by veterinarians and unavailability of select drugs and strengths, the treatments often come from compounded office stock. Mr. McCloud explained the newly required testing could add as much as \$30,000 annually per a medication leaving pets to go untreated due to the costs. Additionally, the requirement for the practitioner to explain why a compounded product over commercial product has been selected seems counterintuitive. Mr. McCloud continued that mandates requiring the office stock to indicate the number of patients the medication is to serve and quantities expected to administer in the clinic as well as the average volume dispensed for a 120-hour supply are illogical in the typical veterinary practice.

Mr. McCloud requested veterinary medications be exempted for these additional requirements because the medical needs for animals are met differently than those of humans. Due to the on-demand service nature of veterinary medicine, the unique nature of veterinary medicines and dosages, the unavailability of most commercial drugs to meet those needs, Road Runner Veterinary Compounding Pharmacy requests a consideration for exemption in veterinary practices or at least request the board place this item on the agenda for further discussion at the next meeting.

The board asked that representatives from Road Runner Pharmacy attend the April 18, 2017, Enforcement and Compounding Committee meeting where this item would be discussed.

Dr. Rebecca Trotzky provided an update on the narcan (naloxone) distribution in her hospital's emergency room. She indicated that patients are reporting that they are unable to obtain naloxone at a pharmacy. Dr. Trotzky conducted a survey and based on the results, it appears that only 2% of independent pharmacies are aware of the naloxone requirements. She requested that the board work with here to improve education on the ability of pharmacists to provide naloxone. The board asked the Communication and Public Education to discuss ways to educate licensees about the new regulation at its March 23, 2017, meeting and asked Dr. Trotzky to present at the meeting. Stephanie Johnson, a pharmacy technician representing SEIU, discussed the training hours requirements for a pharmacy technician and how it is a barrier to licensure for many people. The

board indicated that this item would be discussed at the April 4, 2017, Licensing Committee meeting.

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Pharmacist Stan Goldenberg suggested that the board consider ways to help pharmacists understand that the board is not “the enemy.” He explained that pharmacists have important information to offer the board about their patients and new ways to protect consumers. The board stated that this is an important topic and asked the Communication and Public Education Committee to discuss it at its next meeting.

III. Approval of the October 26-27, 2016, and December 14, 2016 Board Meeting Minutes

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

Motion: Approve the October 26-27, 2016, Board Meeting minutes.

M/S: Weisser/Lippe

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

President Gutierrez noted that section XI of the December meeting minutes needed to be updated to make all references to “county hospital” plural.

Board Member Veale also noted that the dates for the Enforcement Committee were incorrectly listed.

There were no comments from the public.

Motion: Approve the December 14, 2016, Board Meeting minutes with the two corrections indicated by the board.

M/S: Lippe/Law

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Munoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

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

The board recognized Shirley McCloskey and John Murakami for 50 years of service as pharmacists.

V. Update from the Department of Consumer Affairs

Shelly Jones, manager in the Board and Bureau Relations Unit, provided an update from the Department of Consumers Affairs.

Ms. Jones announced that on January 10, Governor Brown released his proposed 2017-2018 budget.

Ms. Jones reported that on January 13th, Governor Brown appointed Jolie Onodera as the Deputy Secretary of Legislation for the Business, Consumer Services and Housing Agency. Prior to her appointment, Ms. Onodera served as the principal consultant for the Senate Committee on Appropriations.

Ms. Jones reminded the board members that they must complete ethics, sexual harassment prevention and defensive driver trainings. She also stated that board members must attend the Board Member Orientation within one year of their appointment and reappointment to the board.

Ms. Jones reported that DCA's Office of Professional Examination Services (OPES) performs all aspects of the examination validation process, including occupational analyses, examination development, test scoring and statistical analyses, and audits to DCA's regulatory entities. OPES has completed its estimate for an occupational analysis for pharmacy technicians, as well as a linkage study to accept an additional national exam pursuant to SB 952, chaptered during the last legislative cycle. She noted that the estimate was provided to board staff.

Ms. Jones stated that the Department’s [Annual Report](#) is available on the DCA website. She explained that in it, each program notes its major accomplishments for the 2015-2016 fiscal year, as well as new laws or regulations. It also includes licensing and enforcement summaries, staff information and more.

VI. Executive Officer’s Report

a. Discussion and Consideration of Possible Board Comments on the FDA’s Draft Guidance Documents:

1. FDA’s Draft Guidance, *Compounding And Repackaging of Radiopharmaceuticals by Outsourcing Facilities*
2. FDA’s Draft Guidance, *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities*

Ms. Herold explained that the FDA released guidances in advance of the change of the administration. Ms. Herold discussed the two documents and highlighted the differences between outsourcing and compounding pharmacy, including the fact that outsourcing follows cGMPs and allows for non-patient specific compounding. Ms. Herold noted that the nuclear pharmacies are to be regulated like sterile compounding pharmacies.

Ms. Herold advised the board that her recommendation is to not provide comments at this time.

Ms. Veale stated that she would like the board to submit comments so that its position on the two documents would be made public.

Steve Gray, pharmacist, spoke in support of the board submitting comments. Dr. Gray noted that with the change in the administration, it is unclear how federal regulations will proceed. Dr. Gray indicated that it seems appropriate to highlight the significant impact such guidance will have on consumer safety. Dr. Gray also stated that it is appropriate to have pharmacists compound medication in a medical office given their expertise.

Board member Law asked how many nuclear pharmacies are in California and was advised that the board does not maintain statistics as they are not regulated separately.

Motion: Direct the executive office and board president to submit comments on the two FDA draft guidance documents. The comments on the *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities* guidance document will express the board’s support. The comments on the *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities* will express the board’s concerns with prescriber office compounding.

M/S: Veale/Weisser

Support: 10 Oppose: 0 Abstain: 0

Board	Support	Oppose	Abstain	Not Present
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Member				
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

President Gutierrez asked if the FDA has taken any action in regards to the one mile radius requirement for compounded medications that is included in the FDA requirements. Ms. Herold responded that the board had submitted comments and she had expressed the board’s concern verbally at a meeting, but the FDA has not taken any action. President Gutierrez asked staff to continue to track the requirement.

b. Final Guidance Documents Issued by the FDA:

1. FDA Guidance, Prescription Requirement Under Section 503A of the Federal Food, Drug and Cosmetic Act
2. Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act
3. Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Ms. Herold reported that the next issue of *The Script* would include summaries of the three guidance documents listed above.

Board member Schaad asked if the board would receive copies of the electronic drug products for outsourcing facilities that are required by the FDA. Ms. Herold responded that the board would be provided copies and would use the data when board staff begins inspecting the outsourcing facilities.

c. Discussion and Consideration of the Planned Decommissioning of CURES 1.0 by the California Department of Justice on March 5, 2017

Ms. Herold advised the board that CURES 1.0 will be decommissioned on March 5, 2017. Ms. Herold explained that this will result in pharmacists needing to sign in to the new system to access CURES. She also stated that the new system may require pharmacists to update their web browsers.

Ms. Herold noted that the transition to CURES 2.0 is needed to allow for implementation of the SB 482, which created the mandate for prescribers to check the system.

Ms. Herold noted that as of January 19, 2017, there are approximately 126,000 prescribers and approximately 39,600 dispensers registered in CURES.

Ms. Herold indicated that one final letter will be mailed out to pharmacists who are still not registered for CURES.

Dr. Gutierrez noted that some pharmacies incorrectly think that the tamper-proof forms required by Medi-Cal are the same as the controlled substance forms. Ms. Herold responded that they would provide an article clarifying the difference in the next issue of *The Script*.

Board member Law confirmed that a pharmacist that logs into CURES will be redirected to CURES 2.0.

Ms. Herold reported that the board has DOJ contact information on its website for pharmacists to use to receive assistance with the change to CURES 2.0.

d. Discussion and Consideration of a Planned Educational Forum Cohosted by the California State Board of Pharmacy and the Drug Enforcement Administration; Request for Authorization to Award Continuing Education Credits To Attendees

Ms. Herold reported that over the past six years, the board has co-hosted with the Drug Enforcement Administration, educational forums for pharmacists on corresponding responsibility, prescription drug abuse and CURES.

Ms. Herold explained that board staff has been working on a new program that will be offered in San Diego in March. The board members and the public were provided with a draft agenda for the event. She reported that the pharmacists who attend the event will receive seven hours of CE.

Ms. Herold asked the board to approve the course and awarding seven hours of CE for attendees.

President Gutierrez asked that the program be videotaped so that the board can place it on its website. She also asked that staff consider creating a program that specifically focuses on hospital settings.

Board member Weisser encouraged board members to attend the event.

Board member Wong asked that staff hold more of these events in different locations in California.

Dr. Gray, pharmacist, spoke in support of the event but expressed concern with the parking at UC San Diego.

Motion: Approve the course in San Diego and award attendees seven hours of CE Direct staff to hold more events in various locations in California.

M/S: Weisser/Lippe

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

VII. Discussion and Consideration of the Proposed Regulation to Add Title 16 California Code of Regulations (CCR) Section 1715.65, Related to Inventory Reconciliation Report of Controlled Substances

President Gutierrez reported that at the July 2016 Board Meeting, the board approved proposed text to add Title 16 CCR section 1715.65, related to inventory reconciliation reporting. The 45-day comment period began on September 16, 2016, and ended October 31, 2016. She explained that at the December 2016 Board Meeting, the board approved a modified text to address concerns expressed by stakeholders and initiated a 15-day comment period.

President Gutierrez stated that the 15-day comment period began on December 23, 2016, and ended on January 7, 2017. She reported that the board received several comments during the 15-day comment period. The comments were provided in the board meeting materials.

President Gutierrez explained that upon reviewing the comments there is confusion on the language – specifically in regards to the definition of perpetual inventory and what would constitute a significant loss. She asked that the Enforcement Committee review the language and focus on ways to clarify the language.

A representative from Pacific West Pharmacy noted that the regulation will be very cumbersome for pharmacies that dispense large volumes of medication. The board asked him to attend the Enforcement Committee meeting to provide suggestions to improve the language.

The board also discussed the need for the committee to consider what volume of loss needs to be reported to the board. Ms. Herold noted that the law already requires the reporting of *any* loss of controlled substances no matter the volume.

Dr. Gray, from Kaiser, spoke in favor of sending the regulation back to the Enforcement Committee. He added that the DEA developed a report that defines “significant loss.”

Dr. Wong commented that the DEA spends a significant amount of time investigating drug losses even when diversion is not suspected. He added that the board needs to focus on losses that are the result of diversion. Ms. Herold noted that the board often works with the DEA on investigations.

Motion: Return the Regulation to Add Title 16 California Code of Regulations (CCR) Section 1715.65, Related to Inventory Reconciliation Report of Controlled Substances to the Enforcement Committee for further review and clarification.

M/S: Lippe/Law

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

A pharmacist noted that in the hospice care setting having a perpetual inventory would be difficult due to the high volume of controlled substances provided to patients.

Motion: Direct the Enforcement Committee to consider creating thresholds of controlled substance losses for purposes of reporting to the board.

M/S: Weisser/Veale

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			

Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

VIII. Discussion and Consideration of the Proposed Regulation to Add Title 16 CCR Section 1746.5, Related to Travel Medications

President Gutierrez reported that at the June 2015 Board Meeting, the board approved proposed text to add Title 16 CCR section 1746.5, related to Travel Medications. She noted that on April 27, 2016, following a 45-day comment period and two 15-day comment periods, the board adopted the regulation language and delegated to the executive officer the authority to make technical or nonsubstantive changes as may be required by Office of Administrative Law (OAL) or the Department of Consumer Affairs to complete the rulemaking file.

DCA Staff Counsel Laura Freedman explained that on December 27, 2016, OAL identified some problems and disapproved the regulation due to issues with clarity, consistency, and necessity. She explained that the main problem OAL had was the difference in the reporting time for travel medicine vs. the reporting time for vaccinations. Staff recommended changing the reporting time to 14 days so that it is consistent with the reporting time for vaccinations.

Ms. Freedman reviewed the *staff recommended modified text* that was provided in the board meeting materials. She explained that the modifications recommended by staff were made to address the concerns raised by OAL.

Ms. Freedman explained that the *staff recommended modified text* was given to OAL for review and they provided some additional recommendations as follows:

- Change section (a)(1) to read: “For a condition that is recognized as both self-diagnosable and recognized as self-treatable...”
- Change the language in (a)(2) so that it makes reference to the use of a prophylactic as recommended by the CDC.
- Change (b)(2) to read: “...section 4052(a)(10)(A)(3) of the Business and Professions Code (hereafter, “travel medications”) shall follow the requirements of this section.”
- Change section (f) to replace “and/or” with “or.”
- Change section (g) to clarify that the written document provided to the patient may be different than the “patient medication record” that the pharmacist must maintain. The board recommended using the term “written document.”

Ms. Freedman noted that OAL also suggested changing the language in (g) to read: “For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner an automated data processing or manual record mode ...”

Ms. Freedman recommended not making the change as the current language is clearer. The board agreed with Ms. Freedman’s recommendation.

Mr. Schaad asked why pharmacists are required to be certified in basic life support. Ms. Herold responded that it is required in order to be able to provide immunizations.

Ms. Freedman noted that even though the language referring to an example document being provided on the board’s website was removed, it doesn’t prevent the board from creating a sample document to provide to pharmacists.

There were no comments from the public.

Motion: Adopt the “Staff Recommended Modified Text” including the changes discussed at the meeting and notice the language for a 15-day comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or nonsubstantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

M/S: Veale/Lippe

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

IX. Discussion and Consideration of the Proposed Regulation to Amend Title 16 CCR Section 1760, Related to Disciplinary Guidelines

Assistant Executive Officer Anne Sodergren reported that OAL disapproved the regulation. She explained that based on the disapproval letter, staff anticipates that there will need to be some changes made to the language in regards to the random drug screening and quarterly reporting.

Ms. Sodergren stated that staff did not receive the disapproval letter until January 23, 2016, so staff work with OAL to address the issues with the language and bring it back to the next board meeting.

The board recessed for a break at 11:55 a.m. and resumed at 1:05 p.m.

X. Enforcement and Compounding Committee Related Items

Part 1: Enforcement Matters

a. CURES 2.0 Prescription Monitoring Program: Presentation by California Department of Justice and Discussion of CURES System Components

President Gutierrez reported that Mike Small from the California DOJ provided a presentation at the January 4 Enforcement Committee meeting on the expanded features of CURES 2.0. She noted that these features include:

- Improved business analytics.
- A fully automated registration process.
- The ability to assign delegates who can initiate CURES 2.0 inquiries.
- Daily alerts with information on patients who reach prescribing thresholds.
- Flagging to allow prescribers to notate patients with treatment contracts.

President Gutierrez explained that the analytics engine in CURES 2.0 identifies the person's current prescriptions based on date filled and number of days' supply. These levels are calculated and compared against pre-established thresholds. Therapy levels exceeding those thresholds trigger patient safety alerts to current prescribers.

President Gutierrez reported that the committee discussed pharmacist feedback that the patient activity report (PAR) report does not indicate the days' supply of medication. At the committee meeting, Mr. Small explained that this information may be available to be downloaded via Excel but is not on the current reports.

President Gutierrez reported that the committee also noted that providers want to know what has been dispensed under their DEA numbers and that other states' PDMP programs do offer this in their reports. She explained that prescribers do not have a method to reconcile their prescription pads and should have a right to this information as it is under the prescriber's DEA number.

President Gutierrez stated that the committee also considered the current timeframe for

reporting dispensing records to CURES and if schedule V drugs should also be reported to CURES as currently only schedule II-IV drugs are required.

President Gutierrez reported that the committee made the following recommendation: Include the days' supply of medication in the PAR as well as the ability for prescribers to have access to the prescriptions written by them and recommend to the board that it promote a change to report dispensing data within 48 hours and that Schedule V prescriptions be reported to the CURES system.

President Gutierrez asked if the committee recommendation would require legislative changes. Ms. Herold responded that changing the reporting timeline and adding schedule V prescriptions would require statutory changes. Ms. Herold also reported that 43 states that are sharing information across state lines are using a portal run by the NABP.

The board asked staff to pursue the necessary statutory changes and added this to the committee recommendation.

Dr. Gray, pharmacist, expressed concern that the day's supply might not be accurate for all prescriptions. Ms. Herold and President Gutierrez stated that this information is important in order for the pharmacist to have the whole picture of the patient's care.

Dr. Gray asked if the board intended to include serial numbers in the CURES reporting. The board responded that this was not included in the committee's recommendation.

Dr. Gray suggested that the board change the reporting timeframe to 72 hours. Ms. Herold responded that most states require reporting within 24 hours and one state requires it within one hour of dispensing.

A representative from Walgreens stated that in Arizona prescriber reports are reviewed and compared to other doctors in similar practice settings to find doctors who may be overprescribing.

Motion: Include the days' supply of medication in the PAR as well as the ability for prescribers to have access to the prescriptions written by them. Recommend to the board that it promote a change to report dispensing data within 48 hours and that Schedule V prescriptions be reported to the CURES system. Direct staff to pursue any necessary statutory changes.

M/S: Veale/Lippe

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			

Gutierrez	x			
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

b. Discussion and Consideration of the University of California, San Diego Pilot Program to Permit Patients to Access Medications from an Automated Drug Delivery System Not Immediately Adjacent to a Pharmacy

President Gutierrez reported that at the 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 drug delivery system (ADDS) for prescription medication from which staff of Sharp Hospital in San Diego and their families, who opted in, could pick up their outpatient medications. She explained that consultation would be provided via telephone before medication could be dispensed to a patient for first-time fills.

President Gutierrez reported that the committee has received quarterly updates on the study, including usage of the system.

Kim Allen with Sharps provided a brief update on the study. The board noted the low number of participants. Ms. Allen responded that the employees are not required to use the location and the intent of the study is to determine if the system is safe and provides appropriate patient consultation.

The board asked that the report be submitted prior to the April 18 Enforcement Committee meeting so the committee members would have time review it and make a recommendation to the full board.

There were no comments from the public.

c. Disposal of Sharps in Pharmacy-Operated Drug Takeback Programs: Discussion and Consideration of Statutory and Regulatory Framework and Possible Changes

President Gutierrez reported that since late 2014, the board has been working on drug takeback regulations for pharmacies. The rulemaking file to implement the board's regulation requirements was submitted to the Department of Consumer Affairs (DCA) in December 2016. She stated that hopes are for the regulation to go into effect toward the end of the first quarter of 2017.

President Gutierrez reported that the committee has been in discussion about how to

address the return of sharps by the public to pharmacy collection of household pharmaceutical waste. Of particular concern is the increasing widespread distribution and availability of EpiPens to respond to various emergencies in locations such as schools and restaurants.

President Gutierrez explained that the board's pending drug takeback regulation provides requirements that signage for collection receptacles contain the following prohibition: "Medical sharps and needles (e.g., insulin syringes) shall not be deposited." This is consistent with pharmacy law. In order to proceed with rulemaking, the board decided to consider the issue of sharps, which includes such items as needles, syringes, lancets and EpiPens as a separate piece.

President Gutierrez reported that the committee discussed that sharps are handled separately from pharmaceutical waste for a number of reasons including the Department of Transportation's (DOT) transport requirements.

President Gutierrez noted that the committee heard comments from several community members, including the:

- Environmental Branch of the California Department of Public Health (CDPH) that regulates the generation, transport and disposal of medical waste in clinical facilities
- Sacramento County's Program Manager for Business Development and Special Waste, that runs a landfill and a transfer station, and collects household hazardous waste
- Californians Against Medical Waste
- California Product Stewardship Council

President Gutierrez explained that several government entities have regulations concerning the disposal of sharps waste, which at times, conflict with each other. For example, DEA regulations require that pharmaceutical waste be disposed of in a liner. However, the DOT requires that sharps be disposed of in rigid containers. President Gutierrez stated that the situation is further complicated because there is the federal overlay, transportation across state lines, and people who have been doing something for years may not be flexible in moving forward with a different solution.

President Gutierrez reported that the committee agreed that the sharps issue should remain with the Enforcement Committee until a solution is identified. She concluded that the committee will work with other agencies to find a solution.

Ms. Herold stated that the board will continue to work with other agencies to find solutions to protect consumers and provide safe places to dispose of sharps. President Gutierrez noted that sharps can be disposed of in locations outside of pharmacies (such as airports) and having many different collection sites is good for consumers.

There were no comments from the public.

d. Automated Drug Delivery Systems (ADDS)

1. Presentations Regarding Options and Features Currently Available

President Gutierrez explained that the board's staff continues to be contacted with questions from entities seeking to use automated drug delivery systems (ADDS) in California. She added that some of these ADDS offer new features not addressed in pharmacy law.

President Gutierrez reported that at the January 2017 Enforcement and Compounding Committee Meeting the board heard abbreviated presentations from ADDS vendors and agreed that there needs to be more discussion as to how to embrace new technology when it conflicts with existing laws.

2. Discussion and Consideration of Refilling of ADDS in Skilled Nursing Facilities

President Gutierrez explained that in skilled nursing facilities, ADDS are sometimes installed to permit furnishing of emergency medications or to start initial doses to patients receiving care in the facilities.

President Gutierrez stated that the board's staff believes that California law directs that drugs in the ADDS are stock of the pharmacy and that the pharmacy is responsible for restocking the device (pharmacist, pharmacist intern, or pharmacy technician under pharmacist supervision). However, board staff is aware that some skilled nursing facilities have begun using nursing staff or perhaps other employees to refill the ADDS.

President Gutierrez noted that consultants from the California Department of Public Health and board inspectors state that the refilling of an ADDS is similar to the restocking of the emergency kits in SNFs, which after medication is removed from a kit, the kit is returned to the pharmacy for inventory, restocking and recordkeeping functions.

3. Next Steps

President Gutierrez reported that the committee directed board staff to host a one day forum with the full board to hear presentations on ADDS, particularly for ADDS intended to be located away from the pharmacy, and then discuss relevant laws that permit or impede their use. She explained that the discussions will be framed around a series of questions, such as how ADDS will be controlled, how vendors ensure that drugs are matched with the correct patient, security features, and who can stock the ADDS.

Ms. Herold announced that the one day forum was scheduled for February 17, 2017, and would be held in Sacramento.

President Gutierrez stated the hope is to have the vendors that provide these machines to come before the board to demonstrate their capabilities.

Ms. Herold explained that the board needs to ensure that the law stays current with the automation that has developed over the last several years in order to ensure consumer safety.

The board discussed the need to ensure that the board's regulations do not conflict with any of CDPH's regulations.

Dr. Gray, representing Kaiser, spoke in support of the meeting on February 17. He added that the board should be provided with an overview of the different legal requirements for various practice settings.

Mark Johnson, CVS Health, explained that many facilities are having nurses fill the machines despite the board's regulation which states that it must be a pharmacist or pharmacy technician who fills the machine.

A representative from Pacific West Pharmacy explained that there are many different types of ADDS devices that the board will need to consider.

Bill McGuire, from OmniCell, asked if vendors can bring new products to the February 17 meeting. Board member Weisser stated that it is important that the meeting is not treated as a trade show. President Gutierrez added that the board cannot endorse specific products. Mr. McGuire stated that he would speak with Ms. Herold directly to determine if the new products are appropriate for the meeting.

Paige Tally, representing California Council for the Advancement of Pharmacy, noted that on the registration form it indicates that the form can be emailed. She asked who it can be emailed to. Ms. Herold responded that it could be emailed to her.

Deanne Allen, a pharmacist from Providence St. John's, asked if there is pharmacy oversight for ADDS machines in skilled nursing facilities. Ms. Herold responded that the pharmacy owns the machines and the drugs. Ms. Allen asked if a nurse can remove the drug from the machine. Ms. Herold explained that the nurse can remove the drug to administer to a patient; however, the nurse cannot re-stock the machine.

e. Discussion and Consideration of Possible Regulations Regarding Patient Enrollment in Automated Refill Programs for Prescription Medications

President Gutierrez explained that traditionally, pharmacies have refilled prescriptions only upon the request of the patient or the patient's prescriber. However, in recent years computer programs have been developed which allow pharmacies to enroll patients in automatic refill programs ("auto-refill"). These programs automatically refill prescriptions before the patient runs out of medication. In most cases, these auto-refill programs are limited to drugs identified as maintenance medications. The argued benefit of auto-refill programs is that they increase patient compliance with drug therapy by automatically

refilling maintenance medications and sending reminders to patients to pick up their prescriptions.

From late 2012 through 2013, the board received over 100 complaints directly related to auto-refill programs due to the media attention. Many of the complaints were from patients who received prescriptions they did not request and who had difficulty returning the prescriptions for a refund. Other patients inadvertently ingested medication they had not requested or ingested medication that was previously discontinued by their prescriber. Some of these events resulted in patient harm.

President Gutierrez stated that in response to the large number of complaints, Ms. Herold and other staff worked with the various agencies to address these concerns and explore possible violations of pharmacy laws and regulations.

President Gutierrez reported that at the October 2016 Board Meeting, staff was asked to develop an analysis and presentation for the next committee meeting to evaluate options for authorization and maintenance of auto-refill documentation in community and mail order pharmacies.

President Gutierrez reported that the committee discussed the draft policy developed by staff on automated refill programs and heard public comments about how other states, including Oregon and Texas, are regulating such programs.

President Gutierrez explained that as part of its discussion the committee made revisions to the draft policy. President Gutierrez reviewed the draft policy as provided below.

**California State Board of Pharmacy
DRAFT Policy on Automated Refill Programs:**

A retail or mail order pharmacy may use a program that automatically refills prescriptions that have existing refills available, in order to improve patient compliance and are consistent with the patient's current medication therapy when all of the following conditions are met:

(1) Written notice or disclaimer of the availability of an auto-refill program shall be given to the patient or patient's agent. The patient or patient's agent must affirmatively indicate if he or she wishes to enroll in such a program and the pharmacy shall maintain documentation of such indication. Notice shall have language that references instructions on how a patient can discontinue participation in the auto-refill program.

(a) A pharmacy patient or the patient's agent shall consent to participation in an auto-refill program with a "wet" signature or an e-signature. If the pharmacy has an online consent option, the patient may enroll in the auto-refill program through that method. The pharmacy shall keep this acknowledgement on file. If the retail pharmacy has an online consent option, the patient or patient's agent can register in that manner and the pharmacy shall keep the acknowledgment on file for one year from date of

dispensing.

- (b) A mail order pharmacy patient or the patient's agent shall consent to participation auto-refill program through the mail order pharmacy's website. The pharmacy shall keep this acknowledgment on file. If the mail order pharmacy does not have an online consent option, the pharmacy shall obtain a signature or email confirmation from the patient or patient's agent consenting to the auto-refill program. Acknowledgement of consent to participate in the auto-refill program shall be kept on file by the mail order pharmacy for one year from date of dispensing.*
- (2) The pharmacy shall have written policies and procedures in place to ensure only medications that are for the auto-refill program are enrolled in the program.*
- (3) The pharmacy must discontinue auto-refill program enrollment at the request of the patient or patient's agent in a timely manner.*
- (4) As is required for all prescriptions, a drug regimen review shall be completed on all prescriptions filled as a result of the auto-refill program. Special attention shall be noted for drug regimen review warnings of duplication of therapy and all such conflicts shall be resolved with the prescribing practitioner prior to refilling the prescription.*
- (5) The retail or mail order pharmacy must reaffirm annually each prescription to be enrolled in the auto-refill program.*
- (6) Upon a receipt of a new prescription from a provider, the patient or patient's agent shall identify if the prescription is to be included in the auto-refill program, even if the new prescription is a continuation of existing therapy.*
- (7) Each time a prescription is refilled a reminder notification will be provided to the patient or patient's agent, affirming that the prescription is enrolled in the auto-refill program.*
- (8) Pharmacies that use an auto refill program will have policies and procedures in place that address the auto-fill program. These policies and procedures will be available for inspection upon request of the board.*
- (9) The pharmacy shall provide a full refund to the patient or the patient's agent and the payer for an auto-refill prescription that is reported as unneeded or unnecessary if the patient or patient's agent can provide evidence or documentation that they did not register for the auto-refill program or the patient notified the pharmacy of disenrollment.*

Mr. Law thanked the Enforcement Committee for working on this important subject.

Mr. Weisser explained that auto refill can cause a financial hardship for patients that find that their medications are not covered by their provider. Ms. Veale stated that patients do not get billed unless the patient picks up the prescription.

Ms. Veale expressed concern that the board may be overregulating the practice of pharmacy in the area of auto refill programs. Ms. Veale stated that many health plans ask for patients to be automatically enrolled in the auto refill program because they see benefits to the program. She noted that she has found at least three articles highlighting the benefits of auto refill programs.

Mr. Weisser stated that many patients seem to have problems with being enrolled in auto refill programs and not realizing that they no longer need the medication and then have no way of getting refunded. He encouraged the board to research the issue to see how widespread the problem really is and if it requires board regulation.

Ms. Veale explained PBMs will allow pharmacies to return medications to stock within 14 days if not dispensed.

President Gutierrez stated that many pharmacists' job performance evaluations include how many patients they enroll in auto-refill programs.

Ms. Veale stated that she is not totally against regulation in this area; however, she feels that the draft language goes too far. She suggested removing No. 9 from the language. She also suggested that the board look at the regulation Texas created.

Mr. Law stated that for maintenance medications it is beneficial for the patient to receive his or her medications on a regular basis.

Dr. Wong stated that he would like to remove No. 7 from the language. Ms. Sodergren clarified that #7 was intended to simply remind the patient that he or she is receiving the medication because the patient is enrolled in an auto refill program, it was not meant to have a patient opt-in every time he or she gets a prescription.

The board expressed their desire to have patients opt-in to auto refill programs; however, there were differing opinions on how often they should have to opt-in.

Board Member Munoz stated that she would like to keep No. 9 in the language as it may hold pharmacies accountable.

Mr. Lippe motioned to have staff condense the language based on the board's discussion and bring it back to the full board. Ms. Freedman recommended that the board be more specific in what items they would like removed from the language. Mr. Lippe withdrew his motion.

Mark Johnson, representing CVS Health, recommended removing No. 5 and No. 6 from the language as they may they may cause a delay in therapy for the patient. He added that personally auto refill helps keep him compliant with his maintenance medications.

Steve Sailor, retired pharmacist, stated that the language was overregulating the practice of pharmacy.

The board took a break from the discussion to recognize Steve Sailor for his service as a pharmacist for 50 years.

The board resumed the discussion on auto refill programs.

Stan Goldenberg, pharmacist, stated that seniors often take multiple medications and they may have difficulty remembering to refill the prescription; however, they may also be receiving medications that are actually harming them. He suggested that pharmacists may consider reviewing patient’s prescriptions to determine if their medications are appropriate and if they would benefit from an auto refill program.

Dr. Gray asked if the board would need to pursue legislation to make a statutory change. Ms. Freedman and Ms. Kellogg responded that at this time they did not believe that legislation would be required.

Motion: Remove No. 5 and No. 6 from the language. Have staff refine the language and bring it back to the full board for further discussion.

M/S: Lippe/Veale

Support: 4 Oppose: 3 Abstain: 1

Note: Mr. Schaad and Ms. Munoz were not present for the vote.

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler		x		
Gutierrez	x			
Law		x		
Lippe	x			
Munoz				x
Sanchez			x	
Schaad				x
Veale	x			
Weisser		x		
Wong	x			

Ms. Herold clarified that the language was to be brought back to the full board. President Gutierrez confirmed this.

The board recessed for a break at 3:10 p.m. and resumed at 3:27 p.m.

f. Discussion and Consideration of the National Council of State Boards of Nursing (NCSBN) Nursys® e-Notify System

President Gutierrez explained that the Enforcement and Compounding Committee expressed interest in learning about this system.

President Gutierrez reported that the National Council of State Boards of Nursing (NCSBN)® e-Notify system is a nurse licensure notification system that provides employers of registered nurses and licensed practical/vocational users with real-time email notifications about nurses they employ. She stated that this e-Notify system alerts subscribers when changes are made to a nurse's record, including changes to: license status, license expiration, pending license renewal, and public disciplinary action, resolution and alerts. Their website states:

The Nursys nurse licensure and disciplinary database is the repository of the license and disciplinary data of the NCSBN member boards of nursing. Through a written agreement, participating individual boards of nursing designate Nursys as a primary source equivalent database. NCSBN posts the information in Nursys when, and as, submitted by the individual boards of nursing.

President Gutierrez reported that the board tries to obtain National Healthcare Integrity and Protection Data Bank Reports on all licensees; however, at a cost of \$2.00 per licensee and 140,000 licensees, it is cost prohibitive.

Ms. Herold explained how the board receives information when licensees are arrested or convicted. Additionally, at each renewal, licensees must certify under penalty of perjury that they have no arrests or convictions since the last license renewal. Ms. Herold added that the board also receives periodic information when a board takes action in another state and reports to the Healthcare Integrity and Protection Data Bank (HIPDB).

Board staff explained that currently pharmacy technician and pharmacist applicants must provide a self-query report from the HIPDB databank. The board asked staff to gather data to determine if useful information was obtained by requiring applicants to provide HIPDB queries when they apply. The board asked the Licensing Committee to take over this agenda item and report back to the full board.

There were no comments from the public.

g. Discussion and Consideration of Possible Revision to Title 16 California Code of Regulations Section 1707, Relating to Off-Site Storage Waivers, to Address Licensees with Previous Records Violations.

President Gutierrez explained that in recent months, the board has identified several pharmacies that requested off-site storage waivers but were ineligible for waivers because they had been cited for storing records off-site without an approved waiver. Their attempt to get a waiver was generated by the citation and a desire to come into compliance;

however, the regulation’s provisions provide no option for the board to grant such a request for five years after the violation is identified.

President Gutierrez reported that the Enforcement Committee considered staff’s request that the board reconsider the full prohibition and authorize discretion in the granting of off-site waivers.

President Gutierrez reviewed the draft language that was approved by the Enforcement Committee. Note: the draft language was provided in the board meeting materials.

Ms. Veale asked if an offsite waiver would be required if documents were being stored in the same building as the pharmacy, but in an unlicensed area. President Gutierrez responded that a waiver would be required and the committee had modified the language to clarify that “offsite” also referred to unlicensed locations in the same building as the pharmacy.

Dr. Gray stated that much of the confusion comes from the fact that the statute uses the term “premises” and the regulation uses the term “offsite.” He recommended that the board create different requirements for hospitals.

Committee Recommendation (Motion): Approve the proposed changes to CCR section 1707 as provided in the meeting materials.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Munoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

h. Discussion and Consideration of Possible Amendment to New Business and Professions Code Section 4316 Regarding Cease and Desist Orders

President Gutierrez explained that last year, one provision contained in the board’s sunset bill, SB 1193 (Hill), provided the board with the ability to issue a cease and desist order to an unlicensed entity operating within the board’s regulatory jurisdiction without a license where one is required. However, following enactment of SB 1193, staff identified items in this

provision which needed clarification.

President Gutierrez reported that the Enforcement Committee considered the proposed changes and received input from counsel on additional modification. After discussion, the committee agreed with the recommendation from DCA’s staff counsel. President Gutierrez noted that that proposed modifications were provided in the board meeting materials.

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

Committee Recommendation (Motion): Approve the proposed amendments to Business and Professions Code section 4316 and pursue the necessary statutory changes.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Munoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

i. Discussion and Consideration of the FDA’s Article, *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry*

President Gutierrez reported that in December 2016, the FDA published a guidance document titled *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry* to clarify when manufacturers and other trading partners should notify the FDA if there is a high risk that a product is illegitimate.

President Gutierrez reported that Supervising Inspector Michael Ignacio provided a presentation on components in this guidance document at the Enforcement Committee meeting. Note: a copy of Dr. Ignacio’s presentation and a copy of the FDA guidance document were provided in the board meeting materials.

President Gutierrez stated that the committee did not recommend submitting comments to the FDA. She noted that the committee directed staff to include an article on this guidance in a future issue of *The Script* and provide a copy of the article to other healing arts boards.

Ms. Herold noted that this is an important guidance document that outlines the reporting

requirements that must be met in order to keep the drug supply chain in the U.S. safe.

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

j. Discussion and Consideration of Beyond Use Labels in Institutional Settings

President Gutierrez explained that Title 16 California Code of Regulations section 1735.1(b) effective 1/1/17 provides that:

(a) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

President Gutierrez stated that the board received a request from Providence Hospital for a modification of the expiration date used on prescription labels from "exp" to "do not start after." The request was made, in part, to make the terminology easier for the nursing staff to easily comply with without questions (vs. using the term BUD). She explained that Providence feels that using the proposed language will help with nurse compliance. President Gutierrez also explained that as the behind-the-scenes EMR work is extensive, Providence asked for board feedback prior to making changes to their medication labels.

President Gutierrez reported that the Enforcement Committee agreed that as long as the licensee meets the minimum label requirements, they can add additional information. The additional information provides clearer direction as to what is appropriate for this medication. President Gutierrez stated that the committee members also agreed that additional information on the label that is intended to clarify the directions is beneficial to the patient.

The board discussed using the phrase "do not start after" on prescription labels in institutional settings when infusion therapy is provided in order to provide clear instructions for doctors and nursing staff.

Ms. Freedman commented that using the term "do not start after" would comply with the current labeling requirements.

After discussion the board determined that the phrase "do not start after" would be used *instead* of the expiration date, not in addition to the expiration date in order to avoid confusion.

Don Kaplan, representing Kaiser, spoke in support of using the term "do not start after."

The board asked staff to include an article in The Script on this topic.

Part 2: Compounding Matters

a. Discussion and Consideration of Statistics for Board-Issued Citations and Fines for Compounding Violations.

President Gutierrez reported that at the Enforcement Committee meeting Mr. Schaad reviewed the compounding citations and fines issued by the board. He noted that most compounding institutions cited had both sterile and nonsterile compounding citations: 75 pharmacies had non-sterile compounding infractions and 38 had sterile compounding infractions. Mr. Schaad also noted that out of the 1,100 sterile compounding pharmacies inspected by the board, 38 pharmacies received citations.

Mr. Schaad noted that he was surprised how low the percentage is for pharmacies that receive citations. He also expressed concern that many of the citations were for pharmacies not having proper policy and procedures in place.

Mr. Schaad stated that he noticed a variation between the length of time inspectors spent in a pharmacy and the types of violations they issued.

Mr. Schaad expressed his personal concern that the board issued two citations for pharmacies compounding commercially available products. He stated that while the law does not allow compounding of commercially available products, in the two circumstances where citations were issued, the commercially available products would have cost over \$1,000 when the pharmacy was able to compound them for around \$15. Ms. Herold explained that in order to be compliant with the FDA requirements there would need to be a note from the prescriber stating that the patient would benefit from this prescription modification for specific reasons. She added that the board does not issue citations for this very often, so there were probably mitigating circumstances that made issuing a citation necessary.

Dr. Wong noted that nonsterile compounding regulations are very strict and many pharmacies are not able to compound because of the regulations. Ms. Herold responded that these regulations have been in place since 2003.

Mr. Law suggested that the board write a newsletter article to discuss common citation violations to educate licensees. Ms. Herold noted that staff provides the top ten violations annually in the board meeting materials.

Mr. Schaad noted that the Oregon Board of Pharmacy holds an annual meeting to educate licensees on common violations. The board asked the Communication and Public Education Committee to research the Oregon model and look for ways to further educate licensees.

A pharmacist expressed frustration in the variation of the inspections conducted by Board of Pharmacy inspectors and with the cost associated with complying with the changing regulations.

b. Update and Discussion of Compounding Construction Waivers for New Requirements in Title 16 California Code of Regulations, Sections 1735 et. seq., and 1751 et. seq.

President Gutierrez reported that Supervising inspector Christina Acosta provided an update on compounding construction waivers at the Enforcement Committee meeting.

President Gutierrez explained that she and Mr. Schaad, Ms. Herold, Chief Enforcement Officer Julie Ansel, Supervising Inspector Acosta have been reviewing these waivers.

President Gutierrez reported that as of January 2, 2017, the board received 493 waiver requests and processed 214 requests (43%). Of the 214 requests processed, about 50 (23%) did not have a sterile compounding license, so the waiver was not related to sterile compounding. Of those processed, 70 were approved and 2 were denied. Of the 214 processed requests, 112 (52%) were for a community pharmacy and 102 (48%) were for a hospital pharmacy.

President Gutierrez reported that Dr. Acosta is working with several waiver applicants to obtain additional information so that their requests can be brought forward to the committee.

President Gutierrez stated that the applicant needs to identify the specific subsection of 1735.6 and 1751.4 to be waived, provide information detailing their attempts to comply with the regulation and when they expect to be compliant. She added that waivers for non-construction requirements, such as not cleaning the facility or complying with policies and procedures, cannot be granted.

President Gutierrez stated that Dignity Health has already submitted waiver requests for all of its facilities. She added that the waivers were very detailed and most of them have already been approved.

President Gutierrez noted that a sample waiver package was provided at the October 26-27, 2016, Board Meeting and can be found on the board's website.

President Gutierrez stated that the board's goal right now is educational compliance. But she noted that if an egregious situation is identified, action will be taken, as the board's underlying core is public protection.

President Gutierrez reported that the Enforcement Committee recommended that pharmacies seeking waivers keep a copy of the waiver request at their pharmacy to show the inspector in the event of a pharmacy inspection.

c. Discussion and Consideration of the United States Government Accountability Office Report to Congressional Committees, *Drug Compounding, FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges*

President Gutierrez reported that in mid-November 2016, the GAO released a report on the regulation of compounding by states following the 2012 New England Compounding Center public health emergency.

President Gutierrez remarked that that other boards of pharmacy are now looking at sterile compounding in non-pharmacy areas, such as physicians' offices; however, the board does not

have regulatory oversight.

There were no comments from the public.

d. Review and Discussion of California Law Governing Compounding and Conflicts with USP Section 800

President Gutierrez explained that staff has been made aware of possible conflicts between the board’s new compounding regulation, USP 800 and other regulatory requirements. The committee asked Dr. Acosta to review the board’s regulations and provide recommendations on modifications required to resolve conflicts with USP 800.

President Gutierrez briefly reviewed the proposed modifications as provided in the board meeting materials.

President Gutierrez noted that in addition to the proposed modifications provided in the meeting materials, the word “venting” needs to be replaced with “exhausting” throughout the language.

President Gutierrez explained that the board would also need to repeal BCP 4127.7 as it conflicts with the Building Standards.

Paige Tally, representing California Council for the Advancement of Pharmacy, asked the board to clarify the difference between exhausting and venting. Ms. Sodergren explained that exhausting is a process that forcibly removes the air, whereas venting is passive.

Motion: Approve the language for pre-notice as provided in the meeting materials, with the word “venting” changed to “exhausting” throughout the language. Repeal BCP 4127.7. Delegate to the executive officer the authority to make any necessary changes to the language to make it consistent with board policy as discussed at the meeting.

M/S: Weisser/Lippe

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez	X			
Law	X			
Lippe	X			
Munoz	X			
Sanchez	X			
Schaad	X			
Veale	X			

Weisser	x			
Wong	x			

e. Presentation of Requirements for Sterile Compounding Master Formulas

President Gutierrez reported that Dr. Acosta provided a presentation to the Enforcement Committee on compounding master formulas.

President Gutierrez noted that a copy of the presentation was provided in the board meeting materials. She added that a sample master formula would be added to the board’s website.

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

f. Discussion and Consideration of the Proposed FDA Rule, *List of Bulk Drug Substances that Can be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act*

President Gutierrez reported that on December 16, 2016, the FDA issued a proposed rule, [List of Bulk Drug Substances that can be used to Compound Drug Products](#), addressing six bulk drug substances the agency has evaluated and is proposing for inclusion on a list of bulk drug substances that can be used in compounding under section 503A of the Food, Drug, and Cosmetic Act. She noted that the proposed rule also proposes that four other bulk drug substances that FDA evaluated not be included on the 503A bulks list.

President Gutierrez explained that if the proposed rule is finalized, the six bulk drug substances proposed for inclusion will be the first ones included on the 503A bulks list.

President Gutierrez reported that she and Dr. Acosta agreed that this topic warrants further discussion and would be agendized for the next Enforcement Committee meeting.

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

Part 3: General Committee Matters

a. Enforcement Statistics

President Gutierrez noted that the Enforcement statistics were provided in the board meeting materials for review.

b. Future Committee Meeting Dates for 2017

President Gutierrez announced the following Enforcement Committee meeting dates.

- April 18, 2017
- July 12, 2017
- October 17, 2017

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

XI. Organizational Development Committee

a. Budget Update/Report

1. Fund Condition Report

President Gutierrez briefly reviewed the fund condition as provided in the board meeting materials.

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

2. Budget for Fiscal Year 2016/17

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. She stated that the board's spending authorization for the year was adjusted from \$20,652,000 to \$19,464,000 in the Governor's final budget released on January 10, 2017.

President Gutierrez explained that this reduction in the budget reflects a change in how statewide pro rata payment is billed. The statewide pro rata of \$1,165,000 will no longer be reflected as an expenditure line item on the budget and will now be a direct withdrawal from the Board's reserve fund.

President Gutierrez stated that the budget includes about \$12.9 million in salary, wages and benefits, about \$2.5 million in pro rata to the DCA as well as \$1.9 million in enforcement costs (including Office of the Attorney General and Office of Administrative Hearings).

President Gutierrez reported that during the first five months of the fiscal year the board received \$9,722,100 in revenue and expended \$7,979,829.

3. DCA Distributed Costs Allocations, including BreEZe Costs

President Gutierrez stated that the board closely monitors its budget and receives quarterly budget reports. She explained that the board pays about \$2.75 million in pro rata to the state, a portion of which is for services provided by DCA including the development and maintenance of the department's new BreEZe system.

President Gutierrez reported that during the October 2016 members requested that information about the board's share of the BreEZe system be provided in the future. Based on information provided by the DCA budget office, the board contributed over \$1.2 million in BreEZe costs through June 30, 2016. She noted that the department projects that the board could contribute another almost \$1.2 million between July 1, 2016, and June 30, 2019.

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

b. Board Member Reimbursement Information

President Gutierrez briefly reviewed the reimbursement information as provided in the board meeting materials.

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

c. Personnel Update

Ms. Herold reviewed the board's new hires, vacancies and recruitments as provided in the board meeting materials.

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

d. Future Meeting Dates

1. Future Board Meeting Dates for 2017

President Gutierrez reported the following future board meeting dates.

- May 3-4, 2017, *Location to be determined.*
- July 25-26, 2017, *Location to be determined.*
- November 8-9, 2017, *Location to be determined.*

2. Automated Drug Delivery Device Demonstration Summit

President Gutierrez reported that as part of the January 2017 Enforcement Committee Meeting, the committee heard very brief presentations from some vendors discussing automated drug delivery devices.

President Gutierrez explained that it was determined at that meeting that the board should convene a special one-day board meeting to allow for demonstrations and education about such devices. As part of this meeting, members will hear presentations on various devices as well as the legal requirements for use and current settings where such devices may be used. President Gutierrez noted that the date of the summit is being determined.

XIII. Closed Session

President Gutierrez stated that pursuant to Government Code section 11126(c)(3), the board would convene in closed session to deliberate on disciplinary matters, including pending litigation, proposed decisions, stipulated decisions, defaults, and any other disciplinary matters.

President Gutierrez announced that during closed session the board would be deliberating on the following pending litigation.

- Cal-Mex Pharmacy v. California State Board of Pharmacy
- DFEH (Broz) v. California State Board of Pharmacy

The board recessed to closed session at 4:50 p.m.

The board reconvened to open session at 5:25 p.m.

President Gutierrez adjourned the meeting for the day at 5:26 p.m.

January 25, 2017

Vice President Veale called the meeting to order at 9:00 a.m. Board members present: Greg Lippe, Lavanza Butler, Stanley Weisser, Victor Law, Debbie Veale, Ricardo Sanchez and Allen Schaad.

Vice President Veale recessed the meeting to closed session at 9:02 a.m.

Note: Albert Wong arrived at 9:10 a.m.

Vice President Veale reconvened the meeting to open session at 10:20 a.m.

The board recognized Irv Sitkoff for 50 years of service as a pharmacist.

The board conducted another roll call. Board members present: Greg Lippe, Lavanza Butler, Stanley Weisser, Victor Law, Debbie Veale, Ricardo Sanchez, Albert Wong and Allen Schaad.

XIV. Licensing Committee

Chairperson Weisser provided a summary of the committee's efforts at its January 10, 2017, meeting.

a. Discussion and Consideration of Certification Programs Developed to Satisfy Requirements for Licensure as an Advanced Practice Pharmacist Pursuant to Title 16, California Code of Regulations Section 1730.2

Chairperson Weisser reported that since the passage of SB 493 (Hernandez, Chapter 469, Statutes of 2013), the board has been working on implementation of the various provisions, including developing regulations to establish the parameters for acceptable certification programs that can be used as one of the qualifications for licensure as an advanced practice pharmacist.

Chairperson Weisser reported that Section 1730.2 establishes the parameters for certification programs in general clinical pharmacy practice. He noted that the regulation requires such a certification program to meet the following:

1. Recognition by the Accreditation Counsel for Pharmacy Education as a continuing education provider **OR**

- Accreditation by the National Commission for Certifying Agencies.
2. Include specified learning objectives in at least five sequentially-ordered education modules covering specific topics.
 3. Include an assessment after completion of each of the education modules to confirm the participant's understanding, knowledge, and application of the learning objective.
 4. Instruction and assessment is be developed and provided by either an advanced practice pharmacist licensed by the board or an expert with experience in the respective area of focus.
 5. A final overall assessment is given.
 6. Ten hours of continuing education every two years to maintain certification.

Chairperson Weisser reported that the Licensing Committee heard presentations from the California Pharmacists Association (CPhA) on its advanced practice pharmacist certification program which was developed in conjunction with the National Association of Chain Drug Stores (NACDS). As part of the presentation CPhA highlighted the elements of the certification program, and how the program complies with the regulation requirements. Chairperson Weisser noted that the committee was advised that the program consists of 30 hours of online self-paced learning covering five modules as well as an eight hour, in-person skills seminar. He added that the committee was advised that 30 participants have completed the initial program.

Chairperson Weisser reported that the committee also heard a presentation from the California Society of Health System Pharmacists (CSHP) that developed a program with Touro University. As part of the presentation CSHP also highlighted the elements of its certification program and how it complies with the regulation requirements. Chairperson Weisser explained that the program offered by CSHP consists of 30 hours of online learning, which must be completed within a 6-8 week timeframe as well as eight hour, in-person "live event."

Chairperson Weisser explained that the committee noted that it does not need to approve these programs but was appreciative of the opportunity to learn about them.

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

b. Discussion and Consideration of Possible Revisions to the Licensure Requirements for a Designated Representative in a Reverse Distributor, Including But Not Limited to Business and Professions Code Section 4053

Chairperson Weisser explained that Business and Professions Code section 4040.5 provides a definition for a reverse distributor to include every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers and other entities by receiving, inventorying, warehousing and managing the disposition of outdated or nonsaleable dangerous drugs.

Chairperson Weisser also explained that Business and Professions Code section 4043 provides a definition for a wholesaler as a person who sells for resale, or negotiates for distribution, or takes possession of, any drug or device. Under this section, a reverse distributor is considered a wholesaler.

Chairperson Weisser stated that Business and Professions Code section 4053 provides the board with the authority to issue a license to a designated representative who shall be responsible to provide sufficient and qualified supervision in wholesaler or veterinary food-animal drug retailer. He noted that this section also provides the application requirements for such an individual. General requirements include:

- minimum age of 18 years old **AND**
- high school graduation or equivalent **AND**
- one year paid work experience related to distribution or dispensing of dangerous drugs or dangerous device **OR**
eligibility to take the pharmacist exam **AND**
- completion of a training program covering specific content areas.

Chairperson Weisser stated that an individual applying for a designated representative veterinary food-animal drug retailer must meet all of the criteria above as well as additional training.

Chairperson Weisser explained that Business and Professions Code section 4053.1 provides the board with the authority to issue a license to a designated representative who shall be responsible to provide sufficient and qualified supervision in a third-party logistics provider. He noted that although similar, the training course requirements for a designated representative-3PL are not as comprehensive.

Chairperson Weisser reported that recently board staff was contacted by a pharmaceutical waste company that is seeking an exemption to the designated representative requirement as well as the requirement to have a designated representative-in-charge.

Chairperson Weisser stated that board staff is not aware of any provision that would provide the board with the ability to make such an exemption. However, staff notes that it may be appropriate to consider if the general licensing requirements for a designated representative are appropriate for a business that solely handles dangerous drugs and pharmaceutical waste for destruction.

Chairperson Weisser explained that under federal law, states shall require personnel employed in wholesale distribution to have appropriate education and/or experience to assume responsibility for positions related to compliance with state licensing requirements.

Chairperson Weisser reported that as part of its discussion the Licensing Committee noted that by law, for a wholesaler to operate, it must have at least one designated representative or a pharmacist on the premises at all times when the wholesaler is open for business [(B&PC 4160 (c)(1)]. He added that a wholesaler must also have a designated representative-in-charge who shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers [(B&PC 4160(d))].

Chairperson Weisser reported that the committee heard a presentation from Bob Shaw and Terry Shane representing Medical Waste Services. The committee was advised that their company has received approval to dispose of pharmaceutical waste using a high heat technology that is more environmentally friendly than incineration. Chairperson Weisser also reported that the committee was also advised that as part of the company's approval process from various state and federal regulators the company was instructed to become licensed by the board as a reverse distributor (a DEA requirement).

Chairperson Weisser explained that the committee discussed the current licensing requirements for a reverse distributor as well as the current licensing requirements for a designated representative that works in a reverse distributor and current impediments to meeting those requirements.

Chairperson Weisser reported that the committee reviewed a draft proposal to establish separate licensing requirements for a designated representative working in a reverse distributor.

Ms. Sodergren reviewed the proposed language as provided below.

Proposed Addition of B&PC 4022.6

4022.6. Designated Representative - Reverse Distributor

"Designated representative - reverse distributor" means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

Proposed Addition to B&PC 4053.2

4053.2. Designated Representative-Reverse Distributor

(a) Notwithstanding Section 4051, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler which only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing and destruction of outdated or nonsaleable dangerous drugs and dangerous devices pharmaceutical waste.

(b) An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third party logistics provider or pharmacy performing duties related to the distribution, dispensing or destruction of dangerous drugs or dangerous devices.

(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs and dangerous devices pharmaceutical waste.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.

(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A reverse distributor shall not operate without at least one designated representative or designated representative reverse distributor present at each of its licensed places of business as required under Section 4160.

Proposed Amendment to B&PC 4400

...(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, [or as a designated representative reverse distributor pursuant to Section 4053.2](#) shall be three hundred thirty dollars (\$330) and may be decreased to no less than two hundred fifty-five dollars (\$255).

(2) The fee for the annual renewal of a license as a designated representative, or designated representative-3PL, [or designated representative- reverse distributor](#) shall be one hundred ninety-five dollars (\$195) and may be decreased to no less than one hundred fifty dollars (\$150)...

Chairperson Weisser reported that the committee made the following recommendation: Pursue statutory changes to develop licensing requirements for a designated representative-reverse distributor including proposed addition of Business and Professions Code (B&PC) sections 4022.6 and 4053.2 and proposed amendment to B&PC 4400 with amendment to the one year of experience requirement specified proposed section B&PC 4053.2 (b)(1)(A).

Mr. Law asked if the designated representative for a wholesaler could also be the designated representative for a reverse distributor. Ms. Sodergren explained that a designated representative for a wholesaler could also serve as the designated representative for a reverse

distributor. However, a designated representative for a reverse distributor could not also be the designated representative for a wholesaler.

There were no comments from the public.

Committee Recommendation (Motion): Pursue statutory changes to develop licensing requirements for a designated representative-reverse distributor including proposed addition of Business and Professions Code (B&PC) sections

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez				X
Law	X			
Lippe	X			
Munoz				X
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

c. Discussion and Consideration of a Statutory Proposal to Establish a Satellite Compounding Pharmacy Licensure Category

Chairperson Weisser explained that Business and Professions Code section 4029(a) provides the definition of a hospital pharmacy as a pharmacy licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care and treatment of human illness, to which persons may be admitted for overnight stay...

Chairperson Weisser reported that Business and Professions Code section 4029(b) also provides that a hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant that is regulated under a hospital’s consolidated license issued pursuant to Health and Safety Code section 1250.8.

Chairperson Weisser stated that Business and Professions Code section 4127.1 generally establishes the requirements for licensure for a pharmacy that compounds sterile drug products. He added that as part of these requirements, 4127.1(b) provides that a license to compound sterile drug products shall be issued only to a location that is licensed as a pharmacy.

Chairperson Weisser reported that the Licensing Committee was advised that as the board implemented the expanded sterile compounding licensure program, both hospitals and board staff have experienced challenges in applying appropriate licensing requirements. He noted

that part of the challenge results from the board's requirements and regulation while considering the regulations that a hospital must also comply with under CDPH requirements.

Chairperson Weisser explained that in order to address some of these challenges board staff met internally as well as consulted with CDPH staff and counsel. The intent of these meetings was to gain a better understanding of the overlay between the two regulators, understand the expectations for patient care as well as determine what changes, if any, staff would recommend to ensure safe and appropriate pharmaceutical services within a hospital.

Chairperson Weisser stated that in addition, board staff was approached by a large health system that is seeking clarification on the board's authority to issue more than one hospital pharmacy license. This request was made noting that a CDPH hospital license includes more than just the physical hospital building, but also includes other "approved services" that may be located off the premises. He stated that the concern expressed was about both the logistics of the main hospital pharmacy provided medications in a safe and secure manner to such facilities that are located off site and if there was an opportunity to provide for better drug control at some of these other locations.

Chairperson Weisser reported that as part of its discussion the committee reviewed proposed statutory changes designed to address some of these challenges as well as create additional options for hospitals. The proposed changes would:

1. Allow a hospital to secure a second hospital pharmacy license from the board to be located within an "approved service" area that is not part of the hospital's physical plant.
2. Establish the authority to issue a satellite sterile compounding pharmacy license to a location separate from the hospital's physical plant under specified conditions.

Chairperson Weisser reported that the committee made the following recommendation: Pursue statutory changes to approve amended language in 4029, add 4127.15 and secure these changes via legislation.

Ms. Sodergren reviewed the following proposed language.

Amend 4029.

(a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The

pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) A hospital satellite compounding pharmacy means an area licensed by the board to perform sterile compounding that is separately licensed by the board and located outside of the hospital in another physical plant that is regulated under a hospital's license issued pursuant to Section 1250.8 of the Health and Safety Code.

Add 4127.15

The board may issue a license to a hospital satellite compounding pharmacy.

(a) A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.

1. A hospital satellite compounding pharmacy shall compound sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.
2. The services provided shall be directly related to the services or treatment plan administered in the physical plant

(b) A hospital satellite compounding pharmacy license shall not be issued or renewed until the board does all of the following:

1. Reviews a current copy of the hospital satellite compounding pharmacy's policies and procedures for sterile compounding.
2. Reviews the hospital satellite compounding pharmacy's completed self-assessment form.
3. Receives a list of all products compounded by the hospital satellite compounding pharmacy since the last license renewal.

(c) A hospital satellite compounding pharmacy must do all of the following:

1. Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy, as defined in 4029(a).
2. Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty as required by law.
3. Ensure immediate supervision, as defined in Title 22, California Code of Regulations section 70065, by a pharmacist of licensed ancillary staff involved in sterile compounding.
4. Provide to the board, within 12 hours, any recall notice issued by the hospital satellite compounding pharmacy for sterile drug products it has compounded.
5. Report to the board, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the hospital satellite compounding pharmacy. Unexpected adverse effects must also be immediately reported to the MedWatch program of the federal Food and Drug Administration.

The board clarified that the satellite locations were only to compound for registered patients in the satellite location, not to provide medications to the main hospital.

Dr. Gray, pharmacist, expressed support of the licensing of satellite compounding pharmacies. However, he expressed concern with certain off-site hospital clinics needing to meet the requirements of a pharmacy in order to receive medications. The board asked Dr. Gray to submit written comments during the legislative process to help the board address the issues he brought before the board.

Committee Recommendation (Motion): Pursue statutory changes to approve amended language in 4029, adding 4127.15 and secure these changes via legislation.

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler	X			
Gutierrez				X
Law	X			
Lippe	X			
Munoz				X
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

d. Discussion and Consideration of a Statutory Proposal to Establish Authority for County Emergency Medical Services Providers to Use Automated Drug Delivery Systems for Purposes of Restocking Ambulances

Chairperson Weisser reported that as discussed during the December 2016 board meeting, board staff have been meeting periodically with the LA County Fire Department headquarters staff on a proposal to allow the Fire Department to establish automated drug delivery systems in certain fire stations from which the department’s ambulances can restock their ambulances. This system would supplement other methods already in place that permit the restocking of ambulances.

Chairperson Weisser explained that the general provisions would be that medications would be owned by LA County Fire and initially purchased and stored centrally in a licensed wholesaler premises licensed by the board that is owned and operated by the Fire Department.

Chairperson Weisser reported that distribution of medications from the wholesaler premises would be to the fire stations with automated drug delivery systems. A fire station with an automated drug delivery system would be licensed (requiring a new license type). He explained that restocking of the automated drug delivery systems would be under the supervision of a

pharmacist. He also noted that the automated dispensing machine would then be available for access by ambulance staff. He said the tracking system for the automated drug delivery system would track the signatures of the two staff who removed medications from the automated drug delivery system to replenish the stock of medications on the ambulance.

Chairperson Weisser stated that as part of its discussion the board expressed concern about who would have access to the system as well as its preference to have pharmacist involvement. Chairperson Weisser reported that at the conclusion of its discussion the board referred this matter to the Licensing Committee for further discussion and development of a statutory framework that would provide such a model of restocking ambulance emergency medical supplies for a county.

Chairperson Weisser reported that the Licensing Committee discussed a draft statutory proposal. The committee was advised that the draft was developed based on the board's discussion as well as review of California's Emergency Medical Services Personnel Programs provided by the Emergency Medical Services Authority (EMSA).

Chairperson Weisser explained the committee noted that while the issue was initially brought forward by LA County, the proposal should not be developed for a single county, but rather needed to work for all counties that wished to use the system.

Ms. Sodergren reviewed the draft language as follows.

Proposed Addition of Section 4034

4034. Emergency Medical Services Automated Drug Delivery System

An emergency medical services automated drug delivery system (EMSADD) is an automated drug delivery system that stores and distributes drugs for the sole purpose of restocking a secured emergency pharmaceutical supplies container that is used by an emergency medical services agency to provide emergency medical services.

Proposed Amendment to Section 4119

4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

(a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to ~~24~~ 48.

(b) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency. Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years. The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act.

(c) Notwithstanding any other provision of law, a pharmacy or wholesaler may furnish dangerous drugs and dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) located within a county operated fire department. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b). The EMSADDS may only be used if all of the following conditions are met:

(1) The county fire department obtains a license from the board to operate the EMSADDS on the premises of a fire station. A separate license shall be required for each location. As part of its license application, the county must provide the address of the fire station, the name of the county medical director responsible for overseeing the emergency medical services system, the name of the designated pharmacist, the policies and procedures detailing the provisions under which EMSADDS will operate, and the name and license number of the pharmacy or wholesaler that will furnish the dangerous drugs and dangerous devices.

- (2) Each automated drug delivery system collects, controls, and maintains all transaction information necessary to accurately track the movement of drugs into and out of the system for security, accuracy and accountability purposes.
- (3) The county medical director and designated pharmacist, develops, adopts and maintains, policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures must address: inventory controls; training, storage and security of the dangerous drugs and dangerous devices; safeguards to limit access to the EMSADDS to only authorized staff.
- (4) A pharmacist stocks and inventories the dangerous drugs and dangerous devices in EMSADDS.
- (5) The designated pharmacist reviews, on a monthly basis, the operation of EMSADDS for compliance with inventory controls specified in the policies and procedures.
- (6) The county medical director and designated pharmacist are jointly responsible for monthly review of the county fire department's training, storage and security of dangerous drugs and dangerous devices, and the restocking procedures. This shall include a review of the use of EMSADDS records to verify that only authorized staff, as defined in this section, accessed and remove dangerous drugs and dangerous devices from the EMSADDS.
- (7) The county fire department limits access to the EMSADDS to only employees of the county that are licensed by the state as paramedics, pharmacists or the fire department's medical director.
- (8) A record of each access to the EMSADDS must be maintained for at least three years in a readily retrievable form. The records must include the identity of the licensed paramedic, pharmacist or fire department's medical director accessing the system as well as the drug, dosage form and quantity removed.
- (9) Violations of the provisions in subdivision (c)(1)-(8) shall constitute unprofessional conduct and shall provide the board the authority to take action against the county fire department's licensure of the emergency medical services automated drug delivery systems.

Board member Lavanza Butler asked if this language would apply to all fire stations. Ms. Herold responded that the language would apply to any public fire department and noted that it is not a requirement for them to use the machines; it was simply another option for them.

Chairperson Weisser reported that the committee made the following recommendation: Pursue statutory changes to secure addition of B&PC 4032 and amendment to B&PC 4119.

Stan Goldenberg, pharmacist, stated that the future of pharmacy will incorporate the use of technology. He spoke in support of the board's upcoming Technology Summit and encouraged the board to consider the benefits and challenges related to the use of technology.

A representative from DynaLabs noted that diversion by first responders is an important topic that needs to be addressed to ensure patient safety.

Deanna Allen, clinical pharmacist, spoke in support of pharmacist oversight of automated drug delivery systems.

Committee Recommendation (Motion): Pursue statutory changes to secure addition of B&PC 4032 and amendment to B&PC 4119.

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez				x
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

e. Licensing Statistics

Chairperson Weisser briefly reviewed the licensing statistics as provided in the meeting materials.

Mr. Law asked why there was such a significant increase in pharmacy applications. Ms. Herold responded that a large pharmacy merger taking place has caused the increase in pharmacy applications.

Ms. Veale thanked board staff for the improvement in application processing times.

There were no comments from the public.

f. Future Committee Meeting Dates

Chairperson Weisser announced the following committee meeting dates.

- Pharmacy Technician Summit - April 4, 2017
- June 29, 2017
- September 19, 2017

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

The board recessed for a break at 11:30 a.m. and resumed at 11:48 a.m.

XV. Legislation and Regulation Committee

Chairperson Lippe provided a report of the Legislation and Regulation Committee's efforts at the January 24, 2017.

Part 1: Legislation for Discussion and Consideration Report

Chairperson Lippe reported that the new legislative session started in December 2016. Since that time board staff has been monitoring new legislative proposals to be brought to both the committee and board for consideration. He noted that the deadline to introduce bills this year is February 17, 2017.

Chairperson Lippe explained that as it is early in the session, only a few measures have been identified and of those, a few consist of intent language only. He noted that copies of all measures identified in section b of this report are provided as attachments.

Chairperson Lippe stated that the Legislation and Regulation Committee discussed these measures but did not take positions at this time.

a. Board Sponsored Legislation

Chairperson Lippe reported that during the October 2016 board meeting, the board voted to pursue a statutory proposal to amend Business and Professions Code section 4013(d)(1) to include designated representatives to the list of individuals required to join board's email notification list.

Chairperson Lippe explained that board staff believes this change would be appropriate for inclusion in an omnibus bill and will be submitting the request to the Senate Business and Professions Committee for consideration.

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

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

Chairperson Lippe explained that AB 12 would require each state agency to, on or before January 1, 2020, review regulations; identify any regulations that are duplicative, overlapping, inconsistent, or out of date; revise those identified regulations, as provided; and report to the Legislature and Governor, as specified. The bill would repeal these provisions on January 1, 2021.

2. AB 29 (Nazarian) Pharmacy Benefits Managers

Chairperson Lippe reported that the intent of AB 29 is to enact legislation related to pharmacy benefits managers.

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

Chairperson Lippe reported that AB 40 would require the Department of Justice to make

the electronic history of controlled substances dispensed to an individual under a health care practitioner's care, based on data contained in the CURES database, available to the practitioner through either an online internet web portal or an authorized health information technology system, as defined. He noted that this bill contains other related provisions and other existing laws.

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

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

Chairperson Lippe reported that SB 17 would state the intent of the Legislature to enact legislation requiring public and private purchasers of health care and health care coverage be given advance notice of price increases for the costs of prescription drugs in order to further the ability to predict and manage these costs and the public be given information about the justification, if any, for the prices of newly emerging medications and price increases for existing prescription drugs. He added that this bill would include the findings and declarations of the Legislature in support of its intent.

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

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

Chairperson Lippe explained that SB 27 would require every board within the Department of Consumer Affairs to grant a fee waiver for the application for and the issuance of an initial license to an applicant who supplies satisfactory evidence, as defined, to the board that the applicant has served as an active duty member of the California National Guard or the United States Armed Forces and was honorably discharged. He stated that the bill would require that a veteran be granted only one fee waiver, except as specified.

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

6. SB 70 (Bates) Health Care Professionals

Chairperson Lippe stated, that SB 70 would amend existing legislative intent language regarding the Legislatures intent to address matters through the Health Care Professional Disaster Response Act.

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

Part 2: Regulations for Discussion and Consideration

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

Chairperson Lippe reported that in July 2015, the board initiated a formal rulemaking to add Title 16 CCR sections 1730, and 1730.1 and to amend section 1749 related to the licensing

requirements for advanced practice pharmacist.

Chairperson Lippe stated that at the August 2016 board meeting, the board adopted the final regulation language. Pursuant to the Administrative Procedure Act (APA), following review and approval by the Department of Consumer Affairs (DCA) and Agency, the rulemaking was submitted to the Office of Administrative Law (OAL) for final review on October 31, 2016. He noted that OAL approved the rulemaking on December 13, 2016, with an immediate effective date.

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

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

1. Proposed Regulations to Amend Title 16 CCR Section 1744 Related to Drug Warnings

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: April 21, 2015
Rulemaking Initiated: September 25, 2015
Adopted by Board: July 27, 2016
Submitted to DCA: August 17, 2016
Submitted to OAL: December 20, 2016

Chairperson Lippe explained that this amended regulation implements the provisions contained in AB 1136 (Levine, Chapter 304, Statutes of 2013) to include a written warning label and updates the drug classes requiring the written warning label.

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

2. Proposed Regulations to Amend Title 16 CCR Section 1707.5 Related to Patient-Centered Labels

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: January 28, 2015
Rulemaking Initiated: October 23, 2015
Adopted by Board: August 31, 2016
Submitted to DCA: September 21, 2016
Submitted to OAL: Pending

Chairperson Lippe reported that this regulation modifies the patient-centered labeling requirements including “generic for” on the prescription label. Additionally, the regulation was amended to require that pharmacies have policies and procedures in place to provide translation services to patients with limited or no English proficiency.

3. Proposed Regulations to Amend Title 16 CCR Sections 1732.05, 1732.2 and 1732.5 Related to Continuing Education

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: October 29, 2015

Rulemaking Initiated: November 13, 2015

Adopted by Board: September 22, 2016

Submitted to DCA: October 3, 2016

Submitted to OAL: Pending

Chairperson Lippe explained that this regulation amends the board's continuing education requirements. Specifically, the amended regulation grants CE credit for serving on a committee developing the California Practice Standards and Jurisprudence Examination (CPJE), grants CE credit for attending board meetings or committee meetings, and defines a specialized subject area necessary to meet the CE hour requirement.

4. Proposed Regulations to Add Title 16 CCR Sections 1776 et seq. Related to Prescription Drug Take Back

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: January 19, 2016

Rulemaking Initiated: February 12, 2016

Adopted by Board: October 26, 2016

Submitted to DCA: December 12, 2016

Submitted to OAL: Pending

Chairperson Lippe reported that this regulation established the regulatory requirements for prescription drug take back programs offered by pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board.

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

5. Proposed Regulations to Amend Title 16 CCR Section 1703 Related to Delegation of Certain Functions

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: February 24, 2016

Rulemaking Initiated: April 22, 2016

Adopted by Board: July 27, 2016

Submitted to DCA: October 27, 2016

Submitted to OAL: Pending

Chairperson Lippe explained that this regulation updates functions delegated to the executive officer including the authority to adopt regulation changes that are deemed to be

“without regulatory effect” in accordance with Title 1 CCR Section 100 and the authority to approve prescription label waivers in accordance with Business and Professions Code section 4076.5(d).

c. Board Adopted – Rulemaking File Being Prepared by Staff for Submission and Review by the Department of Consumer Affairs or the Office of Administrative Law: Proposed Regulations to Amend and/or Add Title 16 CCR Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: July 30, 2013
Rulemaking Initiated: August 12, 2016
Adopted by Board: December 14, 2016
Submitted to DCA: Pending
Submitted to OAL: Pending

Chairperson Lippe reported that this regulation establishes standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as requires nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal.

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

d. Board Approved to Initiate Rulemaking – Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency: Proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board’s Fee Schedule

Chairperson Lippe stated that as the board was advised during the October 2016 Board Meeting, DCA and Agency will now be performing a pre-review of all regulations prior to the board publishing a notice and initiating a comment period.

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: October 26, 2016
Submitted to DCA for Pre-Notice Review: Pending
Rulemaking Initiated: Pending
Adopted by Board: Pending
Submitted to DCA: Pending
Submitted to OAL: Pending

Chairperson Lippe explained that this regulation updates the board’s fee schedule in regulation to be consistent with updates made to the board’s fees in Business and Professions Code section 4400 as the result of SB 1039 (Hill, Chapter 799, Statutes of 2016).

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

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

1. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: October 26, 2016

Rulemaking Initiated: Pending

Adopted by Board: Pending

Submitted to DCA: Pending

Submitted to OAL: Pending

Chairperson Lippe stated that this regulation establishes the regulatory framework for third-party logistics providers.

2. Proposed Regulation to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: October 26, 2016

Rulemaking Initiated: Pending

Adopted by Board: Pending

Submitted to DCA: Pending

Submitted to OAL: Pending

Chairperson Lippe explained that this regulation establishes the training requirements and certification programs and updates the application for licensure of a pharmacy technician. Board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

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

3. Proposed Regulation to Amend Title 16 CCR Section 1735.2 Related to the Compounding Self-Assessment Form 17M-39

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: December 14, 2016

Rulemaking Initiated: Pending
Adopted by Board: Pending
Submitted to DCA: Pending
Submitted to OAL: Pending

Chairperson Lippe stated that this regulation updates self-assessment form 17M-39 (rev. 10/16) as incorporated by reference in 16 CCR section 1735.2. He noted that board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

4. Proposed Regulations to Amend Title 16 CCR Sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: October 27, 2016
Rulemaking Initiated: Pending
Adopted by Board: Pending
Submitted to DCA: Pending
Submitted to OAL: Pending

Chairperson Lippe explained that this regulation updates update self-assessment forms 17M-13 (rev. 10/16), 17M-14 (rev. 10/16), and 17M-26 (rev. 10/16) as incorporated by reference. He added that board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

5. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Trust Ownership

Chairperson Lippe reviewed the regulation timeline as provided below:

Approved by Board: October 27, 2016
Rulemaking Initiated: Pending
Adopted by Board: Pending
Submitted to DCA: Pending
Submitted to OAL: Pending

Chairperson Lippe stated that this regulation amends the Board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies. He added that board staff is currently compiling the initial rulemaking file to submit to DCA for pre-notice review.

Chairperson Lippe announced the following Legislation and Regulation Committee meetings:

- April 12, 2017
- June 27, 2017
- October 18, 2017

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

Vice President Veale adjourned the meeting at 12:20 p.m.

DRAFT