



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

**DRAFT
MINUTES**

DATE: July 25-26, 2017

LOCATION: Sheraton Park Hotel
1855 S. Harbor Blvd.
Anaheim, Ca 92802

BOARD MEMBERS PRESENT: Amy Gutierrez, Licensee Member, President
Victor Law, Licensee Member, Vice President
Allen Schaad, Licensee Member, Treasurer
Lavanza Butler, Licensee Member
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Deborah Veale, Licensee Member (July 26 only)
Stanley Weiser, Licensee Member
Albert Wong, Licensee Member
Amjad Khan, Public Member

BOARD MEMBERS NOT PRESENT: Ryan Brooks, Public Member
Valerie Muñoz, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Counsel
Desiree Kellogg, Deputy Attorney General
Laura Hendricks, Staff Analyst

Call to Order

9:06 a.m.

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

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

Note: Amjad Khan arrived at 10:30 a.m.

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

A pharmacist stated that the board needs to implement online renewals. He also stated that the board should hold pharmacies accountable for workflow and added that technicians should be held accountable for their actions in a pharmacy (rather than the pharmacist who oversees them).

III. January 24-25, 2017 Board Meeting Minutes – Revisions to Previously Approved Minutes

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

Motion: Approve the January 24-25, 2017, revised Board Meeting minutes.

M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 0

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

IV. May 3-4, 2017 Board Meeting Minutes

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

Motion: Approve the May 3-4, 2017, revised Board Meeting minutes.

M/S: Law/Butler

Support: 8 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Gutierrez | x | | | |
| Khan | | | | x |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |

| | | | | |
|---------|---|--|--|---|
| Schaad | x | | | |
| Veale | | | | x |
| Weisser | x | | | |
| Wong | x | | | |

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

The board recognized Peter Perrin for 50 years of service as a pharmacist.

VI. **Enforcement and Compounding Committee Related Items**

Part 1: Enforcement Matters

a. **Discussion and Consideration of Reporting Drug Losses Under State and Federal Laws**

President Gutierrez explained that CCR Section 1715.6 establishes a requirement for the owner to report any loss of controlled substances within 30 days to the board.

President Gutierrez stated that CFR Section 1301.76(b) establishes a requirement for reporting a significant drug loss to the Drug Enforcement Administration.

President Gutierrez reported that at prior meetings, the committee has discussed the federal and state requirements for the reporting of lost controlled substances.

President Gutierrez explained that the DEA requirements specify immediate reporting of “significant” controlled substances losses to the DEA. The board’s regulation uses the broader standard of reporting “any” controlled substances loss to the board, in part to remove the ambiguity of a pharmacy’s ability to determine the meaning of a “significant” loss.

President Gutierrez noted that during a prior discussion of this matter, DCA Legal Counsel Laura Freedman indicated that addition of the word “significant” would create lack of clarity in what licensees are required to do under regulations.

President Gutierrez reported that the committee was provided with statistics on drug losses, including the top 10 losses reported by drug name from FY 2012/13 through May 2017 and a comparison of dosage units lost versus cause of loss. She added that the committee requested additional data elements for consideration at future meetings.

President Gutierrez stated that the committee determined that amending the regulation to include “significant” may be too subjective. As such, amending the regulation would be problematic and would not meet the Office of Administrative Law’s criteria for clarity.

President Gutierrez reported that the committee decided that it would be beneficial to continue to review drug loss data and determine what effect, if any, the board’s inventory regulation has on drug losses. This would allow for pre- and post- data analysis. The committee requested that going forward additional data elements be provided.

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

b. Discussion and Consideration of Reporting Drug Losses Under State and Federal Laws

President Gutierrez explained that Business and Professions Code (BPC) 4104 in part establishes the requirements for a pharmacy to notify the board within 14 days of specified information including theft, diversion or self-use of dangerous drugs.

President Gutierrez reported that during the May board meeting, member Albert Wong asked that the board agenda a discussion on the mandatory reporting of drug diversion and/or theft to the appropriate law enforcement agency.

President Gutierrez explained that there is currently no requirement to report drug diversion and/or theft to law enforcement agencies, although the board has encouraged pharmacies to contact law enforcement agencies when employees admit drug theft or working under the influence. She noted that based on reports to the board under section 4104, the board has opened 112 case investigations.

President Gutierrez reported that the committee discussed the issue and considered language that could be used to facilitate implementation of the requirement. The committee agreed that the requirement, if pursued, should only apply to drug thefts.

President Gutierrez reported that the committee did not take action on this item but requested that staff collect data on drug losses reported to police versus those not reported as well as the case outcomes. She stated that this item will be brought back to the committee for further discussion after the data is available.

Board member Victor Law stated that pharmacies may be afraid to report losses due to employee pilferage because the PIC or the pharmacy might be disciplined by the board. President Gutierrez clarified that pharmacies are already required to report losses to the board – the committee had been discussing reporting losses to law enforcement in addition to the board.

Board member Ricardo Sanchez noted that there are issues that must be considered from a law enforcement perspective, for example what happens if someone is falsely accused by a co-worker.

Board member Albert Wong asked if the board would be pursuing regulations to require the reporting of employee pilferage to law enforcement. President Gutierrez responded that at this time the committee did not feel it was appropriate, whoever they would be reconsidering the issue after staff provided additional data.

c. Update on the Development of the Continuing Education Training from the Board on Prescription Drug Abuse

President Gutierrez reported that in March the board, DEA and the University of California, San Diego (UCSD) provided a day-long conference on prescription drug abuse, corresponding responsibility and preventing drug losses from a pharmacy. There were 200 attendees who earned six hours of continuing education (CE) credits, and another 132 attendees earned one additional hour of continuing education to secure the training needed to provide naloxone.

President Gutierrez reported that since March, Executive Officer Virginia Herold and Enforcement Chief Tom Lenox have been working on additional joint training sessions on opioid abuse for 2017. Below is a tentative schedule for the training.

- August 26 - One full day training session at Cal Northstate University, College of Pharmacy in Elk Grove (7 units).
- October 21 - One full day training session at Keck Graduate Institute in Claremont (7 units).
- November 7 - One three-hour training session from 6 to 9 p.m. at the Catamaran Hotel in San Diego. This session will be a part of the California Opioid Summit hosted by a variety of organizations, including the California Department of Public Health (3 units).

President Gutierrez explained that the committee determined it would be appropriate to award continuing education for participants of these trainings.

Committee Recommendation (Motion): Award continuing education credits for individuals attending the training sessions.

Support: 8 Oppose: 0 Abstain: 0

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

d. Discussion and Consideration of Safe Medication Transitions for Patients Upon Discharge

President Gutierrez reported that the committee heard a presentation from Dr. Rita Shane on *The Safe Medication Transitions: Evidence-Based Solutions Infographic*. President Gutierrez asked Dr. Shane to provide a brief overview of her presentation to the board.

Rita Shane, Pharmacy Director at Cedars-Sinai, reported that a significant number of errors are found on patients' computer hosted medication lists, which results in errors during hospital admissions and adverse outcomes after discharge, including emergency department visits and readmissions. She noted that evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.

Dr. Shane highlighted the benefits to patients when pharmacists and trained technicians are involved in medication reconciliation as part of the admission and discharge of a patient from a hospital. Dr. Shane shared her recommendations for pharmacy staff to ensure the accuracy of the medication lists at admission and discharge for high-risk patients.

Board member Stanley Weisser asked how a patient’s medications can be verified when someone is in the emergency room. Dr. Shane explained that trained pharmacy technicians have multiple ways to obtain medication information. She added that studies have shown that it is more effective to have a pharmacist or trained pharmacy technician handle the medication list while the doctors and nurses care for the patient.

Dr. Shane stated that by leveraging trained pharmacists and technicians to manage medication lists it frees up valuable healthcare resources and benefits patients.

A pharmacist commented that drug therapy is complex and pharmacists need to be involved in the patient’s care.

Dr. Shane explained that she has reached out to various healthcare associations (nursing, physician, etc.) and she has found them to be generally supportive of the idea. Mr. Weisser noted that the California Hospital Association will be a key player in implementing this new practice.

President Gutierrez stated that the committee made the following motion: “Refer a portion of this issue to the Communication and Public Education Committee to develop consumer education materials highlighting the importance of maintaining and conveying medication history to health care providers in a hospital and the importance of understanding how medication lists change at discharge. Further, refer the role a pharmacy technician can play to the Licensing Committee to consider what, if any, changes should be made to the functions a pharmacy technician may perform in a hospital.”

President Gutierrez recommended amending the motion to add education materials for pharmacists. The board agreed with the recommendation.

Motion: Refer a portion of this issue to the Communication and Public Education Committee to develop consumer and licensee education materials highlighting the importance of maintaining and conveying medication history to health care providers in a hospital and the importance of understanding how medication lists change at discharge. Further, refer the role a pharmacy technician can play to the Licensing Committee to consider what, if any, changes should be made to the functions a pharmacy technician may perform in a hospital.

M/S: Gutierrez/Weisser

Support: 8 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Gutierrez | X | | | |
| Khan | | | | X |
| Law | X | | | |

| | | | | |
|---------|---|--|--|---|
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Veale | | | | x |
| Weisser | x | | | |
| Wong | x | | | |

e. Discussion and Consideration of Recalls by Drug Manufacturers at the Patient or Pharmacy Level

President Gutierrez reported that at the request of the board, staff reviewed all subscriber alerts involving recalls that were sent from the board from May 2014 through May 2017 at the patient or pharmacy level.

President Gutierrez stated that there were 785 recalls issued. The largest number of recalls from any manufacturer was 67. The data lists the top 20 manufacturers that had recalls. It should be noted that some of the manufacturers could be subsidiaries to other manufacturers.

President Gutierrez reported that the committee discussed the information provided and requested that staff further separate the data to identify what recalls were to the patient level versus the pharmacy level for the last year and report it to the board.

President Gutierrez explained that as requested by the committee staff reviewed recalls from manufacturers between July 1, 2016, and June 30, 2017. Staff identified 263 recall alerts, 21 of which were to the patient level. She added that some examples of recalls at the patient level included a topical skin product recalled for potential microbial contamination, incorrect labeling of blister cards, potential labeling mix-ups for various strengths of phenobarbital tables, and potential lack of sterility assurance.

Mr. Weisser expressed his concern with the increase in the number of recalls. Board member Lavanza Butler shared Mr. Weisser's concern.

Board Member Allen Schaad noted that some of the recalls were for over-the-counter medications.

There were no comments from the public.

f. Discussion and Consideration of Requests for Wholesalers to Report Suspicious Drug Sales to the Board

President Gutierrez explained that Health and Safety Code (HSC) section 11153.5 prohibits a wholesaler from furnishing controlled substances for anything other than a legitimate medical purpose.

President Gutierrez stated that Code of Federal Regulations Title 21, Part 1301, section 1301.74 (a) (b) requires a DEA registrant to make a good faith inquiry with either the DEA or the appropriate state controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance. Further, this section requires notification to a DEA field office of suspicious orders, including orders of unusual size, orders deviating

substantially from a normal pattern, and orders of unusual frequency.

President Gutierrez explained that earlier this year two large drug wholesale distributors agreed to pay millions of dollars in civil penalties for alleged violations of the Controlled Substance Act (CSA). The distributors allegedly failed to notify the DEA of suspicious orders for controlled substances. McKesson Corporation agreed to pay a record penalty of \$150 million and suspended sales of controlled substances from distribution centers in Colorado, Ohio, Michigan and Florida for multiple years. McKesson also agreed to compliance terms for five years that include specific, rigorous staffing and organizational improvements. Cardinal Health has agreed to pay \$44 million in fines for allegations that it failed to alert the DEA of suspicious orders of powerful narcotics by pharmacies in Florida, Maryland and New York.

President Gutierrez reported that the committee discussed action taken by Oregon requiring wholesale distributors to report “suspicious orders” to the Oregon Board of Pharmacy. The rule went into effect on July 1, 2017.

The committee reviewed the language adopted by Oregon (below):

“A wholesale distributor must notify the Board in writing of suspicious orders of controlled substances to be distributed in Oregon upon discovery. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” OAR 855-065-0010. (This notification must be in writing, which means a written letter, email or fax copy of what is submitted to the DEA)

President Gutierrez reported that the committee considered if California should pursue a similar mandatory reporting requirement and considered possible language that could be used to implement such a requirement:

Upon discovery, a wholesale distributor must notify the board in writing by letter, email or fax, of suspicious orders of controlled substances to be distributed in California. Suspicious orders include, but are not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Daniel Martinez representing CPhA, spoke in support of the proposal. He asked the board to consider allowing pharmacies to submit a copy of the report that they already are required to provide to the DEA. He provided the board with the recommended language from CPhA (below).

A wholesale distributor must notify the Board of suspicious orders of controlled substances to be distributed within California, upon discovery, by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration regarding such suspicious orders. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Ms. Herold explained that if the board approves of the concept it is possible that it can be included in legislation this year.

Mr. Law asked if when a suspicious order is identified if the wholesaler can still sell the medication to the pharmacy. President Gutierrez explained that usually the wholesaler will call the pharmacy and tell them that they need to resolve the discrepancy before they will fill the order.

Motion: Direct staff to pursue legislation to require wholesalers to notify the board of suspicious orders of controlled substances. Delegate the authority to the executive officer to work with legal counsel to modify the language as needed without changing the intent.

M/S: Weisser/Law

Support: 8 Oppose: 0 Abstain: 0

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

The board recessed for a break at 10:20 a.m. and resumed at 10:35 a.m.

President Gutierrez introduced the board’s new member Amjad Khan who arrived at 10:30 a.m.

Part 2: Compounding Matters

- h. Discussion and Consideration of Amendments to the Board’s Compounding Regulations, California Code of Regulations, Title 16, Division 17, Articles 4.5 (Sections 1735-1735.8) and 7 (Sections 1751-1751.10)

1. Committee’s Recommended Changes

President Gutierrez reported that in April 2015, the board formally initiated a rulemaking to promulgate the board’s compounding regulations. The final version of the regulation language was adopted by the board on Jan. 19, 2016, and approved by the Office of Administrative Law on Sept. 13, 2016. She noted that the effective date of the regulations was Jan. 1, 2017.

President Gutierrez explained that since adoption, both the committee and board have received public comments regarding the impact of the regulations on patient populations principally for oral compounded preparations, including animals.

President Gutierrez stated that in response to the comments, the committee held a special

meeting on June 2, 2017, on the board's compounding regulations. The committee reviewed written comments and recommendations from board staff and members of the regulated public and heard public comments during the meeting. She reported that at the conclusion, the committee approved the recommendations offered by staff. The committee also requested that members of the public provide examples of compounded preparations that would provide additional context to support requested changes. President Gutierrez reported that the committee provided guidance to staff in several areas and requested that staff evaluate comments received from the public and provide recommendations.

President Gutierrez asked Ms. Sodergren to review the proposed changes. Ms. Sodergren summarized the proposed changes as follows.

1735.1(c) & (f): Change "venting" to "exhausting". Ms. Sodergren reported that this change has been approved by the board at its January meeting.

1735.2 (i)(1): Amend 1735.2(i)(1) as provided below. President Gutierrez noted that this section is being amended to align the board's regulations with USP 795 for pharmacies that compound oral, non-sterile medications. **Ms. Sodergren reported that this section would be handled via an emergency regulation.**

(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation~~z~~

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended date established by a pharmacist's research, analysis and documentation,

(E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by a pharmacist's research, analysis and documentation, and

(F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by a pharmacist's research, analysis and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation and research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

- (iv) the container in which it is packaged,
- (v) the expected storage conditions, and
- (vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

1735.2(i)(3): Amend to clarify that the section only applies to sterile compounded drug preparations. **Ms. Sodergren noted that this section would also be part of the emergency regulation.**

(3) For sterile compounded drug preparations, ~~E~~extension of a beyond use date is only allowable when supported by the following:

1735.6 (e)(3): Amend to allow for the use of redundant HEPA filters. Ms. Sodergren noted that that amendment had been approved at the January Board Meeting.

(3) Each ~~PEC~~ BSC in the room shall also be externally vented except that a BSC used only for nonsterile compounding may use a redundant-HEPA filter in a series; and

1751.1 (a)(5): Amend to clarify the smoke study requirements.

(5) Biannual ~~V~~video of smoke studies in all ISO Class 5 certified spaces.

1751.4(k): Modify the room temperature requirements to align the board's regulations with USP 797.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of ~~20-24~~ 20-24 degrees Celsius (~~68-75~~ 68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

President Gutierrez reminded the board that USP is modifying their requirements so the board will have to continually review and update its regulations as appropriate.

2. Regulatory Amendments Requiring Emergency Adoption Procedure to Avoid Serious Harm to the Public Peace, Health, Safety, or General Welfare

Ms. Freedman stated the board would need to determine that the emergency rulemaking is necessary for sections 1735.2(i)(1) and 1735.2(i)(3) in order to avoid serious harm to the public peace, health, safety or general welfare.

President Gutierrez explained that the proposed amendments will help make critical compounded non-sterile, oral medications more readily available to high-risk patients. She provided an example of a pediatric patient who needs anti-rejection medications. She explained that without the proposed amendments to 1735.2(i)(1) and 1735.2(i)(3) this patient would have to go to the pharmacy every two weeks to get their medication, which

can have a negative impact on the patient's health and adherence to the medication plan.

The board agreed that the emergency rulemaking to amend 1735.2(i)(1) and 1735.2(i)(3) was necessary to avoid serious harm to the public peace, health, safety or general welfare.

A representative from CPhA spoke in support of the emergency rulemaking.

President Gutierrez recommended amending 1735.2(i)(1)(D), 1735.2(i)(1)(E) and 1735.2(i)(1)(F) as follows so that it is clear that it applies to the pharmacist who is actually preparing the compounded medication. The board agreed with the recommendation.

(D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended date established by a the pharmacist's research, analysis and documentation,
(E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by a the pharmacist's research, analysis and documentation, and
(F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by a the pharmacist's research, analysis and documentation.

Motion: The board believes that the lack of access to the non-sterile, oral compounded medications poses a serious risk to the public peace, health, safety, or general welfare. Approve the proposed changes to CCR Section 1735.2(i)(1) and 1735.2(i)(3) and initiate the emergency rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

1735.2(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation;

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis and documentation,

(E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis and documentation, and

(F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and

literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation and research, analysis and conclusion. The factors the pharmacist must analyze include:

- (i) the nature of the drug and its degradation mechanism,
- (ii) the dosage form and its components,
- (iii) the potential for microbial proliferation in the preparation,
- (iv) the container in which it is packaged,
- (v) the expected storage conditions, and
- (vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

1735.2(i)(3) For sterile compounded drug preparations, Extension of a beyond use date is only allowable when supported by the following:

M/S: Schaad/Lippe

Support: 9 Oppose: 0 Abstain: 0

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

3. Regulatory Amendments Pursuant to Regular Rulemaking Procedure

Ms. Sodergren explained that an emergency rule change can only remain in effect for 180-360 days. As such a standard rulemaking must be initiated at the same time or shortly thereafter to ensure the emergency provisions become permanent. She stated that because of the timeframes for the various notice periods and review periods required in the normal rulemaking process, it is recommended that the board consider initiating the formal rulemaking process at the same time as the emergency rulemaking.

The board agreed with the recommendation to initiate the normal rulemaking process.

At the request of Ms. Freedman Ms. Sodergren again reviewed the proposed amendments.

Motion: Approve the proposed changes to CCR Section 1735.1(c) & (f), CCR Section

1735.2(i)(1) and (i)(3), 1735.6(e)(3), 1751.1(a)(5), and CCR 1754.4(k) and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

1735.1(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding ~~sterile~~ drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ~~ventilation~~ exhausting. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI.

1735.1(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ~~ventilation~~ exhaust. This external ~~venting~~ exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

1735.2(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation^{7z}

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) ~~180 days~~ for non-aqueous formulations, 180 days or an extended dated established by the pharmacist's research, analysis and documentation,

(E) ~~14 days~~ for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis and documentation, and

(F) ~~30 days~~ for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis and documentation.

(G) A pharmacist, using his or her professional judgment may establish an

extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation and research, analysis and conclusion. The factors the pharmacist must analyze include:

- (i) the nature of the drug and its degradation mechanism,
- (ii) the dosage form and its components,
- (iii) the potential for microbial proliferation in the preparation,
- (iv) the container in which it is packaged,
- (v) the expected storage conditions, and
- (vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

1735.2(i)(3) For sterile compounded drug preparations, Extension of a beyond use date is only allowable when supported by the following:

1735.6(e)(3) Each PEC BSC in the room shall also be externally vented except that a BSC used only for nonsterile compounding may use a redundant-HEPA filter in a series; and

1751.1(a)(5) Biannual video of smoke studies in all ISO Class 5 certified spaces.

1751.4(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

M/S: Gutierrez/Schaad

Support: 9 Oppose: 0 Abstain: 0

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

i. Discussion and Consideration of the Status of Waiver Requests for Compounding Construction Compliance Delays Pursuant to Title 16, California Code of Regulations, Sections 1735.6 and 1751.4 and the Process for Review and Appeals of such Requests

President Gutierrez explained that Title 16 of (CCR) section 1735.6 (f) states that where compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver for a period of time to permit the required physical changes. She added that there is a related provision in CCR section 1751.4 which provides the same allowances for sterile compounding facilities.

President Gutierrez stated that a waiver application must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board may grant the waiver for a specified period when, in its discretion, good cause is demonstrated. Initial review of the application is performed by staff led by the executive officer, who approves or denies the request. She added that the approval or denial of a waiver has been provided to facilities in writing. If a waiver is denied by the executive officer, there is an appeal process that is reviewed by two board members, currently Allen Schaad and Victor Law.

President Gutierrez stated that the goal of the waiver process is to secure full compliance at the earliest possible time and no later than the implementation of USP <800> on July 1, 2018.

President Gutierrez reported that the committee was advised that the review process is ongoing, as staff continues to work with facilities that have applied for a waiver. There have been instances where the executive officer has approved extensions to waivers due to construction delays. She added that the executive officer has provided specific timelines to facilities requesting a waiver with respect to the Office of Statewide Health Planning and Development (OSHPD) approval, status reports of construction and final completion dates. Facilities that have been denied a waiver have been informed of the appeal process.

President Gutierrez reviewed the following waiver statistics.

Status of Waiver Requests Received as of 6/27/17:

- Total Waivers Received: 609
- Total Waivers Processed: 607
- Denied: 40 (6.5 percent)
- Withdrawn: 100 (16.5 percent)
- Approved: 380 (62.6 percent)
- Non-responsive letters sent: 21 (3.5 percent)
- In process: 66 (10.8 percent)
- Total Waivers Pending Review: 2
- Total Waiver Extensions Granted: 60

Supervising Inspector Christine Acosta reported that of those who were initially denied approximately 50 percent have reapplied and been approved.

Part 3: Enforcement Statistics

j. Enforcement Statistics

President Gutierrez reported that a review of the three-year comparison reveals the board completed about 600 more investigation in FY 2016/17 versus FY 2014/15. Over the three-year period there has been a slight increase (8 percent) in the number of cases referred to the Attorney General's Office. She added that pharmacy technicians represent the greatest number of licenses revoked by the board, while pharmacists represent the greatest number of licensees placed on probation.

k. Future Meeting Dates

President Gutierrez reported the following committee meeting dates.

- September 15, 2017
- March 28, 2018
- June 7, 2018
- September 5, 2018
- December 13, 2018

VII. Licensing Committee

- a. Summary of Presentation by the Department of Health Care Services on Their Enrollment and Re-Enrollment Process of Fee-for-Service Health Care Providers in the Medi-Cal Program – send him the moratorium memo

Chairperson Weisser explained that this presentation had been cancelled but was inadvertently left on the committee agenda, as such there is nothing to report on this agenda item.

Board member Victor Law asked if this presentation would be re-scheduled. Chairperson Weisser stated that staff would work on possibly re-scheduling this presentation.

- b. Discussion and Consideration of the Re-Take Waiting Period for the North American Pharmacist Licensure Examination (NAPLEX) and California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chairperson Weisser explained that on July 28, 2016, the NABP advised executive officers of changes to the NAPLEX program. Changes included transitioning to a new administration model that included increasing the number of test items, increasing the test administration time and increasing the fee. Chairperson Weisser stated that readers were also advised that the waiting period for the NAPLEX examination would be decreased to 45 days.

Chairperson Weisser reported that at the September 2016 Licensing Committee meeting, the committee discussed NABP's change in policy related to the waiting period for candidates who fail the NAPLEX. The committee discussed that while NAPLEX decreased its waiting period to 45 days, California law will still require a 90-day waiting period for the NAPLEX. As part of its discussion, the committee considered whether the proposed change to the waiting period for the NAPLEX is appropriate. Chairperson Weisser also reported that the committee discussed if the board should consider a change to the waiting period for the CPJE. The committee discussed that, by statute, any changes to the current waiting period for the NAPLEX would require

consultation with Office of Professional Examination Services (OPES). The committee requested that this item be referred back to the committee after consultation with OPES.

Chairperson Weisser reported that at the July 19, 2017, meeting the committee discussed the issue and the conclusion of both OPES and PSI (the board’s contract psychometric firm). As OPES concluded that the 45-day waiting periods are reasonable and PSI agrees that the 45-day waiting period is appropriate for the CPJE, the committee determined that statutory modifications would be appropriate.

Based on comments received at the committee meeting staff drafted a statutory proposal to be brought before the full board. This language has been provided below.

4200.4.

An applicant who fails either the national examination North American Pharmacist Licensure Examination or the California Practice Standards and Jurisprudence Examination for Pharmacists may not retake ~~the that~~ examination for at least ~~90~~ 45 days. ~~or for a~~ The board may, established by regulations adopted by the board in consultation with the Office of Professional Examination Services of the department, adopt a regulation establishing a different retake wait period.

There were no comments from the public.

Committee Recommendation (Motion): Seek statutory amendment to change the examination retake waiting periods for both the NAPLEX and CPJE from 90 days to 45 days and include the CPJE in the statute.

4200.4.

An applicant who fails either the national examination North American Pharmacist Licensure Examination or the California Practice Standards and Jurisprudence Examination for Pharmacists may not retake ~~the that~~ examination for at least ~~90~~ 45 days. ~~or for a~~ The board may, established by regulations adopted by the board in consultation with the Office of Professional Examination Services of the department, adopt a regulation establishing a different retake wait period.

Support: 9 Oppose: 0 Abstain: 0

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

c. Discussion and Consideration of Issuing Board Licenses Including Photos for Individual Licensees

Chairperson Weisser reported that the board has encountered instances of unlicensed individuals posing and working as a licensed pharmacist using a name and license number issued to someone else. In such cases the unlicensed individual has provided a fake license to the employer.

Chairperson Weisser noted that there are several programs within the DCA that currently issue licenses that include a photo of the individual.

Note: Samples of the photo licenses were provided in the board meeting materials.

Chairperson Weisser reported that the committee determined that implementation efforts should focus on pharmacist licensees first. The committee also suggested that licensees be required to update their photo periodically. Chairperson Weisser stated that staff suggested a phased approach where newly licensed pharmacists will be issued the photo license upon licensure and current pharmacists will convert to the photo license as part of the renewal process. The committee agreed with the staff recommendation.

President Gutierrez asked if there would be any additional security measures to ensure that the photo license could not be duplicated. Board member Sanchez provided an example of having the licensee’s thumbprint on the card. Ms. Sodergren responded that the staff recommends using a photo license similar to one that another department uses, which has additional security features such as holographic printing.

Daniel Martinez, representing CPhA, asked if the licensees would have to pay for the photo license (approximately \$50-\$60). Ms. Herold stated that the licensee would have to pay, but the fee would go to the exam vendor not the board.

Mr. Law asked if this would apply to all licensees. Ms. Herold responded that the board would start with pharmacists. Chairperson Weisser added that the board would start with all newly licensed pharmacists and then would require it for existing pharmacists upon renewal. Ms. Herold stated that staff would provide the Licensing Committee with a plan as to how this would be implemented for all 40,000 pharmacists.

Committee Recommendation (Motion): Proceed with implementing photo licenses for pharmacists to be in by July 2018.

Support: 9 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Gutierrez | X | | | |
| Khan | X | | | |
| Law | X | | | |
| Lippe | X | | | |
| Munoz | | | | X |

| | | | | |
|---------|---|--|--|---|
| Sanchez | x | | | |
| Schaad | x | | | |
| Veale | | | | x |
| Weisser | x | | | |
| Wong | x | | | |

d. Discussion and Consideration of Pharmacy Technician Duties and Possible Changes to Such Duties

Chairperson Weisser stated that for several meetings, the board has discussed different facets of the pharmacy technician program. In June 2016, the licensing committee considered the duties of a pharmacy technician.

Chairperson Weisser reported that more recently, the committee held a summit focused on the role of pharmacy technicians in various settings. The summit provided the committee with the opportunity to learn about the functions pharmacy technicians perform in various state jurisdictions and practice settings.

Chairperson Weisser explained that during the summit the committee discussed the various settings where pharmacy technicians may be focused on different types of responsibilities to support a pharmacist – for example, a community pharmacy, hospital pharmacy, etc. – and requested input from the public on each of the settings.

Chairperson Weisser added that during the summit the committee noted the need to review the current marketplace and anticipate future needs when assessing the issue while noting that any changes need to focus on how they will benefit consumers. Chairperson Weisser explained that such benefits could include pharmacists being available to engage in more patient care activities.

Chairperson Weisser reported that during the summit the committee heard public comment about how the role of the technician is evolving in other states as well as recent studies in the area including tech-check-tech in the retail setting and a pilot program study in Iowa.

Chairperson Weisser reported that the July 19, 2017 meeting the committee reviewed comparisons of pharmacy technician duties in other states. The committee discussed the practical implications of a tech check tech model in the community pharmacy setting including questioning the liability to the pharmacist supervising the activities. During the committee meeting counsel noted that creating a new license type with a defined scope of duties could address this concern as the responsibility would be shared.

Chairperson Weisser stated that at its July meeting the committee also spoke about the need to increase the educational requirements if pharmacy technicians are going to be allowed to perform expanded duties and noted the need to consider the full picture when assessing changes to pharmacy technician duties, as it could impact ratio considerations and most importantly how it impacts patient care.

Chairperson Weisser reported that the committee requested that board staff consider the committee comments and prepare a draft framework for discussion at a future committee meeting. The committee authorized staff to work with the committee chair on the development

in order to confirm the staff's direction in drafting the framework is appropriate and consistent with the committee's discussion.

Mr. Law stated that he would be supportive of creating a separate license type for technicians who will be performing expanded duties and requiring them to have higher education level and complete continuing education. He added that the board should consider allowing different ratios for the advanced technicians.

There were no comments from the public.

e. Discussion and Consideration of Pharmacy Technician Ratios in California

Chairperson Weisser explained that BPC section 4115 established the general conditions under which a pharmacy may use a pharmacy technician. Unless otherwise indicated, the ratio of pharmacists to pharmacy technicians is generally 1:1 for the first pharmacist. The ratio for each additional pharmacist on duty becomes 1:2.

Chairperson Weisser stated that CCR section 1793.7 allows the ratio for preparation of a prescription for an inpatient of a licensed health facility to be one pharmacist to two pharmacy technicians.

Chairperson Weisser reported that the committee determined that as it considers changes to the functions that a pharmacy technician is authorized to perform; changes to the ratio may also need to be considered. Chairperson Weisser stated that as part of its discussion the committee reached agreement that the ratio should be raised, but elected not to make a formal recommendation. Rather the committee will continue to discuss this issue as part of the large evaluation of the pharmacy technician program.

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

f. Discussion and Consideration of Application and Renewal Requirements for Pharmacy Technicians

Chairperson Weisser explained that the requirements for licensure as a pharmacy technician are fairly minimal and include:

- Application and fee.
- Fingerprint background check.
- Query from the National Practitioner Data Bank.
- Description on qualifications and supporting documents.

Chairperson Weisser explained that acceptable qualifications include any of the following:

- Completion of a technician training program.
- Certification from a specified program (currently either PTCB or ExCPT).
- Associate degree in pharmacy technology.

Chairperson Weisser noted that currently the only requirement for licensure renewal is a fee.

Chairperson Weisser reported that in addition to the current application and renewal requirements, the committee reviewed pending regulations that impact the licensure and renewal requirements for pharmacy technicians. Chairperson Weisser noted that the regulation pending to update the renewal requirements to also include self-reporting of criminal and disciplinary information is currently undergoing review by the DCA. He added that the regulation to update the application form and strengthen the requirements of some pharmacy technician programs is in the initial stages of the pre-review notice and development.

Chairperson Weisser reported that the committee discussed the current continuing education requirements for pharmacy technicians in other states as well as the requirements for CE to maintain certification. He stated that the committee concluded that a continuing education requirement for pharmacy technicians appears appropriate and requested that board staff draft a possible solution for the committee to discuss at a future meeting.

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

g. Update and Discussion on the Development of Board Provided Law and Ethics Continuing Education Courses

Chairperson Weisser explained that effective July 1, 2017, CCR section 1732.5 (b) Renewal Requirements for Pharmacists is amended to read:

(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a board provided CE course in Law and Ethics. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.

Chairperson Weisser stated that the board requested that the Licensing Committee monitor the development and deployment of the training.

Chairperson Weisser reported that staff routinely provides continuing education on pharmacy law. He noted that such training is generally done in person but can be scalable using other deployment options, including webinars. As the DCA's training department uses an interactive web based platform for training, board staff is exploring that option. Chairperson Weisser added that based on discussions with the department, board staff believe the course could be available by March 1, 2018.

Chairperson Weisser reported that the committee believes that in-person training provides opportunities for outreach and is still an appropriate method of providing CE. During its meeting, the committee discussed the other CE courses that are currently provided by the board including courses covering corresponding responsibility and courses involving the role of a PIC. Chairperson Weisser noted that counsel advised the committee that such courses would fulfill the requirements of the regulation.

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

h. Discussion and Consideration of Pharmacist Consultation in Various Pharmacy Settings

Chairperson Weisser explained that CCR Section 1707.2 establishes the requirements for patient consultation including the conditions when such consultation must occur. Further, this section provides that when a patient or a patient's agent is not present in a pharmacy to receive consultation, the patient shall receive written notice of the patient's right to request consultation and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

Chairperson Weisser stated that CCR Section 1713 provides the authority for a pharmacy to use an automated drug delivery system (ADDS) under specified condition and subsection (d)(5) establishes the requirement for such a pharmacy using an automated drug delivery system to provide an immediate consultation with a pharmacist, either in-person or via telephone, upon the require of a patient.

Chairperson Weisser explained that BPC Section 4112(h) requires the board to adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that dispenses medications to Californians consistent with the consultation requirements established for mail order pharmacies located within California. He noted that the board does not currently have such regulations.

Chairperson Weisser stated that the board has frequently discussed the benefits of patient consultation as an important component of consumer protection and has expressed some frustration with what appears to be a lack of consultation.

Chairperson Weisser reported that during the April 2017 Pharmacy Technician Summit, the committee discussed changes in duties performed by pharmacy technicians in various settings. The committee discussed whether expanding pharmacy technician duties to include more responsibilities while under the supervision of a pharmacist would allow pharmacists to provide more patient care services, including drug utilization review, patient profile review and patient consultation. He added that as part of the discussion, the committee considered various settings including traditional community pharmacy, mail order and closed door pharmacy, inpatient, and other specialty pharmacy settings.

Chairperson Weisser stated that the committee was provided a summary of the workflow in Iowa's tech-check-tech pilot, where the pharmacist is involved at the first level interaction with the patient, performing the data and review prior to printing the label, and providing the final consultation. The committee was also presented with the pharmacist involvement for call-in prescriptions in Idaho. It was explained that in Idaho, the pharmacist would be at the DUR and PU1 station verifying the data entry. Chairperson Weisser added that in regard to patient consultation there is a toll-free number that patients may call.

Chairperson Weisser reported that the committee also discusses mail order pharmacies and staff suggested the need to broaden consultation requirements for mail order pharmacies, noting that consumer complaints surrounding mail order pharmacies involve allegations of delays in therapies because the patient is unable to reach a pharmacist. The committee also heard that medication reconciliation is performed in the mail order pharmacy setting by the pharmacy benefit managers who have access to patient records and would highlight if there was duplication in therapy.

Chairperson Weisser reported that during its meeting the committee noted that currently pharmacies are often structured and staffed so that the pharmacist is in the back of the

pharmacy, and at the front of the pharmacy, interacting with patients, are the pharmacy technicians and cashiers. This is efficient for the cashiering functions, but it interrupts the flow of the pharmacy with respect to patient consultation. Chairperson Weisser explained that this service, and the important drug utilization review, must be performed by the pharmacist and are critical for patient care.

Chairperson Weisser stated that the committee discussed the idea that if pharmacy technicians were to be trained and/or qualified to perform tech-check-tech, to handle insurance functions and perhaps function under a somewhat different ratio, the pharmacist could move forward within the pharmacy to provide more interaction with and services directly to patients. This would also allow pharmacists to perform patient-care functions authorized by protocol (immunizations, naloxone, etc.) or under protocol with primary care providers either as a pharmacist or advanced practice pharmacist. Chairperson Weisser noted that cashiering functions could still be performed by non-pharmacist staff, but the actual handling of the medication could occur by the pharmacist following DUR and during consultation. Chairperson Weisser stated that not all pharmacists may prefer to organize their pharmacies under such a model, but it would permit a pharmacist who does so to focus on the duties he or she is most qualified to perform. Chairperson Weisser also stated that it could also foster the board's long-term goal of increased rates of patient consultation.

Chairperson Weisser reported that as part of its discussion, the committee considered the following questions:

1. Are the requirements currently established in CCR 1707.2 appropriate or is revision necessary?
2. Should changes at the transactional level be considered to ensure pharmacist engagement with patients in the dispensing process?
3. Is the current requirement for a mail order pharmacy sufficient to ensure patients have access to a pharmacist for consultation?
4. Should the board promulgate regulations for nonresident pharmacies consistent with the provisions of BPC 4112?
5. Are the current requirements for the use of an ADDS system sufficient to ensure patients have access to a pharmacist for patient consultation?
6. Do patients discharged from a hospital given sufficient information about their medication by either a pharmacist or registered nurse?

Chairperson Weisser reported that the committee requested that board staff evaluate the committee's discussion and bring this item back for further discussion including how best to incorporate the purpose of the medication and improve access to patient consultation for patients receiving their medication through mail order pharmacies.

Board member Wong asked if labeling requirements are same for mail order pharmacies are retail pharmacies. Ms. Herold responded that all prescriptions written for California patients must follow the patient-center labeling requirements. She added that the board may need to discuss how mail order patients are notified that they have the right to request translations.

Board member Lippe asked why mail order prescriptions are often offered at a cheaper price. President Gutierrez stated that mail order pharmacies can use large scale automation and purchase their drugs in bulk at a cheaper price.

Dr. Wong stated that the Communication and Public Education Committee should discuss how mail order patients can be notified that they have the right to translation services.

Laura Freedman, DCA legal counsel, recommended that the board consider agendaing this discussion for a future meeting.

A pharmacist commented that mail order patients often do not receive appropriate consultations which can result in serious health problems.

Dennis McAllister, representing Express Scripts, recommended that the board work with stakeholders to address concerns with mail order pharmacies. He added that Express Scripts handles approximately 100 million prescriptions per year. Mr. McAllister explained that one of the benefits of mail order pharmacies through Express Scripts is that pharmacists are available to speak with patients 24/7. Mr. McAllister stated that they meet all state laws for translation services. He also stated that studies have shown that mail order patients have lower emergency room admission rates. Ms. McAllister stated that there may be bad mail order pharmacies, but the board should handle them rather than make requirements that apply to all mail order pharmacies.

Chairperson Weisser stated that the board has seen that many California patients do not have adequate access to pharmacists both in the community and mail order settings.

Mr. Law asked how many pharmacy technicians work at mail order pharmacies. Mr. McAllister stated that he did not have an answer to this question.

President Gutierrez asked if the majority of mail order prescriptions are new or refill prescriptions. Mr. McAllister responded that the majority of Express Scripts prescriptions are for refills.

Robert Stein from KGI School of Pharmacy, expressed concern that mail order patients may not know that they have the right to request translation services and encouraged the board to discuss this at a future meeting. Dr. Wong again stated that the Communication and Public Education Committee should handle this item.

A member of the public asked how expanding the role of technicians will help pharmacists provide consultations. Mr. Lippe responded that the intent is to allow pharmacists to have more time to provide consultations by allowing technicians to take over some of the duties currently being performed by pharmacists, the technician would not be the one providing the consultations. The commenter stated that California technicians already are allowed to perform more duties than in other states and asked what other duties the board wanted to give technicians. Chairperson Weisser responded that expanded technician duties are currently being discussed by the Licensing Committee and encouraged the person to attend the meetings to provide input.

i. Discussion and Consideration of the Center for Disease Control's Newly Released Guide for Pharmacists to Establish Collaborative Practice Agreements

Chairperson Weisser reported that the Centers for Disease Control and Prevention (CDC)

recently released a guide entitled “Advancing Team-Based Care Through Collaborative Practice Agreements -- A Resource and Implementation Guide for Adding Pharmacists to the Care Team.”

Note: A copy of this guide was provided in the board meeting materials.

Chairperson Weisser explained that the CDC guide notes the underused role of pharmacists in health care and the value of activating their knowledge through use of collaborative practice agreements and protocols with prescribers.

Chairperson Weisser reported that as part of the discussion, the committee noted that California has long recognized the value of protocols and collaborative practice agreements between pharmacists and prescribers as ways to achieve improved care of patients. In 2013, SB 493 further expanded the role of pharmacists through the use of protocols and creation of the new licensure category of advance practice pharmacists. He added that this law also directed the Board of Pharmacy to develop state protocols that, when approved by the Medical Board, allowed pharmacists to provide self-administered hormonal contraception, nicotine replacement therapy and (through AB 1535) naloxone.

Chairperson Weisser stated that the committee highlighted some of the excerpts from the guide designed to promote the expanded use of collaborative practice agreements include the following:

- The evidence is strong that when pharmacists are members of the health care team, outcomes related to preventing or managing chronic disease (e.g., blood pressure, blood glucose, cholesterol, obesity, smoking cessation) and medication adherence improve. The purpose of this guide is to empower community pharmacists and collaborating prescribers to initiate collaborative practice agreements (CPAs) focused on caring for patients with chronic diseases . . .
- CPAs are built upon a foundation of trust between pharmacists and prescribers and serve as a useful mechanism for increasing efficiencies of team-based care. When designed correctly, CPAs are beneficial to the collaborative delivery of care through delegation by the physician or other prescriber of specific patient care services to pharmacists. This delegation can expand available services to patients and increase coordination of care.

For example, the use of CPAs can decrease the number of requests to authorize refills, modify prescriptions, initiate therapeutic interchanges (in which the pharmacist can substitute another drug for the medication prescribed), and order and interpret laboratory tests while keeping the prescriber apprised of the pharmacist’s actions through established communication mechanisms. This allows each member of the health care team to complement the skills and knowledge of the other members and more effectively facilitate patient care, resulting in improved patient outcomes.

- CPAs offer a unique opportunity for pharmacists to collaborate with prescribers in the treatment and management of chronic conditions, including CVD and hypertension.

Daniel Martinez, representing CPhA, stated that they had assisted with the development of this report and are currently working on incorporating CPAs into their advanced practice pharmacist training program.

j. Licensing Statistics

Chairperson Weisser stated that the licensing statistics were available for review in the meeting materials. He highlighted that the board has licensed 130 advanced practice pharmacists.

k. Future Committee Meeting Dates

President Weisser reported the following committee dates.

- August 21, 2017
- September 19, 2017
- January 16, 2018
- April 19, 2018
- June 26, 2018
- September 26, 2018

Ms. Sodergren explained that the August 21st meeting would focus on technician duties in the community pharmacy setting. She added that additional items such as patient consultation would be scheduled for discussion at subsequent meetings.

The board recessed for a break at 1:00 p.m. and resumed at 2:05 p.m.

VIII. Legislation and Regulation Committee

Part 1: Legislation for Discussion and Consideration Report

a. Board Sponsored Legislation

1. Omnibus Provisions: SB 800 (Hill) Professions and Vocations, Including Changes to Pharmacy Law

Chairperson Lippe provided an update on the bill as provided below.

Version: As amended June 5, 2017

Status: Refer Assembly Appropriations Committee

Summary: SB 800 contains omnibus provisions for various programs within the Department of Consumer Affairs (DCA). Board specific provisions include:

- Section 4013, which would amend (d)(1) to add designated representative to the list of individuals who need to join the email subscriber list.
- Section 4316, which would clarify the board's authority to issue a cease-and-desist for unlicensed activity and would delegate issuing of the order to the executive officer.

He explained that the measure also would repeal section 4001.5, which established a requirement for the Joint Committee to review the state's shortage of pharmacists and to make recommendations on a course of action to alleviate the shortage. The repeal is not

board sponsored but rather was included by the Senate Business, Professions, and Economic Development Committee.

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

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

Chairperson Lippe provided an update on the bill as provided below.

Version: As amended April 4, 2017

Status: Referred to Assembly Appropriations File

Summary: SB 351 creates options for hospitals to obtain additional licenses from the board for purposes of providing pharmaceutical care. The measure would allow the board to issue hospital satellite compounding pharmacy licenses that would not need to be located in the acute care hospital building. This measure also would allow the board to issue a hospital pharmacy license that can be located outside the general acute care hospital.

Chairperson Lippe reported that the committee received comments regarding the measure, including a request to remove the ratio provision currently in the measure and to reduce the supervision requirement from immediate supervision to something less. He added that the committee requested that staff consider these requests.

Chairperson Lippe explained that staff recommends that the measure be maintained in its current form. The ratio requirement established in the measure is consistent with the current ratio requirement for the hospital setting. As the Licensing Committee is currently assessing the pharmacist-to-pharmacy technician ratio and the job duties of a pharmacy technician, it appears appropriate to allow that process to be completed before changes are made. Chairperson Lippe noted that if the Licensing Committee determines changes are necessary, subsequent legislation would be required.

Ms. Sodergren stated that this measure has enjoyed support from both parties in the Capitol, and the author's office has expressed concerns about watering down the current safeguards in place.

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

Chairperson Lippe provided an update on the bill as provided below.

Version: As introduced Feb. 15, 2017

Status: Assembly Appropriations Committee hearing cancelled at the request of the author.

Summary: SB 443 creates an option for county emergency medical services to restock ambulances through use of an emergency medical services automated drug delivery system (EMADDS) that is located within a county operated fire department. As part of the measure, the board would issue a license for the use of the EMADDS and specify the conditions under which it may be used.

Chairperson Lippe reported that at the Senate Business, Professions and Economic Development Committee hearing, the committee requested that the board consider amendments to allow the proposed provisions to also apply to city fire departments and special districts. Board staff has also received requests to allow paramedics to stock the device. If such amendments are included, registration of the paramedic with the board is appropriate.

Chairperson Lippe stated that the committee briefly discussed the measure and was provided the status of amendments.

Chairperson Lippe reported that the hearing in Assembly Appropriations was canceled on July 19, 2017, to allow for the measure to be amended. Although not yet in print, the amendments would:

- Allow Emergency Services Provider Agencies, not just county fire departments, to establish EMSADDS machines in their offices from which to restock emergency containers on emergency response vehicles.
- Add fees for non-government operated EMSADDS units. The annual registration fee for each machine would be \$100. The license must be renewed annually.
- Create a new category of board licensure for “designated paramedics” as an additional group of individuals who may restock the EMSADDS machines (which in the initial version of the bill had been limited to a designated pharmacist or the agency’s medical director). To obtain a designated paramedic’s license, an existing paramedic must apply to the board, pay a \$140 fee and undergo a background check. This is a second license, which the board would issue and when necessary discipline. The license will be issued for two years. Loss of the initial paramedic’s license (issued by an EMS agency) would result in immediate inactivation of the designated paramedic license.
- Allow only a designated paramedic, paramedic, medical director or designated pharmacist to remove drugs from an EMSADDS and require two signatures or two biometric or other unique identifiers associated with each removal from the EMSADDS (for restocking an emergency pharmaceutical supplies container).
- Provide that while medications cannot be stored in nonlicensed locations (e.g., overnight in a medical director’s car), they could be transported to an EMSADDS from a pharmacy or EMS agency headquarters licensed as wholesaler.
- Require reconciliation by the designated paramedic, designated pharmacist or medical director of all drugs in each EMSADDS monthly.

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

4. SB 510 (Stone) Pharmacies: Compounding

Chairperson Lippe provided a report of the bill as provided below.

Version: As introduced Feb. 16, 2017

Status: Assembly Third Reading File

Summary: SB 510 repeals an outdated statutory requirement specifying the environments in which a pharmacy must compound sterile products.

Chairperson Lippe reported that the committee briefly discussed the measure and did not recommend any changes.

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

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

Chairperson Lippe provided a report of the bill as provided below.

Version: As amended March 28, 2017

Status: Passed out of Assembly Appropriations Committee on July 19, 2017

Summary: SB 752 establishes the creation of a designated representative license reverse distributor.

Chairperson Lippe reported that the committee briefly discussed the measure and did not recommend any changes.

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

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

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

Chairperson Lippe provided a report of the bill as provided below.

Version: As amended July 10, 2017

Status: Referred to Senate Appropriations Committee.

Board Position: Support

Summary: 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.

Chairperson Lippe reported that the committee briefly discussed the measure and did not recommend any changes.

Ms. Sodergren reported that this measure was amended after the committee meeting. As amended, the provisions for use of an online access portal would also apply to a pharmacist. She explained that the prior provision limited such access to a health care practitioner. Further, the language now includes explicit authority for the DOJ to terminate access to the CURES system via the online portal under specific conditions.

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

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

Chairperson Lippe provided a report of the bill as provided below.

Version: As amended May 26, 2017

Status: Referred to Senate Suspense File on July 17, 2017

Board Position: Support

Summary: As amended AB 182 requires the Department of Health Care Services (department) to develop and implement an education campaign (HOPE) to combat the growing heroin and opioid medication epidemic in California in consultation with stakeholders. The measure includes some of the information that must be used as part of the campaign as well as targeted audiences. The department would also be required to submit a report annually summarizing its activities and assessment of the effectiveness of the program. Further, the bill clarifies the intent of the measure and establishes a sunset date of Jan. 2, 2023.

Chairperson Lippe reported that the committee briefly discussed the measure and no change was recommended.

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

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

Chairperson Lippe provided a report of the bill as provided below.

Version: As amended March 8, 2017

Status: Senate Appropriations Committee Hearing August 21, 2017

Board Position: Oppose Unless Amended

Summary: AB 208 changes the deferred entry of judgment program to a pretrial program. It expands the conditions under which someone would be eligible for the program and reduces the conditions under which someone could be removed from the program. The bill also reduces the length of the program compliance to six to 12 months and prohibits information sharing once someone is in the program.

Chairperson Lippe reported that the committee briefly discussed the measure and did not recommend changing the position.

Ms. Sodergren reported that staff had shared the board's concerns with the sponsors of the measure. Regrettably, amendments have not been incorporated to address the concerns. Given this, she stated that the board may want to consider changing its position to Oppose.

After discussion, the board decided not to change the Oppose Unless Amended position and asked staff to continue to work with the author's office on amendments. It was noted that if necessary the committee chair and board president can take a position on a bill between board meetings.

4. AB 315 (Wood) Pharmacy Benefits Management

Chairperson Lippe provided a report on the bill as provided below.

Version: As amended July 11, 2017

Status: Referred to Senate Appropriations Committee

Board Position: Support (prior version)

Summary: AB 315 establishes a regulatory framework for PBMs. In its current form, the regulation of the PBM is performed by the Department of Managed Health Care (DMHC), including licensing and renewal requirements. The measure would also require PBMs to disclose specified information on a quarterly basis.

Chairperson Lippe reported that the committee briefly discussed the measure and did not recommend changing the position.

Chairperson Lippe reported that recent amendments include reporting requirements that would provide for additional transparency. Further, the DMHC would no longer have the authority to revoke a license but would retain the ability to suspend a license.

Mr. Weisser asked if the purpose of the bill is to lower drug prices. Ms. Herold responded that the bill is intended to improve transparency as to what goes into the pricing of drugs.

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

Chairperson Lippe provided a report on the bill as provided below.

Version: As amended July 6, 2017

Status: Referred to Senate Appropriations Committee

Board Position: Support If Amended

Summary: AB 401 establishes regulatory framework for telepharmacy. The bill requires that a remote dispensing site pharmacy be owned and operated by a pharmacist(s) and be supervised by a pharmacy also owned by a pharmacist. Further, a pharmacy may only supervise one telepharmacy location.

Chairperson Lippe noted that the committee briefly discussed the measure and was advised that staff had not yet met with the author's office to discuss the requested amendments.

Ms. Sodergren reported that after the committee meeting, board staff requested amendments, which were included in the July 6, 2017 version of the bill. She noted that outstanding policy questions for the board are whether the requirements for a pharmacy technician working in a telepharmacy location should be implemented via regulation or statute, and what such requirements should be. In its current form, the requirements would be done via regulation.

The board discussed the specific telepharmacy provisions that the bill will establish.

Robert Stein, representing KGI School of Pharmacy explained that this will be a technician

run location with the pharmacist supervising from a remote location. He added that if a traditional pharmacy opens in the area the telepharmacy can remain open.

Ms. Butler expressed her concern with a pharmacist having to supervise technicians in their pharmacy as well as technicians in the remote location.

The board expressed concern with the fact that the telepharmacy can remain open even after a traditional pharmacy opens in the underserved area. After discussion, the board determined that the telepharmacy should close if a traditional pharmacy opens in the underserved area. They also decided that the telepharmacy should be given six months to close their location and transition their patients to other pharmacies.

Motion: Support if amended to require that within six months of a traditional pharmacy opening in the underserved area the telepharmacy must close their location.

M/S: Wong/Butler

Support: 9 Oppose: 0 Abstain: 0

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

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

Chairperson Lippe provided a report on the bill as provided below.

Version: As amended June 13, 2017

Status: Enrollment

Board Position: Support If Amended

Summary: AB 602 would require pharmacies that dispense nonprescription diabetes test devices pursuant to a prescription to retain records; require the board to post the names of authorized distributors of such test strips; and make it unprofessional conduct for a licensee to seek reimbursement for such devices under specified conditions or to purchase products from an unauthorized source. Further, it provides the board the authority to embargo devices under specified conditions.

Chairperson Lippe reported that the committee considered the measure and the amendments accepted by the author to address the board’s concerns.

Committee Recommendation (Motion): Change the board’s position to support as the author’s office accepted the board’s amendments.

Support: 9 Oppose: 0 Abstain: 0

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

Ms. Sodergren reported that this measure was recently enrolled and contained urgency provisions, which will require the provisions to take effect immediately. Board staff will prepare communication materials to educate licensees and the public if the measure is signed by the governor.

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

Chairperson Lippe provided a report on the bill as provided below.

Version: As amended July 11, 2017

Status: Senate Appropriations Committee hearing Aug. 21, 2017

Board Position: Oppose Unless Amended

Summary: AB 845 would, if consistent with federal law, authorize prescribing and dispensing a controlled substances prescription that contains cannabidiol.

Chairperson Lippe reported that the committee considered the measure and the amendments accepted by the author to address the board’s concerns relating to corresponding responsibility. Chairperson Lippe added that the committee recommends changing the board’s position to neutral.

Ms. Sodergren stated that amendments made to the measure since the committee meeting appear to be non-substantive.

A member of the public spoke in support of the board changing its position to Neutral.

Committee Recommendation (Motion): Change the board’s position to Neutral as the author accepted the board’s amendments.

Support: 9 Oppose: 0 Abstain: 0

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

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

Chairperson Lippe provided a report on the bill as provided below.

Version: As amended July 5, 2017

Status: Referred to Assembly Appropriations Committee

Board Position: Support

Summary: SB 17 would aim at drug price transparency by establishing reporting requirements for prescription drugs cost and volume for health plans and reporting requirements for drug manufacturers regarding rate increases.

Chairperson Lippe reported that the committee briefly discussed the measure and did not recommend changing the board’s position.

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

9. SB 528 (Stone) Pharmacy: Automated Drug Delivery Systems

Chairperson Lippe provided a report on the bill as provided below.

Version: As amended June 12, 2017

Status: Assembly Suspense File

Board Position: Support if Amended

Summary: SB 528 would allow a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B through the use of an automated drug dispensing system (ADDS) under specified conditions. The ADDS would be licensed by the board.

Chairperson Lippe reported that the committee determined that the amendments incorporated into the measure address the issues identified by the board, including requirements that are similar to those currently in law for ADDS used in other environments and licensure.

Chairperson Lippe stated that the committee is recommending that the board change its

position to Support.

Mr. Weisser asked patient consultation would still occur. Ms. Sodergren responded that there are provisions in the bill that will allow for consultation to occur.

Kevin Rue, representing the sponsor of the bill, explained that consultations will still occur using technology. Initially when the machine is installed there will be a pharmacy technician next to the machine to help patients learn to use the machine and to get their consultation.

President Gutierrez asked who would be restocking the machines. Mr. Rue explained that a technician would actually be restocking the machine.

President Gutierrez asked if these machines could be used for non 340B drugs. Ms. Sodergren responded that this bill is specifically only for 340B drugs. Mr. Rue explained that the machines will be placed in 340B clinics. He stated that if a non 340B patient uses the clinic, the pharmacy will arrange for delivery of the drug not through the machine.

The sponsor of the bill explained that the reason they introduced the bill was to make the pharmacy, rather than the clinic the owner and responsible party for the drugs.

President Gutierrez asked why the sponsor of the bill limited the bill to only to 340B drugs. Mr. Rue responded that this was the area that the author of the bill wanted to expand their services into, but they may be open to expanding to other settings in the future.

The board further discussed the ownership of the drugs being used in the machines. It was noted by Mr. Rue that if a loss occurs it would be the pharmacy that would be held responsible for the loss.

The board expressed confusion as to the purpose of the bill, who owns the drugs and the settings that the machines can be used in. Due to the confusion, the board decided to table the committee motion and direct board staff to work with the author's office to clarify the provisions in the bill. The board also decided to have Chairperson Lippe and President Gutierrez take a position on the bill after staff has worked with the author's office to gain clarity on the board's questions.

10. SB 547 (Hill) Professions and Vocations

Chairperson Lippe provided a report on the bill as provided below.

Status: Referred to Assembly Appropriations

Board Position: Support (established by the Board President and Committee Chair)

Summary: SB 547 includes provisions for several healing arts board within the DCA. As part of the recent amendments, this measure would provide the board with the statutory authority to employ counsel.

Chairperson Lippe explained that neither the committee nor the board has previously considered this matter. Consistent with the board's policy in this area, a support position was authorized by the board president and committee chair as the bill would provide the

board with the ability to have dedicated counsel. Chairperson Lippe explained that currently counsel is provided by the DCA; however, because of limited resources, board counsel provides legal services to other programs and the department. He noted that the Medical Board of California currently employs its own counsel.

Chairperson Lippe stated that staff is requesting that the board ratify the support position established.

Motion: Support SB 547.

M/S: Lippe/Gutierrez

Support: 9 Oppose: 0 Abstain: 0

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

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

Chairperson Lippe reported that the measure failed to meet the policy deadline and would become a two-year bill.

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

12. SB 716 (Hernandez) California Board of Pharmacy: Pharmacy Technician Member

Chairperson Lippe provided a report on the bill as provided below.

Version: As Amended April 26, 2017

Status: Assembly Appropriations Committee hearing postponed

Board Position: Oppose Unless Amended

Summary: SB 716 would increase the number of members of the board to 15 by adding one pharmacy technician appointed by the governor and one additional public member appointed by the governor. The bill would require the pharmacy technician member to have at least five years of experience and to continue to work in California as a pharmacy technician.

Chairperson Lippe explained that the committee discussed the measure and how it impacts

the board's mandate. The discussion included concern that the appointed pharmacy technician would only be required to have five years of experience. Other members spoke in support of a pharmacy technician being added to the board as well as the addition of a public member.

Chairperson Lippe reported that the committee heard from a representative of CPhA recommending that the board maintain its Oppose Unless Amended position. He added that the speaker explained to the committee that CPhA agrees with the addition of a pharmacy technician to the board but has strong concerns about the education differences between a pharmacist and a pharmacy technician.

Chairperson Lippe stated that the committee also heard from a representative from CSHP, the sponsors of the measure. The committee was advised by CSHP that a pharmacy technician is considered an allied health care professional and noted that a pharmacy technician would be the first line of care under the provisions of AB 401.

Chairperson Lippe explained that after hearing public comment and discussion, the committee recommended that the board change its position to neutral.

Dr. Wong and Ms. Butler stated that the Board of Pharmacy should have a majority of pharmacist members.

Mr. Weisser stated that the loss of a pharmacist majority would shift the depth of knowledge on the board, to the detriment of patients. He explained that the issues the board oversees are very complex and it would be difficult for a technician to provide meaningful input. He asked that the board take an Oppose position and reconsider the issue during the board's next Sunset Review.

Cathy Bailey, a pharmacy technician, spoke in support of the bill and asked the board to take a support position on SB 716.

Michelle Reeves, representing CPhA, stated that CPhA is not opposed to having a technician on the board, they took an oppose position when the bill was amended to add an additional public member. She added that CPhA believes that the board should have a majority of pharmacist members.

Angie Menetti, representing CRA, stated that CRA also took an oppose position when the additional public member was added.

Mary Staples, representing NACDS, agreed with the comments made by CRA and CPhA.

Robert Stein, pharmacist, stated that adding a technician to the board does not reduce the expertise of the pharmacist members. He added that the pharmacy health and safety act is to promote the health and safety of Californian's – not to promote the practice of pharmacists. He expressed his support of SB 716.

Lorriann Demartini, representing CSHP (the sponsor of the bill), explained that CSHP was discussing ways to get the pharmacist out from behind the counter and evolve the pharmacy technicians. One of the ways they decided this could be achieved was by adding a technician

to the board so that they would be represented and could help make policy that will help expand the role of pharmacy technicians. She stated that the technician can share their experience as a practicing pharmacy technician and their viewpoint could provide valuable input to the board. Ms. Demartini explained that Senator Jerry Hill expressed concern with having the licensee members outnumber public members by, that is when the bill was amended to add a public member.

A pharmacist stated that technicians do a lot to support pharmacists; however, they do so under the direct supervision of the pharmacist.

Dr. Wong stated the board’s current composition has been effective, so there is no need to change anything.

Dennis McAlliser, stated that the Arizona Board of Pharmacy has a technician member and they have found their input to be extremely valuable.

Mr. Law stated that he does not have a problem adding the technician to the board, but he does have a problem adding an additional public member.

A pharmacist stated that the board should not add a technician member because they work only under the supervision of the pharmacist.

Ms. Butler stated that she would like a technician to be added to the board, but she does not want to add a public member.

Chairperson Lippe called for a vote on the committee’s recommendation to change the position to Neutral.

Committee Recommendation (Motion): Take a Neutral position on SB 716.

Support: 1 Oppose: 7 Abstain: 1

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

Motion: Oppose SB 716

M/S: Sanchez/Wong

Support: 4 Oppose: 5 Abstain: 0

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

Motion: Oppose Unless Amended to remove the addition of the public member.

M/S: Law/Butler

Support: 6 Oppose: 3 Abstain: 0

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

The board recessed for a break at 4:00 p.m. and resumed at 4:19 p.m.

c. Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction Currently being Watched

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

Chairperson Lippe provided a report on the bill as provided below.

Version: As amended June 27, 2017

Status: Senate Third Reading File July 20, 2017

Summary: AB 265 would prohibit a manufacturer from providing a discount, rebate or

other price inducement if a lower cost brand name or non-brand name prescription drug is therapeutically equivalent. The bill specifies that this prohibition does not apply to drugs required under an FDA REMS.

Chairperson Lippe reported that the committee briefly discussed the measure and noted that it is another approach to addressing the high cost of prescription drugs. He added that the committee is not recommending any changes to the board's position.

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

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

Chairperson Lippe reported that this bill failed to meet the policy deadline and will be a two-year bill.

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

3. AB 710 (Wood) Department of Consumer Affairs: Boards: Meetings

Chairperson Lippe reported that this measure will not be moving this year.

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

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

Chairperson Lippe provided a report on the bill as provided below.

Version: As amended April 3, 2017

Status: Senate Appropriations Committee hearing July 17, 2017.

Summary: AB 827 would require DCA to establish a task force to study and issue a report regarding licensing of foreign trained professionals into the state's workforce.

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

5. AB 1048 (Arambula) Health Care: Pain Management and Schedule II Drug Prescriptions

Chairperson Lippe provided a report on the bill as provided below.

Version: As Amended July 3, 2017

Status: Senate Appropriations Committee hearing August 21, 2017

Summary: AB 1048 would authorize a pharmacist to dispense a partial fill of a Schedule II drug if requested by the patient or the prescribing physician. Under the provisions, a pharmacy would have 30 days to fill the remainder of a prescription from the date the prescription was written.

Chairperson Lippe explained that the measure was amended after the committee meeting. The amendments establish an operative date of July 1, 2018, and establish a requirement for a health care service plan or insurer to prorate a copayment for a partial fill of a

prescription.

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

6. SB 212 (Jackson) Medical Waste

Chairperson Lippe stated that the measure failed to meet the policy deadline and would become a two-year bill.

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

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

Chairperson Lippe reported that this bill was moved to the inactive file.

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

Part 2: Regulations for Discussion and Consideration

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

1. Regulations Amending Title 16 CCR Section 1703 Related to Delegation of Certain Functions

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Feb. 24, 2016

Rulemaking Initiated: April 22, 2016

Adopted by Board: July 27, 2016

Submitted to DCA: Oct. 27, 2016

Submitted to OAL: April 17, 2017

Approved by OAL: May 30, 2017

Effective Date: July 1, 2017

Chairperson Lippe explained that this regulation updates the 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).

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

2. Regulations Adding Title 16 CCR Section 1776 et seq. Related to Prescription Drug Take-Back

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Jan. 19, 2016
Rulemaking Initiated: Feb. 12, 2016
Adopted by Board: Oct. 26, 2016
Submitted to DCA: Dec. 12, 2016
Submitted to OAL: April 24, 2017
Approved by OAL: June 6, 2017
Effective Date: June 6, 2017

Chairperson Lippe explained that this regulation establishes 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.

3. Regulations Adding Title 16 CCR Section 1746.5 Related to Travel Medications

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: June 3, 2015
Rulemaking Initiated: Sept. 25, 2015
Adopted by Board: April 27, 2016
Submitted to DCA: May 29, 2016
Submitted to OAL: Nov. 10, 2016
Disapproved by OAL: Dec. 30, 2016
Modified Text Approved by Board: Feb. 17, 2017
Re-Submitted to DCA: March 6, 2017
Re-Submitted to OAL: April 26, 2017
Approved by OAL: June 8, 2017
Effective Date: June 8, 2017

Chairperson Lippe explained that this regulation establishes the requirements and training for pharmacists to furnish travel medications not requiring a diagnosis.

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

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

1. 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 provided a summary of the regulation as provided below.

Timeline:

Approved by Board: July 30, 2013
Rulemaking Initiated: Aug. 12, 2016

Adopted by Board: Dec. 14, 2016
Submitted to DCA: Feb. 7, 2017

Chairperson Lippe explained that this regulation establishes standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives. It also 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.

2. Proposed Regulations to Amend Title 16 CCR Sections 1760 Related to the Board's Disciplinary Guidelines

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: July 29, 2015
Rulemaking Initiated: Sept. 4, 2015
Adopted by Board: April 27, 2016
Submitted to DCA: Aug. 4, 2016
Submitted to OAL: Nov. 30, 2016
Disapproved by OAL: Jan. 13, 2017
Modified Text Approved by Board: Feb. 17, 2017
Resubmitted to DCA: April 27, 2017

Chairperson Lippe explained that this regulation updates the board's disciplinary guidelines that are incorporated by reference. The updated disciplinary guidelines incorporate changes to pharmacy law that occurred between October 2007 and July 2015 and implement SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008).

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

f. Board Approved to Initiate Rulemaking - Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency, or Returned to Board Staff for Revisions Pursuant to Such Review:

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

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Oct. 26, 2016
Submitted to DCA for Pre-notice Review: Feb. 9, 2017

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

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

2. Proposed Regulations 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 provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Oct. 26, 2016

Submitted to DCA for Pre-notice Review: Jan. 23, 2017

Chairperson Lippe noted that this regulation package has been returned to staff with recommended changes. Staff is reviewing the recommended changes to determine a course of action for this package.

Chairperson Lippe explained that this regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

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

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

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Dec. 14, 2016

Submitted to DCA for Pre-notice Review: Feb. 3, 2017

Chairperson Lippe noted that this regulation package has been returned to staff with recommended changes. Staff is reviewing the recommended changes to determine a course of action for this package.

Chairperson Lippe explained that this regulation updates the Self-Assessment Form 17M-39 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1735.2.

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

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 provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Oct. 27, 2016

Submitted to DCA for Pre-notice Review: Jan. 20, 2017

Chairperson Lippe noted that this regulation package has been returned to staff with

recommended changes. Staff is reviewing the recommended changes to determine a course of action for this package.

Chairperson Lippe explained that this regulation updates the Self-Assessment forms 17M-13 (rev. 10/16), 17M-14 (rev. 10/16), and 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR sections 1715 and 1784.

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

5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Oct. 27, 2016

Submitted to DCA for Pre-Notice Review: Jan. 26, 2017

Chairperson Lippe stated that this regulation package has been returned to staff with recommended changes. Staff is reviewing the recommended changes to determine a course of action for this package.

Chairperson Lippe explained that this regulation amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

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

6. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Jan. 24, 2017

Submitted to DCA for Pre-notice Review: April 27, 2017

Chairperson Lippe explained that this regulation amends the board's regulations regarding waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

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

7. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: May 4, 2017

Submitted to DCA for Pre-notice Review: May 31, 2017

Chairperson Lippe explained that this regulation amends the board's regulations regarding the fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

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

g. 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 1735 et seq. and 1751 et seq. Related to Compounding

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: Jan. 24, 2017

Chairperson Lippe explained that this regulation amends the board's regulations regarding compounding to allow the use of a double filtration system. The Enforcement and Compounding Committee continue its review of the board's compounding regulations. He added that initiation of the rulemaking will occur after the committee and board identify all necessary changes.

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

2. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

Chairperson Lippe provided a summary of the regulation as provided below.

Timeline:

Approved by Board: May 3, 2017

Chairperson Lippe explained that this regulation establishes regulatory requirements for automated refill programs. He added that staff is compiling the initial rulemaking file to submit to DCA for pre-notice review.

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

Part 3: General Committee Matters

Chairperson Lippe provided the following future committee meeting dates.

- October 18, 2017
- January 17, 2018
- April 24, 2018
- July 10, 2018
- October 20, 2018

The board recessed to closed session at 4:35 p.m.

July 26, 2017

President Gutierrez called the meeting to order at 9:05 a.m. and recessed the meeting to closed session.

X. Closed Session for Examination Matters

Pursuant to Government Code Section 11126(c)(1), the Board Will Convene in Closed Session to Consider the Preparation, Approval, Grading or Administration of One or More Licensing Examination(s).

President Gutierrez resumed open session at 10:02 a.m.

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

President Gutierrez congratulated the Lavanza Butler and Deborah Veale for their reappointment to the board.

XI. Executive Officer's Report

a. Discussion and Consideration of FDA Draft Guidance, "Product Identifier Requirements under the Drug Supply Chain Security Act -- Compliance Policy"

Executive officer, Virginia Herold reported that in late June, the FDA released a draft guidance document titled: "Product Identifier Requirements under the Drug Supply Chain Security Act -- Compliance Policy." The Drug Supply Chain Security Act establishes product tracing, product identifier, and verification requirements manufacturers, repackagers, wholesale distributors, and dispensers to enable the tracing of a product through the pharmaceutical distribution supply chain.

Ms. Herold explained that in this guidance document, the FDA proposes to extend the compliance deadline from November 27, 2017, until November 28, 2018, by which manufacturers must comply with requirements to attach product identifiers under requirements of the Drug Supply Chain Security Act to individual products to cases of homogeneous products. The use of these identifiers will make it possible to do checking to identify counterfeit or suspect products in the supply chain.

A copy of the proposed guidance was provided in the board meeting materials. She added that comments on this proposed guidance are due towards the end August.

Ms. Veale stated that she is disappointed with the delay in implementation and its possible negative impact on patient safety. Ms. Herold stated that there is currently no way to identify counterfeit drugs which have entered the supply chain.

Mr. Weisser stated that the board has worked hard to implement a tracking system, but was trumped by the federal government when they decided to create a national tracking system.

After discussion, the board decided to send a letter to the FDA.

Motion: Send a letter to the FDA expressing the board’s disappointment in the delay in implementation and the negative impact it will have on consumers.

Support: 10 Oppose: 0 Abstain: 0

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

b. Update on CURES

Ms. Herold explained that staff from the Department of Justice would be providing a presentation on CURES.

Tina Farales from the DOJ and Melanie Fontes-Rainer and Renica George from the Attorney General’s Office provided an overview of the CURES program and an update on the new CURES 2.0 program. Note: Mike Small with the DOJ was also in attendance.

A copy of the presentation is provided following these minutes.

Mr. Weisser asked if the DOJ would be willing to begin tracking Schedule V drugs in CURES. Mr. Small stated that statutory changes would be required to add Schedule V. Ms. Herold noted that board staff is working with staff from the DOJ and the Attorney General’s Office to consider the change. She also added that the Medical Board is also willing to assist in the process.

President Gutierrez asked why a prescriber cannot currently run a report to show all of their patents to ensure that someone is not fraudulently using their information to obtain drugs. Ms. Farales explained that the statute is very limited in who can run what reports and what information they can obtain. She stated that a statutory change would be required in order allow prescribers to view their entire prescriber report. Ms. Fontes-Rainier expressed support from the Attorney General’s office to find ways to improve the system and its functionality.

Mr. Weisser asked if CURES will be changed to allow information sharing with neighboring states. Ms. Farales explained that a statutory change would be required and they will be happy to work with board staff to consider making the change.

Ms. Herold asked if the DOJ knows when CURES 2.0 will be certified. Ms. Farales stated that they are still working on getting the system certified and explained that some of the delay is due to the need to onboard new staff.

A member of the public asked if the CURES system can alert the DOJ if there is a prescriber who is overprescribing. Ms. Farales explained that the Medical Board and the Pharmacy Board both have access to this information. Ms. George added that the Attorney General's Office works with the Medical Board and Board of Pharmacy to prosecute over prescribing and filling of inappropriate prescriptions.

A pharmacist recommended creating a smartphone app for CURES. Ms. Farales stated that she would bring this feedback to her IT department.

Robert Stein from KGI School of Pharmacy asked if a patient is able to obtain a copy of their CURES report to verify that someone is not using their information fraudulently. Ms. Farales responded that patients can request a copy of their patient activity report from the DOJ under the Information Practices Act.

XII. Organizational Development Committee

a. Discussion and Possible Action to Increase the Exempt Salary Category Level for the Position of Executive Officer

Nicole Le, assistant personnel officer for DCA explained that process for increasing the salary category for the executive officer position. She explained that the HR department facilitates the process for submitted the salary category increase, but it is ultimately the decision of the administration to grant or deny the request.

Ms. Freedman clarified that the board would be setting a salary *range* for the executive officer position, not the specific salary for the current executive officer. The specific salary for the executive officer would be determined in closed session after the salary category increase is approved by the administration.

President Gutierrez highlighted the following as the reasons for the need to increase the salary category for the executive officer position.

- Salary Disparity
All the board's 50 pharmacy inspectors and supervising inspectors are compensated at a salary level higher than the board's executive officer. Additionally, the board's assistant executive officer was in a position to be compensated at a level above than the executive officer – to prevent this, the AEO's salary was adjusted to be \$1 less per month than the EO's.
- Salary Comparison with Other Boards of Pharmacy Executive Officers

California is the largest board of pharmacy in the nation (with more staff and more licensees than other boards) with over 140,000 licensees spread out among over more than 25 categories of licensure. In a salary survey conducted by NABP (cite date), it was identified that California’s executive officer’s salary is less than 42 percent of the nation’s other executive officers.

- Level of Influence

The board is heavily involved in working with other state and federal agencies (CDPH, DHCS, FDA, DEA, FBI, county DAs) particularly in the area of complex investigations.

- Program Complexity

The board’s licensing and enforcement functions are more complex than other programs in the department as demonstrated by the failure of the board to be able to use the BreEze computer system because its functionality was unable to track complex ownership structures and multiple respondents at the level evidenced in the board in discipline.

President Gutierrez explained that the salary category levels are arranged by letter and currently the executive officer salary category is “G.”

Ms. Le provided the board with the following salary category levels.

- G = \$10,054 - \$11,200
- F = \$10,320 - \$11,498
- E = \$10,545 - \$11,746
- D = \$10,925 - \$12,168
- C(1) = \$11,071- \$12,335
- C(2) = \$11,425 - \$12,726
- B = \$11,952 - \$13,316 (this level is usually reserved for Department Directors)

Ms. Le reported that in 2015 the board had asked for a salary level increase to level “F” but the administration only approved an increase to “G.”

The board discussed what salary level increase would be appropriate. Most member stated that category “D” would be appropriate, while others felt that the board should request a higher level increase.

Motion: Modify the salary category level to “D.”

M/S: Veale/Weisser

Support: 7 Oppose: 3 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Gutierrez | X | | | |
| Khan | X | | | |
| Law | | X | | |
| Lippe | | X | | |
| Munoz | | | | X |

| | | | |
|---------|---|---|--|
| Sanchez | x | | |
| Schaad | x | | |
| Veale | x | | |
| Weisser | x | | |
| Wong | | x | |

The board recessed for a break at 11:15 a.m. and resumed at 11:45 a.m.

Note: Ms. Herold left the meeting at 11:15 a.m.

b. Budget Update/Report

1. Fund Condition Report

President Gutierrez reviewed the fund condition report prepared by the Department (below). The fund condition includes the midyear augment the board received to ensure sufficient funding for continuity in enforcement related activities through the end of the 2016/17 fiscal year. She noted that it also includes an augment the board received as the result of an increase in employee compensation as part of a new union contract. The information below reflects the estimated fund condition:

| Fund Condition: With Fee Increase Effective July 1, 2017 | | |
|---|---------------------|--------------------------|
| Fiscal Year | Fund Balance | Months in Reserve |
| 2015/2016 | \$10,518,000 | 5.5 |
| 2016/2017 | \$6,858,000 | 3.5 |
| 2017/2018 | \$8,609,000 | 4.3 |
| 2018/2019 | \$9,945,000 | 4.9 |

2. Budget for Fiscal Year 2016/2016

President Gutierrez explained that fiscal year 2016/2017 ended on June 30, 2017. However, the final FY 2016/2017 numbers will not be available until the beginning of August. A final budget report will be provided at the next board meeting.

President Gutierrez reported that the board received \$20,301,100 in revenue originating from the following:

| Revenue Sources | | |
|------------------------|---------------|-------------------|
| Source | Amount | Percentage |
| Licensing | \$16,934,500 | 84% |
| Citation Fines | \$2,094,200 | 10% |
| Cost Recovery | \$1,206,600 | 6% |
| Interest | \$67,800 | 0% |

President Gutierrez stated that the board expended \$21,257,076, which is approximately 97% of its authorized budget. The largest expenditure categories are detailed below.

| Expenditures | | |
|--------------|--------------|------------|
| Source | Amount | Percentage |
| Personnel | \$13,601,614 | 64% |
| Enforcement | \$3,377,112 | 16% |
| Prorata | \$2,586,632 | 12% |

President Gutierrez reported that the new fiscal year started July 1, 2017. The board's authorized expenditures for the year will be \$22,317,000. She noted that detailed budget information is not yet available, but will be provided as the next quarterly board meeting.

c. Budget Update/Report

President Gutierrez explained that board members may seek reimbursement for travel expenses and per diem payments. Board members are paid for each day of a board meeting but, in accordance with board policy, may also submit hours for work performed doing additional board business. It is important to note that these figures only represent hours and travel expenses where reimbursement was sought. It is not uncommon for board members to waive their per diem payments or only request partial reimbursement of travel expenses. President Gutierrez stated that the detailed board member reimbursement information was provided in the meeting materials.

President Gutierrez reported that the Department has recently released a new form (Member Per Diem Certification Form) that must be signed by each board member in order to claim per diem for attending a board or committee meeting. She explained that the form requires the member to certify that they are not receiving compensation, including vacation pay, from their regular public employment for the day of the meeting.

Ms. Sodergren reported that recently staff was notified by the department that this form is still being modified so it is not yet available for use. She added that once the form is finalized staff will have the forms available at the end of each meeting and will submit the completed form to the Department to process the appropriate per diem payment.

d. Personnel Update

President Gutierrez reported that the board currently has one vacancy. The position is a public member appointment that was formerly held by Greg Murphy.

President Gutierrez stated that recently board staff analyst Marcie Stratton passed away. Ms. Stratton reviewed sterile compounding applications and renewals. She worked to make what was a busy and complex desk well-functioning. She was a very well-liked by staff, applicants and licensees. The board expressed their condolences to her family.

President Gutierrez briefly reviewed the recent hires, departures and recruitments as provided in the board meeting materials.

e. Future Board Meeting Dates

President Gutierrez announced the following future board meeting dates.

1. Future Board Meeting Date for 2017

- November 8-9, 2017, *Sacramento*

2. Future Board Meeting Dates for 2018

| Full Board Meetings | Petitioner Board Meetings |
|---------------------|---------------------------|
| February 6-7, 2018 | March 27, 2018 |
| May 2-3, 2018 | June 6, 2018 |
| July 24-25, 2018 | September 6, 2018 |
| October 23-24, 2018 | December 12, 2018 |

XIII. Discussion and Consideration of the University of California, San Diego’s Pilot Program to Permit Patients to Access Medications from an Automated Drug Delivery System (ADDS) Not Immediately Adjacent to the Pharmacy, Including Medications Requiring Consultation by a Pharmacist

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. Consultation would be provided via telephone before medication could be dispensed to a patient for first time fills. The board authorized this study pursuant to its authority under 16 CA Code of Regulations 1706.5.

The study’s researcher, Jan Hirsch, BS Pharm, PhD. And Kim Allen from Sharp Hospital provided a presentation of the final report (the presentation has been provided immediately following these minutes). The board also viewed a video of the ADDS as it operates at Sharp.

Following the presentation, the board asked Ms. Allen and Dr. Hirsch questions regarding the outcome of the study.

Board member Veale noted that she was surprised that patients delayed picking up their medications when they used the kiosk rather than picking it up right away. Ms. Allen stated that they were surprised as well; however, she noted that the kiosk allowed the patient more flexibility in deciding what time worked best for them to pick up the medication.

Board member Lippe stated that the anticipated usage of the kiosk higher than the actual usage. Ms. Allen stated that there were some barriers

Dr. Wong asked if there was a breakdown of new prescriptions vs. refill prescriptions. Dr. Hirsch stated that there were 1,484 prescriptions picked up from the kiosk. She explained that 474 were new prescriptions, 426 were refill prescriptions, and 584 were over-the-counter medications.

Ms. Sodergren asked what the definition of a new prescription was for the purposes of the study. Ms. Allen stated that Asteres views every new prescription number as a new prescription, however the law defines new prescriptions as any change in dose, new physician, or medication the patient has never received.

Ms. Sodergren stated that the law currently allows the use of these machines for previously dispensed medications. She asked if of the prescriptions that were categorized as “new” in the study, how many were previously dispensed medications. Dr. Hirsch stated that they do not have that data. Sara Lake, representing Asteres, stated that in the study consultations were only given for prescriptions that were “new” as defined by the law, so the number of consultations would equal the number of new prescriptions as defined by the law.

Ms. Sodergren stated that it would be helpful if the board could be provided with a breakout of the number of previously dispensed medications. She explained that when the board is considering changes in the law it is useful understand the expansion of new prescriptions so that the board could determine if there is a correlation with patient care.

Board member Victor Law stated that many of the employees did not sign up for the program. Ms. Allen explained that they conducted outreach, but it is often difficult to onboard participants. Mr. Law stated that it did not seem that there was demand for these machines by the employees.

Board member Weisser stated that given the fact that the participation was less than expected and the pick-up time was longer when using the kiosk, he wondered if these kiosks were necessary.

Board member Albert Wong stated that employees may have been worried that their personal medical information would be used by their employer.

Board member Greg Lippe stated that he didn't see the downside of using the machines, however he questioned how economical the machines would be for the employer.

Ms. Veale stated that these machines are the going be part of the future of pharmacy and the board needs to seriously look at their use and would like to see the parameters expanded to allow for more use of the machines.

Board member Lavanza Butler stated that this study was a good starting point.

Ms. Allen stated that they would like to continue to use the kiosk so they are requesting to continue the study while the board amends 1713 to allow for the use of the machines in locations not immediately adjacent to a pharmacy. Mr. Weisser asked what they would like to change in 1713. Ms. Allen responded that they would like to change it to allow for new prescriptions to be dispensed from the machines and to allow the machines to be in locations not immediately adjacent to a pharmacy.

President Gutierrez stated that these ADDS machines are going to be the wave of the future and the board needs to determine how to regulate them.

Staff counsel, Laura Freedman, stated that the board would need to agendaize modifying 1713 for a future meeting.

Ms. Freedman stated that she would need to review the original study parameters to determine if the waiver can be extended, thus allowing the machine to continue to be used.

Dr. Hirsch stated that she would be willing to work with the board on amending 1713 at future meetings. She also noted that if the study were to continue they would request that the board remove the requirement to compare the kiosk data to the data for patients that used the actual pharmacy. She explained that gathering the data from the pharmacy is time consuming and costly.

Ms. Freedman explained that the provision that allows the board to waive the provisions of 1713 is intended to allow the board to gather data via a study. Now that the study is complete, she would need to consider if an extension can be granted. She requested that the board give her time to review the original study parameters.

President Gutierrez asked if 340B drugs are dispensed via the kiosk. Ms. Allen stated that they are a contract pharmacy for 340B entities so it is possible that there are 340B drugs in the machine.

Sara Lake, stated that the only reason they are willing to extend the study so that patients can continue to use the kiosk.

Ms. Sodergren stated that the board needs to determine if additional study is necessary in order to make an informed decision to modify 1713.

President Gutierrez noted that 40 percent of the medications dispensed from the kiosk were for over-the-counter medications. She stated that the board could consider expanding the study to allow for non-employees to use the kiosk.

Ms. Sodergren stated that it would be helpful to receive data on the number of new prescriptions vs. previously dispensed prescriptions.

Ms. Freedman asked if the IRB has been extended. Dr. Hirsch stated that it had been extended to September.

A representative from Scripps Health stated that they are very interested in seeing the use of the kiosks expanded.

Mark Curry, representing Asteres, stated that large organizations have begun using the Asteres machines, including the Department of Defense. He stated that he would be happy to provide board members with tours of military bases that use the machines.

The board moved on to another agenda item to allow Ms. Freedman time to consider the study parameters.

XIV. Update from the Department of Consumer Affairs

There was no update from the Department of Consumer Affairs.

XV. Discussion and Consideration of the Proposed Regulation to Amend Title 16 CCR Section 1749, Related to Fees

President Gutierrez reported that in order to address a structural imbalance in the board's budget, the board worked with the Department of Consumer Affairs on a fee analysis, where the department determined the cost the board incurs to provide various services. She noted that the results of this analysis were included in the board's Sunset Report as well as served as the baseline for the development of the legislative proposal to recast the board's fees. This proposal was included in SB 1039 (Hill, Chapter 799, Statutes of 2016) and was signed by the governor on September 29, 2016, with an effective date of July 1, 2017.

President Gutierrez explained that in addition to the statute, the board's fees are specified in Title 16 CCR section 1749. This regulatory change is necessary to provide the board's regulated public with a clear understanding of the fees that will be assessed for the various services, including application and renewal as well as delinquent fees.

President Gutierrez stated that at the October 2016 Board Meeting, the board approved proposed text to amend 16 CCR Section 1749, related to the board's fee schedule. She reported that the 45-day comment period began on April 14, 2017 and ended May 30, 2017.

Ms. Sodergren reported that the board received one comment during the comment period in which the commenter questioned why the fees are higher for renewal versus initial application and also asserts that pharmacists should shoulder the higher fees rather than increasing the fees for pharmacy technicians. Ms. Sodergren explained that the board's fees are specified in statute and since the fees are currently set at the statutory minimum, the board cannot lower them as part of the regulation process. She noted that the staff recommendation is to reject the comment.

Board member Law asked why some of the renewal fees are higher than the application fees. Ms. Sodergren explained that prior to pursuing the statutory fee changes the board worked with the Department to conduct a fee analysis to determine how much it costs to provide services to licensees. The board then used this analysis to determine what the appropriate minimum and maximum fee range should be for each license type. Sodergren added that the intent of this regulation is to provide clarity to the regulated public as to where in the fee range their application or renewal fee falls.

Board member Veale stated that during the fee analysis the department's budget analysts had explained that some renewal fees were higher than the application fees because of the cost of conducting enforcement investigations and hearings of that specific license type.

The board agreed with the staff recommendation to reject the comment.

Motion: Adopt the regulation language as noticed on April 14, 2017, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by a Control agency to complete the rulemaking file.

M/S: Veale/Weisser

Support: 10 Oppose: 0 Abstain: 0

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

XVI. Discussion and Consideration of the Proposed Regulations to Add Title 16 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 Section 1715.65 of Title 16 CCR, related to Inventory Reconciliation Reporting. She stated that at the January 2017 Board Meeting, following a 45-day and a 15-day comment period, the board returned the regulation to the enforcement committee for further review and discussion, which took place in April 2017. President Gutierrez added that at the May 2017 Board Meeting, the board approved a modified regulation text and initiated a second 15-day comment period.

President Gutierrez explained that the second 15-day comment period began on May 16, 2017 and ended on May 31, 2017. She noted that the board received several comments during this comment period.

President Gutierrez stated that the board will have the opportunity to discuss the regulation, the comments received and determine what course of action it wishes to pursue. She explained that among its options are:

1. Adopt the regulation as approved at the May 2017 Board Meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a third 15-day comment period.

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

President Gutierrez asked Anne Sodergren, assistant executive officer, to provide the staff recommendation on the comments received.

Ms. Sodergren stated that the staff recommendation is to reject all the comments received during the second 15-day comment period. She explained that many of the comments were outside of the scope of the comment period and other comments provided language that board staff did not feel was necessary to include in.

Board Member Veale asked if a perpetual inventory would meet the requirements of the regulation. Ms. Sodergren responded that the intent of the language is to have physical counts and reconciliation of the Schedule II controlled substances. She explained that in order to meet the requirements of this regulation the perpetual inventory must include a physical count and reconciliation of all Schedule II controlled substances.

President Gutierrez asked staff to create an FAQ after the regulation is finalized to clarify some of the specific requirements in the regulation.

President Gutierrez noted that the intent of the regulation is to discover diversion before it reaches a large scale.

Ms. Freedman noted that some commenters stated that the term “disposition” is confusing. She explained that based on the dictionary definition of disposition (the final arrangement or the transfer of care or possession to another) she felt the term “disposition” is appropriate and does not need to be changed. The board agreed with Ms. Freedman.

Tim Lopez, pharmacy manager at Community Regional Medical Center, asked the board to further define “disposition” because the term is used in different contexts in the board’s lawbook. He asked the board to hold another 15-day comment period so that his colleagues could submit language defining disposition. The board decided that this would be more appropriately handled in a guidance document after the regulation is finalized.

Mr. Lopez asked if the new pharmacist-in-charge and the outgoing pharmacist-in-charge can conduct the inventory together to fulfill the requirement in the regulation (below). Ms. Sodergren responded that it is not mandated for the outgoing PIC to complete an inventory, it is just whenever possible. President Gutierrez explained that the board heard testimony that the outgoing PIC is often not available to conduct an inventory, so the board did not make it a requirement.

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

Motion: Adopt the regulation language as approved at the May 2017 Board Meeting (provided below), and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

Title 16. Board of Pharmacy Second Modified Text

Changes made to the originally proposed language are shown by ~~striketrough~~ for deleted language and underline for added language.

Changes made to the first modified language are shown by ~~double striketrough~~ for deleted language and double underline for added language.

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

1715.65. Inventory Reconciliation Report of Controlled Substances

- a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
- b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
- c) A pharmacy or clinic shall compile an ~~in~~ Inventory Reconciliation Report of all federal Schedule II controlled substances at least every three months. This compilation shall require:
 - 1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
 - 2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last ~~in~~ Inventory Reconciliation Report;
 - 3) A comparison of (1) and (2) to determine if there are any variances; ~~and~~
 - 4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; ~~and~~
 - 5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.
- d) ~~A pharmacy or clinic shall report in writing identified losses and known possible causes, shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions security improvements necessary to prevent additional losses of controlled substances.~~
- ~~e) Likely Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.~~
- e) ~~f)~~ The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director, (if a clinic), and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.
- f) ~~g)~~ A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).
- g) ~~h)~~ For inpatient hospital pharmacies, a separate quarterly in ~~Inventory Reconciliation Report~~ shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.
- h) ~~i)~~ The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

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

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, 4105.5, 4119.1, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

M/S: Weisser/Lippe

Support: 10 Oppose: 0 Abstain: 0

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

The board returned to agenda item XIII: Discussion and Consideration of the University of California, San Diego’s Pilot Program to Permit Patients to Access Medications from an Automated Drug Delivery System (ADDS) Not Immediately Adjacent to the Pharmacy, Including Medications Requiring Consultation by a Pharmacist.

Ms. Freedman stated that following her review of the study parameters, she has concluded that the board could extend the study in its current form. She also stated that the board could modify specific aspects of the study in order to gather certain data. Ms. Freedman recommended against modifying the foundation of the study.

President Gutierrez asked if the board if could extend the current study and ask Dr. Hirsch and Ms. Allen to return to the Enforcement Committee to discuss beginning a new study. Ms. Freedman responded that this was possible.

Ms. Freedman expressed concern with the request from Dr. Hirsch to remove the data collection from the physical pharmacy because this was a core element of the original study approved by the board. She stated that the board could modify the study parameters to collect data on new vs. previously dispensed medications.

Ms. Freedman again explained that in order for the board to waive requirements of a regulation, it must be done in order to gather data necessary to determine if modification of the regulation is appropriate. Waivers cannot be granted simply to allow patients to continue to use the kiosk.

Ms. Allen asked if the board is agreeing to amend 1713 if they extend the study. Ms. Freedman stated that the board cannot agree to this, the board must receive and consider the data from the study and then make their determination.

President Gutierrez explained that the board is concerned that the study size is not large enough and too many of the medications that were dispensed were over-the-counter for the board to use the study data as a justification to modify 1713.

Ms. Lake, stated that Asteres can provide the board with data from the other major organizations that use the machines. She stated that they do not want to continue the study if in the end the board will not be modifying 1713. President Gutierrez responded that the additional studies may be helpful, but it will not help the board determine if it is appropriate to extend the study. Ms. Freedman added that modifying regulations takes time.

Ms. Freedman stated that the board can extend the study if the board believes that that new information will be obtained that will assist them in making the determination to modify the regulation. She added that the board could make the motion to extend the study and then Asteres and UC San Diego could determine if from a business standpoint they would like to continue on with the study.

Motion: Extend the pilot study UC San Diego study for another 12 months. Additionally, request that the data provided to the board include a distinction between new prescriptions (as define by law) and previously dispensed prescriptions.

M/S: Veale/Weisser

Support: 10 Oppose: 0 Abstain: 0

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

The board recessed to closed session at 12:30 p.m.

XVII. Other Closed Session Matters

President Gutierrez returned the meeting to open session at 1:54 p.m. and adjourned the meeting at 1:55 p.m.

California Department of Justice

CURES 2.0

Prescription Drug Monitoring Program

July 26, 2017

CURES 2.0

1939

The California Triplicate Prescription Program (TPP) was created in 1939, capturing Schedule II prescription information.

1997

CURES was initiated, operating in parallel with the TPP's Automated Triplicate Prescription System (ATPS) to evaluate the comparative efficiencies between the two systems.

1999

CURES replaced the TPP/ATPS and began capturing Schedules II through IV prescription information.

2005

TPP/ATPS decommissioned after Senate Bill (SB) 151 eliminated the triplicate prescription requirement for Schedule II controlled substances, making CURES permanent.

2009

The Prescription Drug Monitoring Program (PDMP) was introduced as a searchable, client-facing component of CURES application.

2016

CURES 2.0

CURES 2.0

Health and Safety Code section § 11165. (a)

To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall . . . maintain the Controlled Substance Utilization Review and Evaluation System (CURES)...

CURES 2.0

Registered Users: 1/1/2017 - 6/30/2017

| | JAN | FEB | MAR | APR | MAY | JUN |
|---|----------------|----------------|----------------|----------------|----------------|----------------|
| Clinical Roles | | | | | | |
| Prescribers | 126,388 | 127,085 | 127,676 | 128,208 | 128,715 | 129,289 |
| Dispensers | 39,629 | 39,782 | 39,878 | 39,955 | 40,006 | 40,097 |
| | 166,017 | 166,867 | 167,554 | 168,163 | 168,721 | 169,386 |
| License Type | | | | | | |
| Doctor of Podiatric Medicine | 848 | 1,076 | 1,081 | 1,090 | 1,093 | 1,102 |
| Registered Nurse Practitioner/Nurse Midwife | 8,815 | 9,837 | 10,036 | 10,261 | 10,384 | 10,498 |
| Medical Doctor | 76,102 | 90,153 | 90,529 | 90,901 | 91,109 | 91,407 |
| Naturopathic Doctor | 128 | 132 | 135 | 147 | 147 | 148 |
| Osteopathic Doctor | 4,409 | 5,198 | 5,241 | 5,281 | 5,315 | 5,345 |
| Physician Assistant | 5,624 | 6,801 | 6,924 | 7,031 | 7,103 | 7,164 |
| Doctor of Optometry | 486 | 557 | 561 | 567 | 570 | 571 |
| Pharmacist | 32,830 | 34,839 | 35,185 | 35,418 | 35,548 | 35,715 |
| Doctor of Dental Surgery/Dental Medicine | 7,217 | 7,435 | 7,555 | 7,704 | 7,766 | 7,823 |
| Doctor of Veterinary Medicine | 2,011 | 2,133 | 2,193 | 2,258 | 2,275 | 2,289 |
| Other (Non-Specified License Type) | 27,547 | 8,706 | 8,114 | 7,505 | 7,411 | 7,324 |

CURES 2.0

Number of PARs Ran: 1/1/2017 - 6/30/2017

| | JAN | FEB | MAR | APR | MAY | JUN |
|---|----------------|----------------|----------------|------------------|----------------|------------------|
| Clinical Roles | | | | | | |
| Prescribers | 332,522 | 379,718 | 351,808 | 418,240 | 373,401 | 432,537 |
| Dispensers | 533,179 | 563,771 | 535,374 | 623,507 | 571,024 | 635,920 |
| | 865,701 | 943,489 | 887,182 | 1,041,747 | 944,425 | 1,068,457 |
| License Type | | | | | | |
| Doctor of Podiatric Medicine | 596 | 603 | 611 | 981 | 1,188 | 1,114 |
| Registered Nurse Practitioner/Nurse Midwife | 43,540 | 51,311 | 48,174 | 60,109 | 57,176 | 67,187 |
| Medical Doctor | 208,273 | 240,911 | 221,693 | 260,459 | 231,787 | 264,673 |
| Naturopathic Doctor | 2 | 2 | 1 | 7 | 7 | 4 |
| Osteopathic Doctor | 24,076 | 28,995 | 26,961 | 33,252 | 27,732 | 33,384 |
| Physician Assistant | 50,642 | 54,845 | 52,382 | 61,758 | 54,112 | 64,435 |
| Doctor of Optometry | | - | 3 | - | 2 | - |
| Pharmacist | 532,108 | 562,520 | 533,993 | 621,622 | 568,685 | 633,626 |
| Doctor of Dental Surgery/Dental Medicine | 1,118 | 1,180 | 1,092 | 1,187 | 990 | 1,037 |
| Doctor of Veterinary Medicine | 19 | 41 | 55 | 54 | 100 | 84 |
| Other (Non-Specified License Type) | 5,327 | 3,081 | 2,217 | 2,318 | 2,646 | 2,913 |

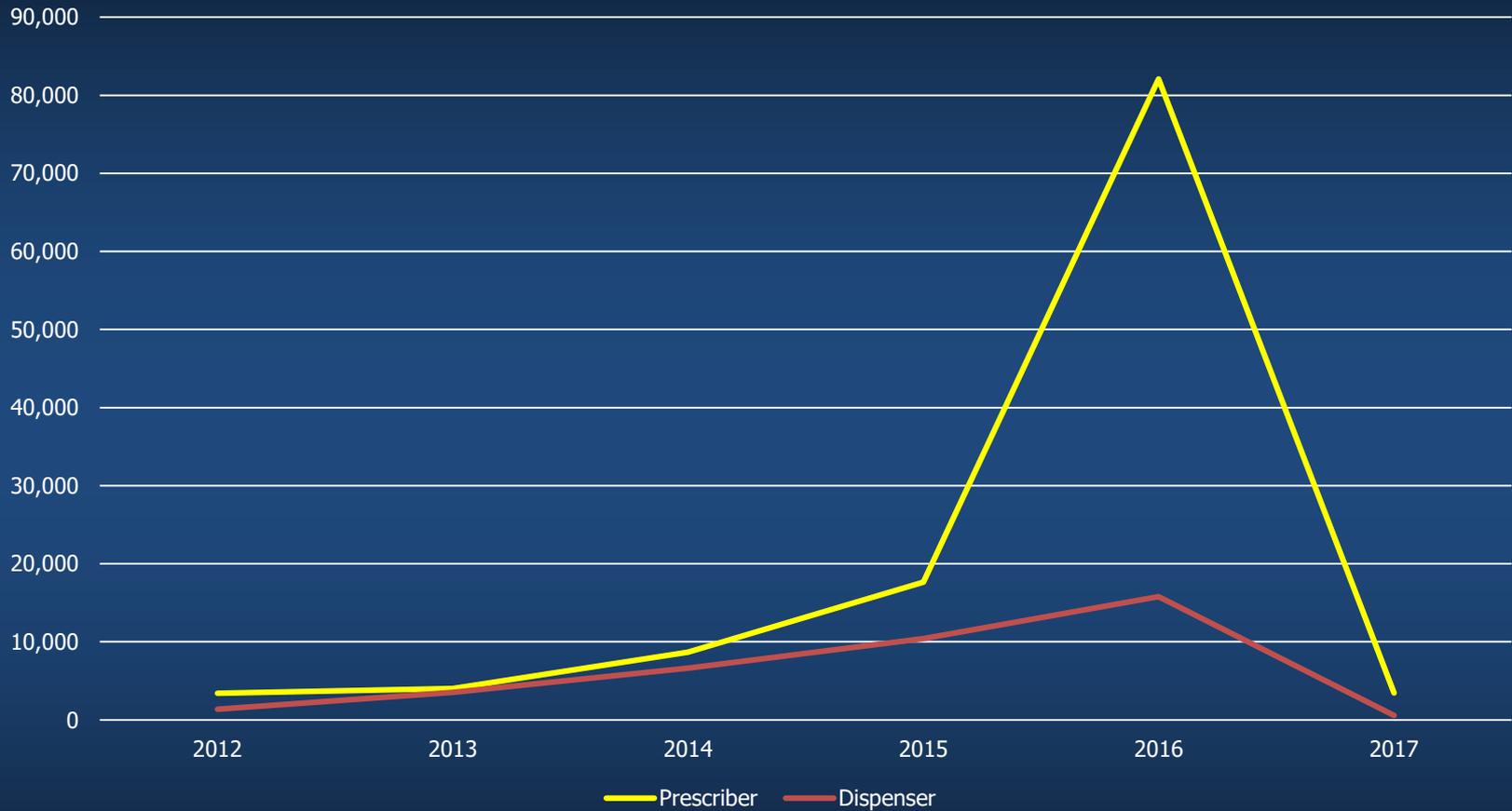
CURES 2.0

Times System was Accessed: 1/1/2017 - 6/60/2017

| | JAN | FEB | MAR | APR | MAY | JUN |
|---|----------------|----------------|----------------|----------------|----------------|----------------|
| Clinical Roles | | | | | | |
| Prescribers | 165,976 | 188,212 | 172,062 | 209,538 | 184,337 | 201,464 |
| Dispensers | 256,199 | 271,068 | 256,815 | 311,122 | 279,685 | 299,883 |
| | 422,175 | 459,280 | 428,877 | 520,660 | 464,022 | 501,347 |
| License Type | | | | | | |
| Doctor of Podiatric Medicine | 185 | 243 | 251 | 402 | 325 | 328 |
| Registered Nurse Practitioner/Nurse Midwife | 21,323 | 23,927 | 22,458 | 28,377 | 25,585 | 28,406 |
| Medical Doctor | 103,838 | 119,569 | 108,602 | 131,836 | 115,129 | 125,480 |
| Naturopathic Doctor | 4 | 5 | 9 | 23 | 5 | 10 |
| Osteopathic Doctor | 12,754 | 15,110 | 13,595 | 16,079 | 13,810 | 15,493 |
| Physician Assistant | 24,944 | 26,860 | 25,181 | 30,323 | 27,546 | 29,889 |
| Doctor of Optometry | 31 | 67 | 39 | 36 | 21 | 21 |
| Pharmacist | 255,310 | 270,254 | 256,092 | 310,254 | 278,847 | 299,005 |
| Doctor of Dental Surgery/Dental Medicine | 961 | 1,235 | 1,238 | 1,579 | 1,251 | 1,221 |
| Doctor of Veterinary Medicine | 155 | 176 | 161 | 315 | 251 | 189 |
| Other (Non-Specified License Type) | 2,670 | 1,834 | 1,251 | 1,436 | 1,252 | 1,305 |

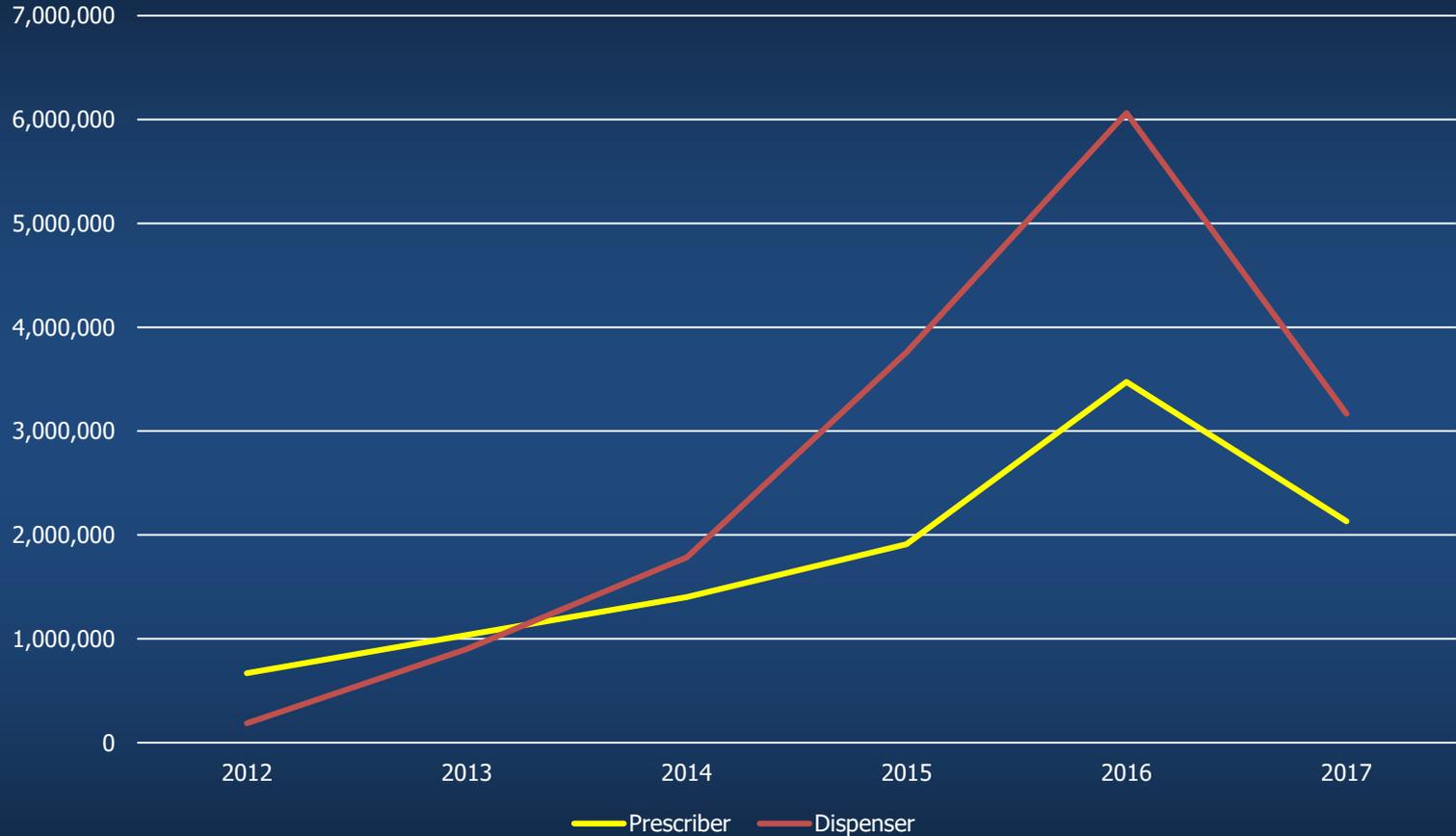
CURES 2.0

Prescriber and Dispenser Registrations by Year, 2012 to June, 2017



CURES 2.0

Prescriber and Dispenser PAR Generations by Year 2012 to July, 2017

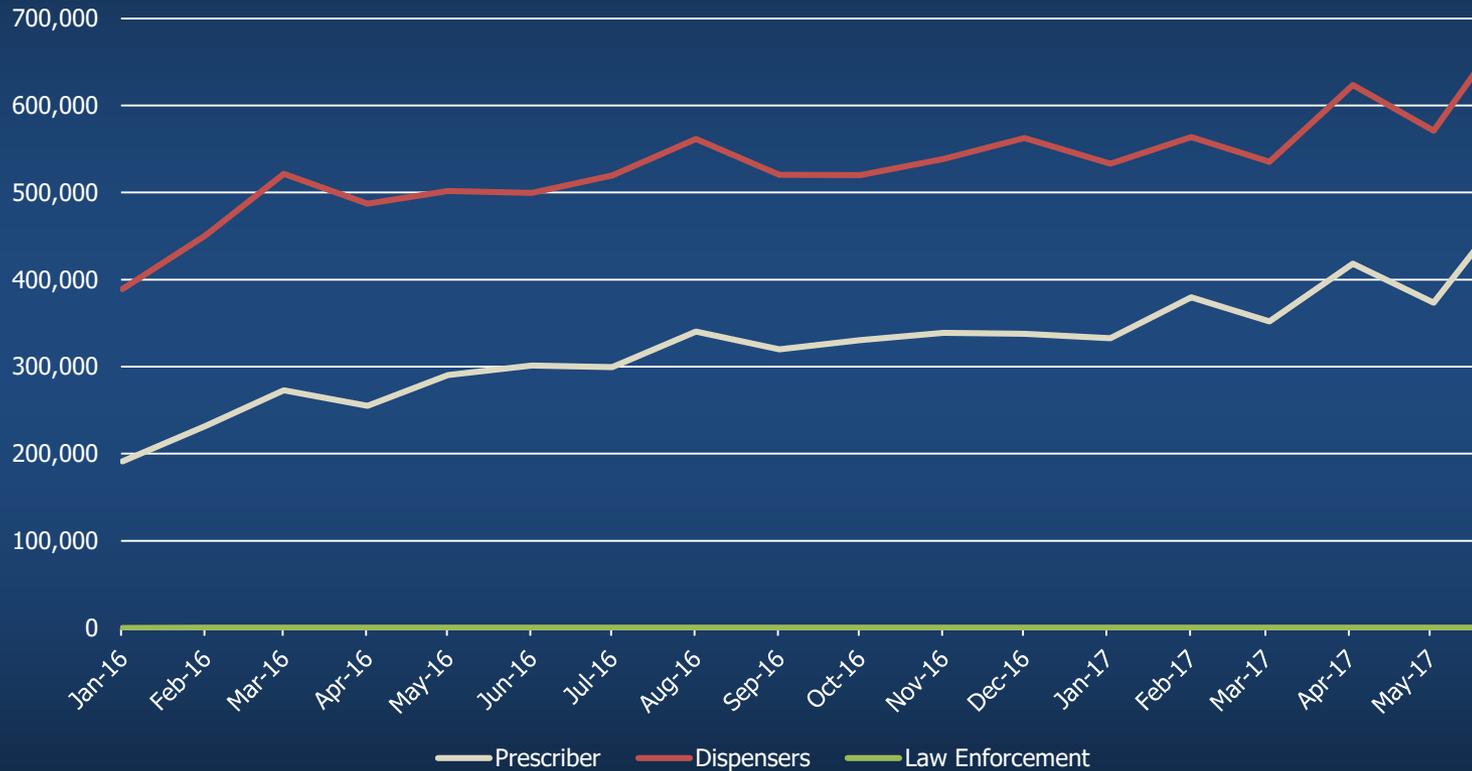


CURES 2.0

Patient Activity Report Requests by Prescribers, Dispensers, and Law Enforcement January, 2016 to June, 2017

| Month/Year | Prescriber | Dispensers | Law Enforcement |
|---------------|------------------|------------------|-----------------|
| Jan-16 | 190,992 | 389,156 | 29 |
| Feb-16 | 231,910 | 450,923 | 135 |
| Mar-16 | 272,683 | 521,431 | 61 |
| Apr-16 | 254,916 | 487,308 | 245 |
| May-16 | 290,435 | 501,675 | 79 |
| Jun-16 | 301,292 | 499,624 | 90 |
| Jul-16 | 299,418 | 519,699 | 94 |
| Aug-16 | 340,208 | 561,452 | 76 |
| Sep-16 | 319,896 | 520,442 | 177 |
| Oct-16 | 330,425 | 519,952 | 94 |
| Nov-16 | 338,707 | 538,474 | 54 |
| Dec-16 | 337,791 | 562,471 | 73 |
| Jan-17 | 376,911 | 567,361 | 88 |
| Feb-17 | 354,635 | 538,119 | 111 |
| Mar-17 | 413,315 | 622,014 | 155 |
| Apr-17 | 309,810 | 468,568 | 99 |
| May-17 | 347,604 | 500,856 | 144 |
| Jun-17 | 432,537 | 635,920 | 205 |
| Totals | 5,796,899 | 9,535,382 | 2,009 |

Patient Activity Report Requests by Prescribers, Dispensers, and Law Enforcement January, 2016 to June, 2017



CURES 2.0 Application Updates

CURES 2.0 launched June, 2016.

CURES 1.0 was decommissioned on March 5, 2017.

Only CURES 2.0 is now available to users employing a secure internet browser such as Microsoft Internet Explorer, version 11.0 or higher, Mozilla Firefox, Google Chrome, or Apple Safari.



CURES & UC San Diego Interoperation Pilot

CURES Program is partnering with Hydrant IDx in a National Institute of Standards in Technology (NIST) sponsored interoperation pilot with University of California San Diego (UCSD).

If successful, a prescriber or pharmacist's sign-on into the UCSD electronic health record will also sign-on to CURES.

Lewis v The Superior Court of Los Angeles County,
Respondent: Medical Board of California, Real Party in Interest

~

Oregon Prescription Drug Monitoring Program, Plaintiff and
ACLU Foundation of Oregon, Intervenor-Plaintiffs-Appellees

v.

U.S. Drug Enforcement Administration, Defendant-Appellant

CURES 2.0

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