



California State Board of Pharmacy

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BUSINESS, CONSUMER AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: April 21-22 2015

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

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Amy Gutierrez, PharmD, Vice President
Deborah Veale, RPh, Treasurer
Greg Lippe, Public Member
Gregory Murphy, Public Member
Victor Law, RPh
Allen Schaad, RPh
Ramón Castellblanch, PhD, Public Member (4/21/15 only)
Albert Wong, PharmD
Lavanza Butler, RPh
Ryan Brooks, Public Member

**BOARD MEMBERS
NOT PRESENT:** Rosalyn Hackworth, Public Member
Albert Wong, PharmD

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Michael Santiago, DCA Staff Counsel
Anne Hunt, Supervising Inspector
Joshua Room, Deputy Attorney General
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting can be found at:

<http://www.pharmacy.ca.gov/about/meetings.shtml>

Tuesday, April 21, 2015

Call to Order

10:36 a.m.

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

President Weisser called the meeting to order and established a quorum of the board. Board members present: Ryan Brooks, Lavanza Butler, Greg Lippe, Deborah Veale, Victor Law, Amy Gutierrez, Stanley Weisser, Ricardo Sanchez, Gregory Murphy, Allen Schaad and Ramon Castellblanch.

Board members not present: Rosalyn Hackworth and Albert Wong

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

There were no comments from the board or from the public

III. Approval of January 27-28, 2015 and March 9, 2015 Meeting Minutes

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

Motion: Approve the January and March board meeting minutes.

M/S: Lippe/Law

Support: 11 Oppose: 0 Abstain: 0

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

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

There were no 50-year pharmacists in attendance.

V. Communication and Public Education Committee

In Rosalyn Hackworth's absence, Allen Schaad provided a report of the March 23, 2015 committee meeting.

a. Future Board Forum on Elements of Quality Patient Consultation and Instruction of Patient Consultation by California's Schools of Pharmacy

Mr. Schaad reported that the importance of patient consultation by a pharmacist has been discussed by the board and committee and all agree that consultations are still not being

conducted as they should be, despite studies that have shown there is better patient adherence when consultations are provided.

Mr. Schaad stated that the board recently directed the committee to begin planning a forum on consultation to be held during a board meeting with an emphasis on how pharmacy students are trained to do consultation. The committee determined the forum should coincide with the July board meeting. Mr. Schaad noted that the committee plans to invite the deans of all 11 pharmacy schools in California to present information on how their schools teach pharmacy students to conduct consultations.

Mr. Schaad explained that the committee determined that a pharmacist survey could be conducted via the board website to ask pharmacists various questions about consultation and about how they were educated to conduct consultations.

The board discussed the struggle pharmacists have in balancing their workload and providing consultations. It was noted that this issue occurs in both chain pharmacies and independent pharmacies

Victor Law expressed the need for pharmacists to be reimbursed for consultations and encouraged the board to increase the fines for pharmacists who do not provide consultations. Dr. Gutierrez agreed that increasing the fines may encourage pharmacists to take consultations seriously.

President Weisser stated that pharmacists are required to consult patients about their new or changed prescriptions and it is a critical part of the pharmacists' role as a health care provider.

Ryan Brooks stated that the board should continue to educate pharmacists on the requirements for consultations.

Joshua Room reported that significant fines had been levied against two chain pharmacies for widespread failure to consult. Laura Freedman explained that the board could fine up to \$5,000 per investigation.

The board noted that many pharmacies choose to pay the fines for their pharmacists who do not consult rather than change their practices.

The board expressed the need to research why pharmacists are not providing consultations. Dr. Castellblanch stated that the board should also look at how pharmacy owners and management influence their pharmacists.

Mr. Schaad asked if the board receives complaints from consumers who do not receive consultations. Ms. Sodergren responded that the board does receive complaints and added that often the board finds medication errors that could have been prevented if the pharmacist had provided a consultation.

Steve Gray, representing Kaiser, stated that failure to consult is a problem regardless of setting. Dr. Gray added that pharmacists often are not confident enough to provide consultations because they didn't get the training in school they needed. Dr. Gray noted that Kaiser's policy is to not pay the fine of pharmacists and encouraged the board to consider fining both the individual and the organization for failure to consult.

President Weisser asked the Enforcement Committee to look at this issue and report back to the board with recommendations.

Mr. Brooks left the room at 11:13 a.m.

b. Presentation on Approaches to Use Social Media by the Board of Pharmacy

Mr. Schaad reported that the committee heard a presentation on the use of social media by Robert Schmidt, Agency Information Officer and Director, California Department of Food and Agriculture.

Mr. Schaad reported that the committee discussed that devoting valuable staff time to social media would warrant further discussion.

Mr. Schaad stated that the committee agreed that social media could be a good way to reach consumers to educate them about pharmacy topics and to share information about who the board is and what it does.

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

c. Translation Surveys Conducted by Board Inspectors

Mr. Schaad explained that during the past few months when inspecting pharmacies, board inspectors surveyed pharmacists about whether or not they were using the standardized directions for use from the board website and if and how they provide translations to patients for directions for use. The surveys were conducted to supplement the information the board already had on translations.

Mr. Schaad reported that inspectors completed 89 surveys. Of those surveyed, 50 respondents indicated they were using the board's standardized directions for use with 20 percent of those using the directions most of the time. Mr. Schaad noted that this contradicted their other answers on the survey, such as that 77 of the respondents don't deviate from what the prescriber writes and others use software to provide their directions for use.

Mr. Schaad stated that many of the pharmacies indicated they were providing translations using staff members or software. He added that of the pharmacies surveyed, most provided translations in Spanish.

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

d. Proposed Regulation to Require Pharmacies to Develop Written Procedures for Providing Written Language Translations

Mr. Schaad reported that in January 2015, the board voted to approve a committee recommendation to modify subdivision (d) of Title 16 CCR section 1707.5 to require that, in addition to having policies and procedures for interpretive services, the pharmacy must also have policies and procedures to provide (written) translation services in the patient's language.

The modified language approved by the board at the January 2015 meeting follows:

Subdivision (d) of Title 16 CCR section 1707.5(d)

1707.5 (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and

procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

Mr. Schaad reported that in the next few months board staff will initiate a rulemaking (combined with other regulations to be noticed) to require pharmacies to develop written procedures for providing written language translations. Mr. Schaad concluded that staff expects the board will be able to vote on adoption at the October 2015 Board Meeting and that the regulation should be completed by the end of this year.

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

e. Redesign of the Board's Website in 2015

Mr. Schaad reported that board IT staff is currently updating the board's website to make it more user friendly and to reformat it to conform to the state's new website model.

Mr. Schaad stated that staff is planning to provide a report on the progress of the new website and present a snapshot of the new look at the July Board Meeting.

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

Mr. Brooks returned to the meeting at 11:16 a.m.

f. Board's Newsletter ("Script")

Mr. Schaad reported that the winter 2015 Script was completed and is live on the board's website. He noted that the Script is one of the board's most popular items on its website and the current issue contains articles on new pharmacy laws, new regulations, licensing for third-party logistics providers, the Medical Board's revised pain management guidelines, drug diversion in hospitals, new regulations and disciplinary actions.

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

g. Media Activity

Mr. Schaad summarized the board's media activity since the last board meeting. There were no comments from the board or from the public.

h. Public Outreach Activities Conducted by the Board

Mr. Schaad summarized the board's public outreach activities since the last board meeting. There were no comments from the board or from the public.

VI. Prescription Medication Abuse Subcommittee

Dr. Castellblanch provided a report of the March 9, 2015 committee meeting.

a. CURES, California's Prescription Drug Monitoring Program

Dr. Castellblanch reported that the committee heard a presentation on CURES, California's prescription drug monitoring program, made by Mike Small and Robert Sumner from the Department of Justice.

Dr. Castellblanch reported that CURES 2.0 is on schedule and on budget and will launch on June 30, 2015 and will be fully functional by October 2015.

The board asked staff to write a letter to Mr. Small expressing the board’s support of the CURES program and encouraging the DOJ to continue their efforts to implement the new system. President Weisser noted that he would sign the letter on behalf of the board.

A member of the public noted that many pharmacists struggle with the constant need to reset their CURES password and he explained the difficulty they have if the password expires.

William Cover, president of the Indiana Board of Pharmacy, stated that having other healing arts boards sign the letter may add to the impact.

Motion: Direct board staff to draft a letter expressing the board’s support of the CURES program and encouraging the DOJ to continue their efforts to implement the new system.

M/S: Lippe/Law

Support: 11 Oppose: 0 Abstain: 0

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

b. Pharmacist’s Corresponding Responsibility in Regards to Dispensing Prescription Medications

Dr. Castellblanch reported that the committee discussed three recent board disciplinary actions which cited pharmacists demonstrating a lack of corresponding responsibility.

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

c. Discussion and Possible Action to Require Continuing Education on Pain Management

Dr. Castellblanch reported that at the January Board Meeting, the board approved amendments to § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations. The board-approved amendments to require pharmacists to complete at least six of 30 required units of continuing education in the areas of emergency/disaster response, patient consultation, maintaining control of a pharmacy’s drug inventory, ethics, substance abuse and compounding.

Dr. Castellblanch stated that the committee discussed the fact that many pharmacists still are not aware of the prescription drug abuse epidemic, of the red flags that could indicate a prescription

may be for abuse, or of a pharmacist’s corresponding responsibility in dispensing scheduled medications. The committee discussed amending the regulation to add “including red flags and corresponding responsibility” to the “Substance Abuse” category.

The current language approved at the January Board Meeting follows.

§ 1732.5. Renewal Requirements for Pharmacist

(b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy’s Drug Inventory
4. Ethics
5. Substance Abuse
6. Compounding

Committee Recommendation (Motion): Amend § 1732.5 , subsection d, subsection 5, in Article 4 of Division 17 of Title 16 of the California Code of Regulations as follows.

§ 1732.5. Renewal Requirements for Pharmacist

(b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy’s Drug Inventory
4. Ethics
5. Substance Abuse, Including Indications of Red Flags and a Pharmacist’s Corresponding Responsibly
6. Compounding

Support: 11

Oppose: 0

Abstain: 0

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

d. University of California, San Diego’s Webinar and Other Activities Related to Prescription Drug Abuse

Dr. Castellblanch reported that Nathan A. Painter, Pharm.D., CDE and Associate Clinical Professor at the University of California, San Diego Skaggs School of Pharmacy and Pharmaceutical Science,

shared an overview of a webinar presentation that will be given to University of California Student Health physicians, physician assistants, nurse practitioners, pharmacists, pharmacy technicians, psychologists and therapists through the UC health clinics.

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

e. Report on the Proposal to Prepare a Draft Report on the Subcommittee's Findings and Recommendations on the Opioid Epidemic

Dr. Castellblanch reported that the subcommittee has been meeting for more than a year and has heard from many presenters about the prescription drug abuse crisis.

Dr. Castellblanch stated that he will prepare a report on what the committee has learned so that the board can use the information moving forward. President Weisser thanked Dr. Castellblanch for his work on the subcommittee and for preparing a report.

Dr. Castellblanch noted that there are still many issues relating to the opioid epidemic remaining unresolved.

f. Summary of Activities to Promote Prescription Drug Abuse Awareness Month, ACR 26 (Levine)

Dr. Castellblanch noted that staff leveraged ACR 26, which recognizes March as Prescription Drug Abuse Awareness Month, to conduct an outreach to licensees about what the board has available in regards to prescription drug abuse prevention materials including the website, public service announcement videos and corresponding responsibility materials.

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

g. Review of Articles Regarding Prescription Drug Abuse

Dr. Castellblanch reported that the committee reviewed articles regarding prescription drug abuse. There were no comments from the board or from the public.

h. Public Outreach to Address Prescription Drug Abuse

Dr. Castellblanch reported that the committee reviewed the board's public outreach activities to address prescription drug abuse. There were no comments from the board or from the public.

VII. Enforcement and Compounding Committee

Dr. Gutierrez provided a report of the March 26, 2015 committee meeting. Dr. Gutierrez noted that there was no quorum of the committee.

Part 1: Enforcement Matters

a. EMD Serono's Program to Permit Patients to Authenticate Medication via Checking a Serial Number on a Medication Container Against a Manufacturer's Data Base

Dr. Gutierrez reported that the committee was provided an overview of the "Check My Meds" smartphone application created by EMD Serono that helps patients and their health care professionals verify the integrity of EMD Serono prescriptions. This application was developed to meet the requirements of the U.S. Food and Drug Administration's (FDA) effort to verify the authenticity of all drugs dispensed to patients regarding product integrity to safeguard patients against counterfeiting.

Dr. Gutierrez explained that the application would allow a patient to scan the two-dimensional barcode on the packaging. The two-dimensional barcode includes the global trade identification

number, expiration date, lot number and serial number encoded into the barcode, which is then generated and printed on each package during the packing process. This is the fulfillment of the e-Pedigree requirements established by the board in 2006 and preempted in late 2013 for a national model.

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

b. MatchRx's Model to Enable the Transfer of Prescription Medication in Short Supply Between Two Pharmacies

Dr. Gutierrez reported that MatchRx is a private web-based, inter-pharmacy marketplace for non-controlled, non-expired overstocked prescription drugs and drugs in short supply.

Dr. Gutierrez explained that the committee was provided with a summary of MatchRx's services which connects independent pharmacies in resolving three longstanding problems: 1) eliminating costly overstock before it expires; 2) locating small quantities of difficult to find medications; and 3) minimizing pharmaceutical waste.

Dr. Gutierrez noted that the committee members questioned whether a pharmacy could sell across state lines, and to whom MatchRx would report a drug loss.

Mr. Schaad noted that this type of program may allow counterfeit or illegally obtained drugs to enter the drug supply chain.

Ms. Freedman noted that the board's executive officer and legal counsel would be looking at Match Rx's business model to determine if they can be licensed as a 3PL. It was noted that Match Rx is not conducting business in California until they receive approval and proper licensure from the board.

Ms. Veale asked if the medication is provided in the original manufacturing packaging. Dr. Gutierrez responded that Match Rx does not require original packaging.

Mr. Sanchez left the room at 11:56 a.m.

Dr. Gray noted that many rural pharmacies may have a need for the services that Match Rx offers.

The board asked that the Licensing Committee place the Match Rx business model on their agenda for future meetings.

c. Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication and Development of Regulations for Pharmacies and Reverse Distributors Who Take Back Prescription Medication from Patients

Dr. Gutierrez reported that on September 9, 2014, the DEA released its regulations on the take-back of drugs from the public – specifically, the take-back of controlled substances.

Dr. Gutierrez explained that the final rule authorizes certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. All collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program. Retail pharmacies and hospitals/clinics with an on-site pharmacy may operate collection

receptacles at long-term care facilities.

Dr. Gutierrez stated that at the December 2014 committee meeting, Ms. Herold provided an overview of the DEA's new drug take-back regulations. Dr. Gutierrez stated that committee discussion included how an average person would know which drugs are acceptable for disposal. Dr. Gutierrez added that the committee heard comments from the public in which the board was asked not to place the collection burden on pharmacists.

Dr. Gutierrez stated that the committee will include this item on the June 2015 committee meeting.

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

Ms. Herold arrived at the meeting at 12:04 p.m.

d. University of California, San Diego's Request for Waiver of Title 16, California Code of Regulations, Section 1713, to Permit a Pilot Program to Allow Patients to Access Medications from an Automated Storage Device Not Immediately Adjacent to a Pharmacy

Dr. Gutierrez explained that several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of vending-machine like automated delivery devices, to permit the furnishing of refill medication in specified circumstances, to include the requirement that the patient must opt in to use the machine and that the medication to be refilled through the machine is appropriate.

Dr. Gutierrez reported that in recent years, the board has received several requests to use automated delivery devices in a variety of settings including workplace clinics, hospital lobbies, other areas on a hospital campus, and in employment locations. During each of these discussions, several concerns were raised about whether the request would comply with current regulations and whether the board had the authority to approve the request without specific regulatory changes. Dr. Gutierrez noted that to date the board has not approved any waivers since enactment of the regulation.

Dr. Gutierrez explained that at the July 2013 board meeting where this proposal was discussed, the board asked that Dr. Castellblanch provide assistance in developing a more traditional research protocol. At the March Enforcement Committee meeting Dr. Castellblanch advised the committee that he reviewed the current IRB protocol and indicated that it is a well-designed protocol for the committee to consider. Dr. Castellblanch further indicated that he was not a pharmacist and could not comment on potential risks or the need for informed consent.

Dr. Hirsh, of University of California, San Diego and Kim Allen, of Sharp Rees-Stealy, provided a PowerPoint presentation to the board that offered an overview of the research study and protocol. If approved by the board under the authority provided in section 1706.5, the board would agree to waive the requirements in 1713 for purposes of the research study.

The presentation is provided following these minutes.

Mr. Sanchez returned to the meeting at 12:14 p.m.

The board stated that they would like a pharmacist to be on call 24-hours a day to provide consultations to patients using the device after business hours. Dr. Hirsh and Ms. Allen agreed that this is possible.

The board discussed the security of the device, including the video surveillance that will be in use. Mr. Schaad asked what the goal was for the use of the device after the completion of the study. Ms. Allen responded that they would consider placing these machines in unlicensed locations, such as corporate headquarters.

Mr. Brooks asked what would happen if there was a technological failure that prevented the medication from being dispensed. Ms. Allen explained that the patient would speak with the on-call pharmacist, via telephone, who would ensure that the patient received his or her medication.

The board discussed the security features of the device, including the video surveillance that will be in use.

Ms. Herold reviewed the timeline for the study and it was determined that a report would be provided to the board at the October, 2016 board meeting.

Motion: Approve UCSD’s pilot program and request for an 18-month waiver of 16 California Code of Regulations section 1713, provided that the pilot program makes available an on-call, after hours pharmacist for patients using the automated dispensing device.

M/S: Lippe/Veale

Support: 10		Oppose: 0		Abstain: 1	
Name	Support	Oppose	Abstain	Not Present	
Brooks	X				
Butler	X				
Castellblanch	X				
Gutierrez	X				
Hackworth				X	
Law			X		
Lippe	X				
Murphy	X				
Sanchez	X				
Schaad	X				
Veale	X				
Weisser	x				
Wong				X	

The board recessed for lunch at 12:50 p.m. and resumed at 1:32 p.m.

e. Evaluation of Title 16 California Code of Regulations, Section 1744 Regarding Required Warning Labels on Prescription Container Labels

Dr. Gutierrez explained that prior to July 1, 2014, Pharmacy Law required a pharmacist to inform a patient orally or in writing about the harmful effects of a drug: (1.) if the drug posed a substantial risk to the person consuming the drug when taken in combination with alcohol, or if the drug could impair a person’s ability to drive a motor vehicle, and (2.) the drug was determined by the Board of Pharmacy to be a drug or drug type for which the warning must be given.

Dr. Gutierrez stated that Assembly Bill 1136 (Levine), signed by the Governor on September 9,

2013, amended existing law to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. Dr. Gutierrez noted that the required label may be printed on an auxiliary label that is affixed to the prescription container.

Dr. Gutierrez stated that section 1744 of the board's regulations provides the specific classes of drugs which trigger a pharmacist's verbal or written notice to patients where a patient's ability to operate a vehicle (and now a vessel) may be impaired. Dr. Gutierrez noted that this section has not been revised in a number of years, so recently the schools of pharmacy were asked to provide comments to the list of medications listed in this regulation. A number of California's schools of pharmacy provided comments. Those comments were integrated in the first draft.

Dr. Gutierrez reported that at the committee meeting members requested counsel to modify the language so that it could be brought to the board at the April 2015 meeting.

Below is the draft language as modified by staff and DCA counsel.

1744. Drug Warnings.

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because the following classes of drugs may impair a person's ability to operate a vehicle or vessel, a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel.

- (1) Muscle relaxants.
- (2) Antipsychotic drugs with central nervous system depressant effects
- (3) Antidepressants with central nervous system depressant effects.
- (4) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (5) All Schedule II, III, IV and V agents with central nervous system depressant effects.
- (6) Anticholinergic agents that impair vision.
- (7) Any other drug based upon a pharmacist profession judgment that may impair a patient's ability to operate a vehicle or vessel.

(b) Because the following classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall provide a written warning notice on the label to alert the patient about possible potentiating effects:

- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.
- (4) Cycloserine.
- (5) Insulin (hypoglycemia) antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).
- (6) Any other drug based upon a pharmacist profession judgment that may pose a substantial risk to the person consuming the drug when take in combination with alcohol.

Dr. Gutierrez noted that item (a) (7) should be modified to read: "Any other drug which, based on

the pharmacist’s professional judgement, may impair a patient’s ability to operate a vehicle or vessel.” Ms. Freedman added that this language would also be used in item (b) (7).

Mr. Freedman noted that item (a) (6) should be amended to read: “Anticholinergic agents that may impair vision.”

Dr. Gutierrez asked that (b) (5) be amended to read: “~~Insulin (hypoglycemia)~~ Antidiabetic agents including insulin and sulfonylureas due to risk of hypoglycemia.

Motion: Approve the proposed language for Title 16 California Code of Regulations section 1744 as provided below. Initiate a rulemaking to release the language for 45-day public comment.

M/S: Gutierrez/Lippe

Support: 11 Oppose: 0 Abstain: 0

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

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(a) Because the following classes of drugs may impair a person’s ability to operate a vehicle or vessel, a pharmacist shall include a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel.

- (1) Muscle relaxants.
- (2) Antipsychotic drugs with central nervous system depressant effects
- (3) Antidepressants with central nervous system depressant effects.
- (4) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (5) All Schedule II, III, IV and V agents with central nervous system depressant effects.
- (6) Anticholinergic agents that may impair vision.
- (7) ~~Any other drug based upon a pharmacist profession judgment that may impair a patient’s ability to operate a vehicle or vessel.~~ Any other drug which, based on the pharmacist’s professional judgement, may impair a patient’s ability to operate a vehicle or vessel.

(b) Because the following classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall provide a written warning notice on the label to alert the patient about possible potentiating effects:

- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.
- (4) Cycloserine.
- (5) ~~Insulin (hypoglycemia)~~ Antidiabetic agents including insulin and sulfonylureas due to risk of hypoglycemia.
- (6) ~~Any other drug based upon a pharmacist professional judgment that~~ Any other drug which, based on the pharmacist's professional judgement, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

f. Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances

Dr. Gutierrez reported that at the March 2014 Enforcement and Compounding Committee meeting, Chairperson Gutierrez led a discussion of losses of controlled substances reported to the board as required by California Pharmacy Law.

Dr. Gutierrez noted that board staff compiled some statistics regarding drug losses reported to the board over the last few years. The tables displaying the losses of controlled substances reported to the board was provided in the meeting materials.

Dr. Gutierrez reported that in 2013, 3.06 million dosage units of controlled substances were reported to the board as lost. This includes 1.7 million units that were from a major manufacturer who had a truck stolen. Dr. Gutierrez noted that these numbers are only estimates provided by the entity when they first realize there has been a loss. As such, the reported numbers are most likely significantly less than actual losses.

Dr. Gutierrez stated that the committee expressed concern about the significant losses and the need for more stringent inventory controls in pharmacies to identify losses resulting from employee pilferage. Comments from the committee included developing steps for inventory controls, which could be done either by regulation, statute or policy and perhaps reconciling the top-10 drugs for the pharmacy.

Dr. Gutierrez reported that at the January 2015 Board Meeting, the board reviewed proposed language from the committee. The proposed language was rejected by the board and was sent back to the committee for further revision. Below is the revised the language for consideration:

1715.65 Monthly Inventory Counts of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall maintain a perpetual inventory for all Schedule II controlled substances acquired by the licensee. A perpetual inventory as used in this article shall mean an inventory system whereby the pharmacy's or clinic's records about stock on hand for every Schedule II controlled substance acquired and dispensed are continuously updated to reflect the actual quantity of stock on hand. Such an accounting will include all acquisitions and all dispositions for each Schedule II controlled substance.

(b) As an alternative to the maintenance of a perpetual inventory for Schedule II controlled substances in subdivision (a), a pharmacy or clinic must have a written policy that identifies a monthly reconciliation process for the five highest volume controlled substances acquired by the licensee in the last year (or as determined by the last DEA biennial inventory, or as purchased by the pharmacy if there has been no biennial inventory taken). This policy shall address reconciliation of all purchases and acquisitions, dispensings, transfers and current inventory, including the inventory in quarantine for a reverse distributor. The pharmacy or clinic shall perform a count of these five controlled substances pursuant to this policy at least every month.

(c) The pharmacist-in-charge of a hospital pharmacy or of pharmacy servicing skilled nursing homes wherever an automated drug delivery system is used shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(d) Losses of controlled substances identified by pharmacies from the perpetual inventory or monthly audit shall be reported to the board as required by section 1715.6 and California Business and Professions Code section 4104.

(e) A clinic shall report to the board all losses detected from the perpetual inventory or monthly audit undertaken pursuant to this section within 14 and no later than 30 days.

(f) The pharmacist-in-charge or consultant pharmacist for the clinic shall sign and date each monthly reconciliation within 14 days of completion. These signed reconciliations shall be retained by the licensed premises for three years and be readily retrievable for review by the board.

(g) The pharmacist-in-charge of a pharmacy or consultant pharmacist for the clinic shall review all inventories and reconciliations to establish and maintain secure methods to prevent losses of dangerous drugs.

The board discussed if requiring perpetual inventory only for Schedule II drugs would capture other drugs that are being diverted.

Dr. Castellblanch asked if the DEA has a list of the most abused or diverted drugs that the board could utilize. Ms. Herold responded that she would research the information available from the DEA.

Ms. Herold noted that the board could identify the top-10 diverted drugs in California and require pharmacists to keep a perpetual inventory of these drugs.

Mr. Lippe stated that originally the committee discussed requiring inventory for the top-10 drugs purchased by the pharmacy.

Dr. Gutierrez stated that the board could provide a list of the top-10 drugs on the board's website and update it annually. Ms. Freedman noted that the board would have to go through the entire regulation process each time this list changed. Ms. Herold stated that there may be a way to work around going through the regulation process each time the list changes and added that she would work with DCA legal counsel to provide the committee with options.

President Weisser and Mr. Brooks stated that the committee needs to look at ways to draft the language so that pharmacies can tailor the inventory requirements to fit their purchasing and dispensing trends.

The board asked that the Enforcement Committee continue to work on the language based on the board's discussion.

Brian Warren, from the California Pharmacist Association, noted that not all pharmacies currently have perpetual inventory systems in place, and putting one in place can be very costly. He encouraged the board to educate licensees on the top-10 diverted drugs.

Karen Craddick, from Cedars Sinai Hospital, expressed concern with some of the requirements in section (c), section (f) and section (g). The board asked Dr. Craddick to provide her comments to the Enforcement Committee when they discussed this language at future meetings.

g. Carefusion's Drug Diversion Deterrent Reports Available with Its Automation Storage Cabinets

Dr. Gutierrez reported that representatives from Carefusion appeared before the committee to provide information on the features of the Pyxis system that helps deter controlled substance diversion and the available drug diversion reports available within the system.

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

h. Discussion of Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to 16 California Code of Regulations Sections 1780 -1786

Dr. Gutierrez reported that in 2014, the board sponsored legislation to enact provisions to license third-party logistic providers as a separate class and not as the board had previously done under the category of wholesaler. This legislation was enacted by AB 2605 (Bonilla, Chapter 507, Statutes of 2014). Dr. Gutierrez stated that this legislation was needed because federal law enacted in 2013 prohibited licensure of third-party logistics providers as wholesalers.

Dr. Gutierrez explained that the board needs to amend its regulations to ensure that third-party logistics providers also must adhere to board regulations for all drug distributors, whether they are a wholesaler or third party-logistics provider.

Dr. Gutierrez stated that the regulations for wholesalers were developed over a period of time and that some of the language is now in statute and will be removed from the regulation. Dr. Gutierrez stated that the revised language provides added details on how a third-party logistics provider is directed to protect the products in storage or being selected at its facility.

Dr. Gutierrez also indicated that the board's goal is to create a self-assessment which includes the general requirements a board inspector will look for when inspecting a facility.

Ms. Herold stated that the proposed language is still a draft and the board is still in the process of setting up the program. Ms. Herold added that the meeting materials contain a copy of the proposed regulation and self-assessment for third-party logistics providers.

Dr. Gray, from Kaiser, asked if a wholesaler and 3PL can share the same physical location. Ms. Herold responded that 4160 and 4161 allow wholesalers and 3PLs to be in the same physical location as long as they have a separate drug stock and different people serving as the 3PL manager and wholesaler designated representative in charge, as well as the appropriate designated representative for each license.

i. CURES Data on the Impact of the Federal Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II

Dr. Gutierrez stated that board staff compiled data regarding the number of oxycodone and hydrocodone prescriptions dispensed before and after hydrocodone was rescheduled to Schedule II in October. Twenty percent less hydrocodone was dispensed during the same period in 2014/15 when compared with 2013/14. The compiled data and information regarding losses reported for hydrocodone and oxycodone products during 2014 can be found in the board meeting materials.

j. Discussion Regarding the Adoption of e-Prescribing

Dr. Gutierrez explained that e-prescribing had been required for all New York State prescriptions effective March 27, 2015, pursuant to regulations adopted by New York State. Recent legislation has delayed this implementation for one year, to March 27, 2016. Dr. Gutierrez noted that at the last committee meeting, the committee heard a presentation by New York's Board of Pharmacy Executive Officer Larry Mokhiber.

Mr. Sanchez left the room at 2:26 p.m.

Ms. Herold stated that she requested the DEA to post on their website a list of audited and approved software that prescribers and pharmacies can use.

There were no public comments.

k. Opportunity to Provide Comments on U.S. Food and Drug Administration Draft Guidance Documents

Dr. Gutierrez reported that the FDA recently released five guidance documents on various aspects of sterile compounding by pharmacies and the production of medication by outsourcing facilities. She explained that at the March Board Meeting and again at this meeting, each of these guidance documents has been agendaized so the board may discuss and take action on any of them.

Dr. Gutierrez stated that comments are due on May 20, 2015, except for the proposed MOU. Dr. Gutierrez stated that if comments are desired, the board may direct staff to develop comments based on board discussion and have the board president approve and sign them.

Below are the five FDA documents open for comment.

1. Draft Guidance: For Entities Considering Whether to Register As Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
2. Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities
3. Draft Guidance for Industry: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (BLA)
4. Draft Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
5. Draft Memorandum of Understanding Between A State and the U.S. Food and Drug Administration Addressing Certain Distributions of Compounded Human Drug Products

Mr. Sanchez returned to the meeting at 2:39 p.m.

Mr. Room briefly explained the FDA's requirements for outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act.

Mr. Room noted that there are some topics in document No. 1 that the board should provide comments on.

Dr. Gutierrez noted that there is an outsourcing facility located in Switzerland, which would be difficult to regulate. Ms. Herold responded that California's outsourcing requirements would require a company to be located in the United States to be licensed to do business in California as an outsourcer.

Mr. Room stated that the board should consider if California should enter into the Memorandum of Understanding (document No. 5) and if so, what edits the board would make prior to entering into it.

Mr. Room clarified that if California enters into the MOU, 30 percent of a 503A (compounding pharmacy) facility's total dispensed products could be distributed interstate. If California does not enter into the MOU, only five percent of a 503A facility's total dispensed products could be distributed interstate.

President Weisser asked Mr. Room if he would recommend signing the MOU. Mr. Room responded that the board should provide comments on the draft and then decide if California should sign the MOU once the FDA releases the final document.

President Weisser expressed concern with limiting the amount of product a licensed facility can ship interstate. Mr. Room stated that the board could ask the FDA for the reasoning behind setting the limit at 30 percent.

Dave Jones, from McGuff Compounding Pharmacy, stated that there is confusion on whether the FDA's intent is to require 503A and 503B to be in separate geographic locations. Mr. Jones explained how McGuff leverages resources from their 503B facility for use by their pharmacy facility.

Mr. Jones encouraged the board not to sign the MOU in its current form and expressed concern with how the FDA calculates the 30 percent and five percent thresholds.

Dr. Gutierrez noted that the FDA's adverse event reporting has different requirements than California's reporting requirements. The board asked that comments be provided on this item (document No. 4).

Bill Jones, from Central Admixture Pharmacy Services (CAPS), asked that the board review the dating requirements for repackaging in document No. 2, as they were unclear to CAPS staff.

Ron McGuff, President of McGuff Pharmacy, stated that the 30 percent and five percent limit can create a shortage of compounded products available to consumers. Mr. McGuff also expressed concern with how the FDA calculated the percentages.

The board asked staff to draft comments for signature by the board president.

Motion: Direct board staff to work with Supervising Deputy Attorney General Joshua Room to draft comments on the FDA documents listed below for signature by the board president.

- Draft Guidance: For Entities Considering Whether to Register As Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
- Draft Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act
- Draft Memorandum of Understanding Between A State and the U.S. Food and Drug Administration Addressing Certain Distributions of Compounded Human Drug Products

M/S: Brooks/Castellblanch

Support: 10

Oppose: 0

Abstain: 1

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

I. Enforcement Statistics

Dr. Gutierrez briefly reviewed the enforcement statistics provided in the meeting materials. There were no comments from the board or from the public.

m. Remaining Meeting Dates for 2015

Dr. Gutierrez reported the future Enforcement Committee dates listed below. There were no comments from the board or from the public.

- June 24, 2015
- September 2, 2015
- December - to be determined

The board took a break from 3:16 p.m. and resumed at 3:34 p.m.

Note: Gregory Murphy left the meeting during the break.

Part 2: Compounding Matters

a. Summary of the Report of Sterile Compounding Pharmacy Inspections Conducted

Dr. Gutierrez reported that the committee heard a presentation on the sterile compounding pharmacy inspections conducted.

Dr. Gutierrez noted that she would be working with board staff to change the way that the inspection data is reported.

There were no comments from the public.

VIII. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 California Code of Regulations Section 1735 et seq., and 1751 et seq., Relating to Pharmacy Compounding

Dr. Gutierrez provided a brief timeline of the regulation process.

Dr. Gutierrez stated that she recommends withdrawing the existing rulemaking and reissuing the language for comment. She explained that the current language is extremely difficult to read due to the amount of edits that have been made and added that some verbal comments made at a prior hearing had been inadvertently excluded from the rulemaking comments. Ms. Herold agreed that the language was difficult to read due to the numerous edits, and adding additional comments could cause confusion for the public as to which items were open for comments.

Judith Brosz, PharmD, shared that because she has a health condition she is unable to complete the physical component of the training required in the compounding regulation.

Dr. Gutierrez asked Dr. Brosz to submit comments when the board releases the language for public comment.

Motion: Withdraw the existing rulemaking and initiate a 45-day comment period using the “clean version” of the compounding regulation language.

M/S: Gutierrez/Schaad

Support: 10

Oppose: 0

Abstain: 0

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

IX. Board Member Officer Elections

The board conducted elections for the offices of president, vice president and treasurer.

Dr. Castellblanch left the room at 3:48 p.m.

Motion: Nominate Amy Gutierrez for Board President.

M/S: Brooks/Veale

Support: 8 Oppose: 0 Abstain: 1

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

Motion: Nominate Deborah Veale for Board Vice President.

M/S: Lippe/Gutierrez

Support: 8 Oppose: 0 Abstain: 1

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

Dr. Castellblanch returned to the meeting at 3:50 p.m.

Motion: Nominate Victor Law for Board Treasurer.

M/S: Butler/Lippe

Support: 9 Oppose: 0 Abstain: 1

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

The board thanked President Weisser for his hard work and dedication during his term as president.

X. Closed Session

The board recessed to closed session at 3:52 p.m. to deliberate on disciplinary matters, pending litigation and to perform the annual evaluation of the executive officer.

XI. Reconvene Open Session

The board reconvened open session at 4:41 p.m. and adjourned for the day at 4:42 p.m.

Wednesday, April 22, 2015

President Weisser called the meeting to order at 8:34 a.m., and established a quorum of the board. Board members present: Lavanza Butler, Gregory Lippe, Deborah Veale, Victor Law, Amy Gutierrez, Stanley Weisser, Gregory Murphy and Allen Schaad.

XII. Closed Session

The board recessed to closed session to deliberate on disciplinary matters at 8:35 a.m.

XIII. Reconvene Open Session

President Weisser reconvened open session at 9:06 a.m., and established a quorum of the board. Board members present: Lavanza Butler, Gregory Lippe, Deborah Veale, Victor Law, Amy Gutierrez, Stanley Weisser, Gregory Murphy, Ricardo Sanchez and Allen Schaad.

XIV. Public Comments on Items Not on the Agenda

Dennis McAllister, from Express Scripts, commented that Express Scripts supports SB 671. He noted that similar language is used in other states and has been successful.

Mr. Lippe commented that the Legislation and Regulation Committee had opposed SB 671 because of concern with the requirement for pharmacists to report substitutions within five days.

Dr. McAllister stated that Express Scripts believes that most patients will not be paying cash for these medications and therefore the physician could check Sure Scripts to see if the pharmacist had made any substitutions. He added that there is an application program available that would allow the physician to check for any substitutions. Dr. McAllister concluded that Express Scripts feels that the pharmacist's use of the application program or checking Sure Scripts would fulfill the notification requirement in the bill.

Robert Stein, from KGI School of Pharmacy, stated that putting the responsibility on the physician to check Sure Scripts or download an application program does not fulfill the pharmacist's duty to report any substitutions to the physician within five days.

XV. Organizational Development Committee

a. Future Board Meeting Dates for 2015

President Weisser reported the dates below for the future board meeting dates.

- April 21 & 22, 2015
- June 3 & 4, 2015
- July 28 & 29, 2015
- October 28-29, 2015

b. Budget Update/Report

1. Budget Report for 2014/2015

President Weisser reported that the new budget year began July 1, 2014. The board's spending authorization for the year is \$19,881,000 which is a seven percent increase from the prior year.

President Weisser noted that as of March 30, 2015, the board has expended \$12,597,900 of its current year budget. President Weisser added that 58 percent of the expenditures are attributed to salary and wages and 17 percent is attributed to enforcement related costs.

President Weisser stated that the board's revenue for the first eight months of this year is \$13,945,000 and has come primarily from application and renewal fees (88 percent), with citation and fines accounting for approximately 8 percent.

2. Fund Condition Report

President Weisser briefly reviewed the fund condition provided in the meeting materials which reflects the estimated fund condition with the additional revenue from the approved fee increase.

President Weisser reported that the fund condition provided in the meeting materials also includes a pending \$1.4 million augmentation of the board's Attorney General expense line item. President Weisser noted that the augmentation is pending approval by the legislature and is expected to be approved by the end of April 2015.

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

3. Discussion on Holding a Special One-Day Board Meeting

President Weisser explained that the board initially envisioned convening a one-day board meeting to hear petitions for penalty reductions and license reinstatements. Subsequently it was determined that a second day was needed in order to give the board the opportunity to respond to possible changes to the naloxone protocol if requested by the Medical Board during their May board meeting.

President Weisser stated that the board has selected June 3-4, 2015 as the board meeting dates. He added that the meeting will be held in Irvine at the University of Southern California, Orange County Center.

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

4. Board Member Reimbursement and Mail Vote Information

President Weisser directed the board members and the public to review the meeting materials for information on board member reimbursement and mail voting.

There were no comments from the board or from the public

c. **Personnel Update**

Ms. Herold reviewed the personnel update as provided in the meeting materials. There were no comments from the board or from the public.

XVI. Review and Discussion of Office of the Attorney General Legal Opinion Relating to SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) Relating to Substance Abusing Healing Arts Licensees

Ms. Sodergren explained that California Code of Regulations section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action.

Ms. Sodergren reported that Business and Professions Code Section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The committee was charged with formulating uniform and specific standards in several areas for dealing with substance-abusing licensees.

Ms. Sodergren reported that in April 2011, the uniform standards required in B&PC section 315 were finalized. Over the course of the next year, the board initiated discussion about a rulemaking to update the disciplinary guidelines and incorporate the SB 1441 uniform standards as the board deemed appropriate considering comments from counsel and staff.

Ms. Sodergren explained that in addition to the standards themselves, the board also received opinions on what was required to implement the uniform standards. The board was provided a copy of a legal opinion from the Legislative Counsel Bureau, an executive summary issued by the Office Of the Attorney General as well as an implementation memo from Doreatha Johnson, Deputy Director of Legal Affairs, DCA.

Ms. Sodergren stated that the opinions provided did not provide consistent guidance and as such the board requested a formal legal opinion from the Office of the Attorney General in January 2013. The board received a response to this request on April 8, 2015.

Ms. Freedman noted the specific areas the board sought opinion on and the general conclusion of the Attorney General opinion.

Ms. Freedman stated that a significant question was if the board had discretion in the application of the Uniform Standards. She explained that the opinion states that the board must use the Uniform Standards, but may still exercise its discretion if the board feels there is reasonable need to modify the standards for a particular licensee. Ms. Freedman noted that this deviated from the department's original interpretation of SB 1441.

Ms. Freedman explained that the executive officer and legal counsel would be reviewing the April 8 response from the Attorney General and providing the board with new recommendations. Ms. Herold added that this would be discussed again at the June board meeting.

Dr. Gray, from Kaiser, asked the board to consider how this legal opinion could potentially conflict with federal law.

XVII. Licensing Committee

Chairperson Veale provided a report of the April 7, 2015 committee meeting.

a. Status of Implementation of Recently Enacted Legislation Impacting Licensing Programs for the Board

1. Implementation of Assembly Bill 2605 (Bonilla, Chapter 507, Statutes of 2014) Regarding Licensing of Third-Party Logistics Providers.

Chairperson Veale explained that AB 2605 was board sponsored to ensure the appropriate and continued regulation over third-party logistics providers. Specifically, the measure creates three new licensing categories for the board, and establishes the requirements for application, licensure and renewal. The specific new licensing classifications include:

- Third-Party Logistics Providers
- Nonresident Third-Party Logistics Providers
- Designated Representative-3PL

Chairperson Veale stated that board staff posted the approved applications in early February on the board's website and sent out a subscriber alert advising that the applications were available. In addition, the most recent issue of the *Script* includes an article on the subject. Chairperson Veale noted that staff has recently developed a guidance document designed to highlight the steps licensees and applicants must take to secure compliance with the new law.

Chairperson Veale concluded that the first licenses were issued in February, but the staff had not received the volume of applications expected based upon the inquiries received.

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

2. SB 1159 (Lara) Professions and Vocations: License Applicants: Individual Tax Identification Number

Chairperson Veale explained that this legislation requires the board on or before January 1, 2016, to accept either a social security number or an individual tax identification number as a condition of licensure. Prior to this legislation, the board could only collect a social security number.

Chairperson Veale reported that board staff has undertaken revisions of several of the application forms and instructions.

Chairperson Veale explained that as the pharmacy technician application is incorporated by reference in regulation, implementation of this update needs to occur via regulation. The formal rulemaking process was initiated on February 20, 2015 and runs through April 6, 2015.

Chairperson Veale stated that absent any negative comments, the rulemaking will be brought back to the board for final adoption. Ms. Sodergren reported that to date the board had not received any comments.

3. SB 1226 Veterans: Professional Licensing

Chairperson Veale explained that this measure requires the board, on or after July 1, 2016, to expedite the initial licensure process for an applicant who supplies satisfactory evidence to

the board that the applicant has served as an active duty member of the Armed Forces and was honorably discharged. Implementation of this provision will require updating application and instruction forms.

Chairperson Veale stated that this legislation takes effect on July 1, 2016, so implementation efforts are not yet underway.

Chairperson Veale added that DCA has advised all boards and bureaus within the department that no modifications will be made to legacy computer systems. As such any implementation efforts necessary will require manual workarounds by the board to implement.

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

4. **SB 1466 (Omnibus) Business and Professions**

Chairperson Veale explained that SB 1466 contained two provisions that impact board licensing programs. The first amends the definition of a correctional facility. Implementation of this provision will require updating application and instruction forms, as well as securing changes to the existing licensing and application system.

Chairperson Veale stated that SB 1466 also changed the requirements for an applicant for a designated representative license to require that the individual be at least 18 years of age.

The board discussed the need to evaluate larger issues relating to operations of licensed correction facilities and possible regulations in this area to address the unique operational needs.

Dr. Gray, from Kaiser, noted that there are significant differences in the operational needs in the many different types of correctional facilities in California.

b. Department of Education's Acceptance of Additional Tests for Fulfillment of General Educational Development Certificate Equivalency

Chairperson Veale explained that Business and Professions Code Section 4202 establishes the requirements for licensure as a pharmacy technician, including the provision that an application be either a high school graduate or possess a general education development (GED) certificate equivalent.

Chairperson Veale reported that board staff was advised that the Department of Education has recently approved two additional exams that will satisfy our requirements. Below is a list of the three exams:

- GED – General Education Development Test
- HiSET – High School Equivalency Test
- TASC – Test Assessing Secondary Completion

Chairperson Veale concluded that board staff is in the process of updating the instruction sheets to incorporate reference to these additional examinations.

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

c. Status of Board Sponsored Legislation to Change the Documentation Requirements for Pharmacy Practice Experience, (SB 590, Stone)

Chairperson Veale stated that during its October 2014 meeting, the board voted to pursue a

legislative change to streamline the documentation required for pharmacist practice experience for students who graduate after January 1, 2016, from an ACPE school of pharmacy or a school of pharmacy recognized by the board.

Chairperson Veale reported that Senator Jeff Stone is authoring this bill for the board. The provisions are contained in SB 590, which was introduced on February 26, 2015.

Chairperson Veale noted that board staff received concerns from California Pharmacy Council (a group representing the California schools of pharmacy, associations and the board's executive officer) regarding some of the language contained in the bill. Chairperson Veale stated that based on discussions, board staff requested that clarifying language be amended into the bill to address the comments of the California Pharmacy Council.

Ms. Sodergen reported that Senator Stone accepted the amendments and noted that the proposed amendments are not yet in print and would be included as part of the floor action.

d. NAPLEX Exam Content Outline

Chairperson Veale explained that NABP recently completed its process to ensure its exam includes the most current standards for safe and effective pharmacy practice. As a result, the NAPB has released its new Competency Statements, which will go into effect on November 1, 2015.

Chairperson Veale explained that this revised competency statement will be evaluated by the board's competency committee as part of its work to evaluate the board's current content outline for the CPJE.

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

e. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chairperson Veale explained that effective February 26, 2015, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

At the request of Dr. Gutierrez, Chairperson Veale briefly explained the quality assurance process.

Ms. Herold noted that the board knows that some people try to cheat on the exam or steal exam questions to give to future test-takers; the quality assurance review is part of the board's efforts to ensure that the exam remains psychometrically sound.

Chairperson Veale noted that the board expects to release the scores in May 2015; however, the board will release exam scores more quickly if the review is completed sooner.

Examination Development

Chairperson Veale reported that the Competency Committee workgroups are meeting several times this year to continue examination development activities. In addition, the committee has completed its review of the revised NAPLEX content outline as a precursor to updating the CPJE content outline. Chairperson Veale stated that it is anticipated that a recommended revised content outline will be ready for board review and consideration during its October 2015 Board Meeting.

Examination Statistics

Chairperson Veale reported that the semi-annual CPJE statistical report for October 1, 2014 through March 31, 2015 reflects that the overall passage rate for the CPJE was 70.3%.

Chairperson Veale stated that the passage rate for graduates from the California Schools of Pharmacy was 66.7%. The overall passage rate for the NAPLEX was 94.5%.

Mr. Law noted that the passage rate for graduates from the California Schools of Pharmacy is lower than out-of-state graduates. Ms. Herold stated that she is working with the exam vendor to ensure that the results are correct.

The board discussed the high-level process by which the Competency Committee develops the exam.

Mr. Brooks arrived at 9: 55 a.m.

Robert Stein, from KGI School of Pharmacy, stated that it would be helpful for the report to show if someone took the exam before. Chairperson Veale responded that this information would be provided the next time the exam statistics are reported.

Dr. Gray stated that he teaches pharmacy law at the University of California, San Diego and he explained that many of his students innocently discuss the exam on social media after they take it. He noted that he warns his students not to discuss the exam on social media and recommended that the board educate candidates on the seriousness of exam. Ms. Herold responded that she would be willing to speak to students on how seriously the board takes protecting the security of the exam.

President Weisser noted that there are significantly more schools of pharmacy and asked if the admission standards have become less stringent.

Dr. Gray responded that Kaiser has been working with pharmacy schools to discuss recruitment standards. Dr. Gray stated that he has been very impressed with the quality of the applicants to the new schools of pharmacy. He added that the increase in the number of the schools has created competition among the schools and has encouraged the schools to specialize their programs.

Mr. Stein, stated his he is very impressed with the quality of applicants that KGI receives.

Dr. Gray noted that some organizations have stopped hiring graduates from out-of-state schools of pharmacy because they do not graduate quality pharmacists. He added that he has not seen this problem in California.

Dr. Gutierrez asked if out-of-state schools are expanding their curriculum in response to SB 493. Dr. Gray responded that he has not seen that out-of-state schools are changing their curriculum in response to SB 493.

Dr. McAllister, representing ACPE, stated that the ACPE Standards for 2016 will become effective next year and he noted that there are significant changes to the previous standards.

f. Statistics Relating to Pharmacy Technician Application Denials

Chairperson Veale reported that during the July 2014 Board Meeting, board members requested

further discussion on the basis for denials of pharmacy technician applications. She noted that this issue was referred to the Licensing Committee and was discussed in detail at the last meeting.

Chairperson Veale explained that in 2014, the board denied 45 pharmacy technician applications. Of those applicants, 73% qualified by completing a technician training program, 18% qualified through certification by the PTCB and 9% earned an associated degree in pharmacy technology. The primary basis for denials include convictions for:

- Theft/Forgery, Identify Theft, Fraud
- Multiple DUIs and/or combinations with other violations
- Vandalism, Disorderly Conduct, Obstruction
- Drug Related (possession, under the influence, selling)

Chairperson Veale reported that the committee discussed this item quite significantly including the application requirements, renewal requirements and the scope of duties of a pharmacy technician. Based upon the discussion, the committee requested that this item come back to the committee for a more comprehensive review of the pharmacy technician application requirements as well as renewal requirements.

The board expressed their desire to raise the bar to qualify for licensure as a pharmacy technician.

The board also expressed concern with the schools accepting students with criminal backgrounds, who will likely not become licensed.

Ms. Herold stated that if the board wants to take a firm position on certain types of automatic disqualifying convictions, then the board will have to promulgate a regulation.

Dr. Gutierrez noted that the Licensing Committee should consider the possibility of creating different types of pharmacy technician licensure (i.e., hospital, compounding, community, etc.). Dr. Gray stated that the American Society of Health-System Pharmacists recommends licensing three levels of pharmacy technicians based on the setting they will be working in.

Mr. Murphy explained that in law enforcement, they created a personal history statement that every applicant must complete prior to entering into the academy. The applicant must disclose criminal convictions on their personal history statement. He added that they have automatic disqualifications that prevent applicants from entering into the academy with no chance of getting hired upon completion.

Mr. Brooks asked if there was a way that the board could make potential students aware of items that may disqualify them from licensure prior to registering for classes. Ms. Herold offered to reach out to the Bureau for Private Postsecondary Education who regulates these training schools.

Mr. Room noted that there is a larger issue with the admission standards of private vocational schools.

The board stated that they would like to find a way to provide notice of potential disqualifying convictions to applicants before they enroll in a training program. Mr. Room stated that this may require legislation and agreed with Ms. Herold's recommendation to work with the Bureau for Private Postsecondary Education. Ms. Herold and Chairperson Veale stated that the Licensing

Committee would continue to work on this issue.

Dr. Gray explained that programs are hiring technicians to go into homes of patients and go through the medicine cabinets to see what the patients are really taking. He said this is concerning if the technician has a criminal background.

The board recessed for a break at 10:54 a.m. and resumed at 11:17 a.m.

g. Common Deficiencies for Pharmacy Technician Applications

Chairperson Veale stated that the board has processed 4,449 pharmacy technician applicants that have been received since July 1, 2014. Of those processed, 2,392 (54 percent) were deficient upon initial review.

Chairperson Veale explained that over the years the board has tried various approaches to reduce the deficiency rate, including updating the application form and instructions to provide more specificity. She noted that regrettably, even with these efforts, the deficiency rate is still very high.

Chairperson Veale reported that the most common deficiencies include the following:

- Application not completed in its entirety, including missing signatures and dates, former names, etc.
- Training program affidavit (used to confirm completion of the training program) being completed before the applicant completes the training program or not being completed in its entirety.
- Livescan submission, high school diploma and self-query report provided under different names. (Including the AKA on the application would resolve many of these.)

Chairperson Veale explained that board staff will be developing a fact sheet that will be included as part of the application materials to assist with educating applicants.

h. Common Deficiencies for Pharmacy Applications

Chairperson Veale reported that earlier in the year the processing times for pharmacy applications was beyond the desired time of less than 60 days. She noted that as of April 17, 2015, the pharmacy applications are currently being processed in under 60 calendar days from receipt.

Chairperson Veale explained that while staff continues to work to reduce this processing time, they have also identified that a large percentage of the applications the board receives are deficient upon initial submission, which results in further delays in issuing the license.

Chairperson Veale read the list of common deficiencies:

1. A copy of the approved wholesale credit application is not provided. Many applicants provide a copy of the approval letter, which is not the same thing.
2. The lease is missing information (term of the lease, etc.)
3. A fictitious name statement is not provided when the pharmacy is using a "doing business as."
4. Forms are not complete in their entirety.
5. There are issues with determining the ownership structure of the pharmacy.

Chairperson Veale reported that the committee was advised on efforts being undertaken by board staff to reduce processing times, as well as provide better education to applicants about the application process and requirements, including creation of a video.

Chairperson Veale noted that Ms. Sodergren provided a presentation on the application process at the California Pharmacist Association's Exchange.

Mr. Lippe stated that there are companies that are paid to assist pharmacies with the application process. Ms. Herold responded that the board is aware of these companies and noted that applicants who use these companies are not processed any faster than those who complete the applications themselves.

Ms. Herold noted that the board often finds very complicated ownership structures. She added that the *Sacramento Bee* printed an article late last year that criticized the Department of Public Health for not gathering information on the ownership of skilled nursing facilities.

Mr. Lippe asked if there is a warning on the application that states that incomplete applications will cause a delay in licensure. Dr. Gutierrez responded that at the top of the application it states: "Failure to submit the necessary items will delay the processing of your application."

i. Licensing Statistics

Chairperson Veale reviewed the licensing statistics as provided in the meeting materials.

Chairperson Veale reported that the committee did not take action on this item, but noted some of the workload challenges including spikes in workload that occurs when a change of ownership occurs in a large chain.

Mr. Law asked the board if there was a trend as to what type of pharmacy the board is licensing (chain, community, institution, etc.). Ms. Herold responded that about 60 percent of the pharmacies in California are considered chains. Ms. Herold added that staff would look at what data could be provided to the board on site licensing trends.

j. Future Committee Meeting Dates for 2015

Chairperson Veale reported that the next committee meeting would be June 19, 2015.

The board recessed for lunch at 11:50 a.m. and returned at 12:45 p.m.

Note: Mr. Sanchez left the meeting at 11:50 a.m.

XVIII. SB 493 Implementation Committee

President Weisser provided a report of the February 25 and April 13, 2015 meetings as follows.

a. Regulations Detailing Licensure Requirements for Advanced Practice Pharmacists

President Weisser reported that at the January 2015 board meeting, the board approved and moved to initiate a regulation rulemaking on proposed text that specifies the ways and supporting documentation needed to qualify for registration as an advanced practice pharmacist. Additionally a fee of \$300 was selected as the application and renewal fee for this license.

President Weisser explained that at the February and April 2015 committee meetings, the committee made several modifications to the text.

President Weisser stated the committee is recommending that the board release the finalized text as it appears below, and then direct staff to initiate a rulemaking and release the text for the 45-day comment period.

Article 3.5

Advanced Practice Pharmacist

1730 Acceptable Certification Programs

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

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

- (a) Documentation of possession of a **current** certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:
- (1) A **notarized** copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or
 - (2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.
- (b) Documentation of completion of a postgraduate residency earned **in the United States** through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:
- (1) A **notarized** copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
 - (2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.
- (c) ~~Documentation of~~ Experience earned under a collaborative practice agreement or protocol **must have been earned within 10 years of the time of application for APP licensure. Additionally, the one year of experience must be comprised of** ~~for at least one year with~~ no fewer than 1,500 hours **earned over a period of no longer than four years. as specified in** ~~California Business and Professions Code section 4210(a)(2)(C) shall be via~~ **The documentation of this experience that shall be provided to the board shall include both:**
- (1) A copy of an agreement or protocol under which the applicant pharmacist has provided clinical services to patients, and
 - (2) ~~(1) A letter~~ **An attestation from the applicant pharmacist attesting under penalty of perjury that he or she has earned this experience, and:.**
 - (2) An **attestation or letter** from the supervising practitioner, **program director or health facility administrator** attesting under penalty of perjury that the applicant pharmacist has completed at least one year of ~~the~~ experience providing clinical services to patients.

Liz McCaman reviewed the changes made by the committee to the language at the last meeting.

Ms. Veale asked if there was any issue with the phrase "certification award." Mr. Room responded that the language as provided was appropriate.

The board discussed whether 1730.1 (b) should be amended to remove the word "institution." Ms. Herold clarified that the statute uses the term "postgraduate institution" and thus it should remain in the language. Dr. Gray noted that the word institution was used deliberately to allow

flexibility in the types of settings the postgraduate program could occur in.

The board discussed whether the experience in 1730.1 (b) and (c) could be gained simultaneously. Ms. Herold stated that the statute requires that the experience be earned separately.

Dr. Gutierrez stated that the phrase "Experience earned under a collaborative practice agreement or protocol..." in 1730.1 (c) is too vague. She expressed concern that board staff would be unable to determine what an appropriate protocol was for an APP to gain experience; she recommending removing "or protocol" from the language.

Ms. Freedman explained that the statute allows for experience under a collaborative practice agreement *or* protocol, so it could not be removed from the language.

The board discussed whether an APP pharmacist would be considered a prescriber. Ms. Herold and Mr. Room did not want to equate APP pharmacists to prescribers without further research.

The board elected to add a cross reference to 4052.1 (4) and 4052.2 (a)(4) to provide clarity on the type of protocol required. Ms. Freedman and Ms. Herold recommended adding a subdivision to 1730.1 (c) to clarify that under the protocol the pharmacist must initiate or adjust the drug regimen of a patient pursuant to an order or authorization by the patients prescriber or an advanced practice pharmacist authorized to prescribe. President Weisser asked Ms. Freedman and Ms. McCaman to further refine the new subdivision of 1730.1 (c) to define the experience gained under protocol.

Motion: Initiate the rulemaking of 1730.1 as listed below with the additional subdivision under 1730.1(c) being drafted by staff to clarify the experience gained under protocol.

1730.1 Documentation Requirements for Advanced Practice Pharmacist Licensure

- (a) Documentation of possession of a current certification as specified in California Business and Professions Code section 4210(a)(2)(A) shall be via:
 - (1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or
 - (2) A letter from the certification program attesting the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

- (b) Documentation of completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in California Business and Professions Code section 4210(a)(2)(B) shall be via either:
 - (1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or
 - (2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and areas of specialty.

- (c) Experience earned under a collaborative practice agreement

or protocol must have been earned within 10 years of the time of application for APP licensure. Additionally, the one year of experience must be comprised of no fewer than 1,500 hours earned over a period of no longer than four years. The documentation of this experience that shall be provided to the board shall include both:

- (1) An attestation from the applicant pharmacist attesting under penalty of perjury that he or she has earned this experience, and:
- (2) An attestation or letter from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant pharmacist has completed at least one year of experience providing clinical services to patients.

M/S: Gutierrez/Lippe

Support: 9 Oppose: 0 Abstain: 0

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

President Weisser reviewed the proposed amendments to section 1749 (board fees) as provided below.

Section 1749 (board fees)

(f)(1) The fee for the issuance of an original pharmacist license is one hundred fifty dollars (\$150).

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

(g)(1) The fee for the biennial renewal of a pharmacist's license is one hundred fifty dollars (\$150). The penalty fee for failure to renew is seventy-five dollars (\$75).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

Ms. Herold noted that the fees in the language were not current. Staff was instructed to update the language to reflect the current pharmacist renewal fees.

Motion: Initiate the rulemaking on 1749 and instruct staff to update the language to reflect the current pharmacist renewal fees. **Note:** the language below includes the correct fees.

Section 1749 (board fees)

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

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

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

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist’s license as specified in paragraph 1.

M/S: Gutierrez/Lippe

Support: 9

Oppose: 0

Abstain: 0

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

b. Regulations to Implement the Protocol For Pharmacists Who Furnish Naloxone

President Weisser reported that on April 10, 2015, the board’s naloxone protocol became effective under emergency provisions that will last 180 days.

President Weisser explained that the board now has slightly fewer than 180 days to notice and promulgate a naloxone protocol regulation to replace the emergency adoption version of the

protocol. The Medical Board will also need to approve the protocol. He added that this is planned for review by the Medical Board on May 8, 2015, in Los Angeles, at a hotel near LAX.

President Weisser explained that during the April SB 493 Implementation Committee meeting, the committee discussed several modifications to the emergency protocol. President Weisser clarified that these changes would not affect the emergency rulemaking protocol that has already been filed.

President Weisser stated that board staff amended the protocol based on discussion at the April committee meeting. The revised language was distributed at the board meeting and is provided below. The language with strikeout and underscores is provided immediately following these minutes.

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

- (1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.
- (2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride. Before providing naloxone hydrochloride, the pharmacist shall:

- (1) Screen the potential recipient by asking the following questions:
 - (A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids? (If the recipient answers yes, the pharmacist may skip screening question ii.);
 - (B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. If the recipient answers yes, the pharmacist may continue.
 - (C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to Naloxone. If the recipient answers yes, the pharmacist may not provide the Naloxone. If the recipient responds no, the pharmacist may continue.

These screening questions shall be made available on the Board of Pharmacy's website in alternate languages for recipients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient to how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. The pharmacists may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector, or other FDA approved products. The pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) Labeling: A pharmacist shall label the naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Authority and Reference: Section 4052.01, Business and Professions Code.

Ms. McCaman reviewed the changed that had been made to the protocol based on the committee discussion.

Ms. Herold noted that the committee elected to remove the suggested labeling from the protocol and place it on the board's web site for pharmacists to refer to if needed.

Mr. Schaad left the room at 11:40 a.m.

Motion: Approve the Naloxone protocol as provided at the board meeting (see above). If the protocol is approved by the Medical Board, initiate a rulemaking to formally adopt the regulation.

M/S: Lippe/Veale

Support: 8 Oppose: 0 Abstain: 0

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

Mr. Schaad returned to the meeting at 11:44 p.m.

c. Review and Discussion About the Factsheet on Naloxone

President Weisser reported that the committee also reviewed a factsheet on naloxone.

President Weisser stated that the committee expressed concern that a pharmacist may not dispense naloxone if he or she did not have a translated fact sheet available or screening questionnaire available. President Weisser explained that to solve this issue, Ms. McCaman added a statement to the naloxone protocol that clarified that the board would place translated factsheets on its website for pharmacists to provide to patients.

d. Discussion and Identification of Materials Where Board Guidance Is Envisioned:

1. Development of Proposed Requirements For Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices

President Weisser explained that under Business and Professions Code section 4052.8, immunizations may be provided by pharmacists who possess the required training to provide immunizations. Specifically, to initiate immunizations, a pharmacist must:

- complete an immunization training program endorsed by the CDC,
- be certified in basic life support,
- comply with all state and federal recordkeeping requirements,
- provide information to the patient’s primary care physician and into the appropriate immunization registry designated by the immunization branch of the CDPH.

President Weisser reported that during the April meeting, the committee made various recommendations to a proposed regulation to specify parameters for pharmacists who provide immunizations.

President Weisser stated that board staff amended the regulation based on the discussion at the April committee meeting. The revised language is provided below. The language with strikeout and underscores is provided immediately following these minutes.

§1746.X Pharmacists Initiating and Administering Vaccines

(a) A pharmacist initiating and/or administering vaccines pursuant to Section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

- (1) Completion of an approved immunization training program;
- (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient’s primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 3 months of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist

shall advise the patient to consult an appropriate health care provider of the patient's choice.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 3 months of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours.

A pharmacist shall provide the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Authority and Reference: Sections 4052(a)(11), 4052.8, Business and Professions Code.

Ms. McCaman reviewed the changes she made to the regulation based on the committee's discussion. She noted that at the next SB 493 committee meeting the committee will review the regulation in detail.

Ms. Herold asked stakeholders to review the language and provide comments at the next committee meeting.

2. Development of Proposed Requirements For Pharmacists For Prescription Medications not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

President Weisser reported that at both the February and April meetings, the committee discussed the parameters for travel medications.

President Weisser stated that at the April committee meeting, the committee reviewed a draft regulation establishing requirements.

President Weisser stated that board staff amended the regulation based on the discussion at the April committee meeting. The revised language is provided below. The language with strikeout and underscores is provided immediately following these minutes.

§1746.X Pharmacists Furnishing Travel Medications

(a) For purposes of section 4052(a)(10)(A)(3), "not requiring a diagnosis" means either
(1) a self-diagnosable and self-treatable condition under the federal Centers for Disease Control and Prevention's (CDC) Health Information for International Travel (commonly called the Yellow Book); or
(2) a prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to Section 4052(a)(10) of the Business and Professions Code shall

follow the requirements specified in subdivisions (c) through (f) of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of:

- (1) Completion of an approved travel medicine training program, which must consist of at least 20 hours and cover the International Society of Travel Medicine's body of knowledge;
- (2) Completion of the CDC Yellow Fever Vaccine Course;
- (3) Basic life support certification.

This documentation shall be kept on site and available for inspection.

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

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

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 3 months of the date of dispense, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code, and title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel plan. An example of an appropriate and comprehensive progress note is available on the Board of Pharmacy's website.

Authority and Reference: Sections 4052(a)(10)(A)(3), 4052(a)(10)(B), Business and Professions Code.

Ms. McCaman reviewed the changes she made to the regulation based on the committee's discussion. She noted that at the next SB 493 committee meeting the committee will review the regulation in detail.

Ms. Herold again asked stakeholders to review the language and provide comments at the next committee meeting.

3. Requirements For Pharmacists For Ordering and Interpreting Tests to Monitor and Manage Drug Therapies

President Weisser reported that at the February committee meeting, the committee discussed and determined at this time they did not wish to develop regulation requirements or guidance at this time regarding ordering and interpreting tests.

The board recessed for a break at 2:00 p.m. and resumed at 2:24 p.m.

Note: Gregory Murphy left the meeting at 2:00 p.m.

XIX. Legislation and Regulation Committee

Chairperson Lippe provided a report of the April 21, 2015 Legislation and Regulation Committee meeting.

Part 1: Legislation Report

a. Board-Sponsored Legislation

1. *AB 1073 (Ting) Prescription Drug Labels*

Chairperson Lippe explained that this bill would require dispensers to use a standardized direction for use on the label of a prescription container when applicable and would require a dispenser, upon request, to select the appropriate translated directions for use to include on the prescription label or supplemental information. This bill allows for a dispenser to provide his or her own translated directions. He added that the bill specifies that a dispenser using board provided translated directions will not be liable for civil damages for any error in the “cutting and pasting” of the translated directions.

Chairperson Lippe reported that during the committee meeting yesterday members learned that the author will be accepting some clarifying amendments.

Chairperson Lippe reported that this bill was heard in Assembly Business and Professions Committee yesterday where Ms. Herold testified. Chairperson Lippe reported that this bill passed out of committee.

Ms. Herold noted that the board had to remove the immunity protection for pharmacies that are currently providing their own translations in order to get the bill in print.

William Cover, from Walgreens, reported that Walgreens has put significant time and effort into providing patients with translation services. He expressed concern with providing the translated directions for use, as well as the English directions for use on the label itself.

Ms. Veale explained that there are two options: 1) provide the English directions for use on the label and the translated directions for use on a supplemental document; or 2) provide both the translated and English directions for use on the label.

Dr. Cover explained that Walgreens currently provides the translated directions for use on the label and the English directions for use on a supplemental document.

Dr. Gutierrez noted that her health system provides both the English and translated directions for use on the label.

The board asked how many different written translations Walgreens can provide. Dr. Cover responded that Walgreens can provide translated directions on the label in 17 languages.

2. *SB 590 (Stone) Intern Licenses*

Chairperson Lippe explained that during the October 2014 Meeting, the board voted to amend Business and Professions Code section 4209 to streamline the application process for graduates from an ACPE-accredited school or school of pharmacy recognized by the board for purposes of confirming completion of the required pharmacy practice experience requirements.

Chairperson Lippe reported that board staff received comments from a group representing the deans of the California Schools of Pharmacy. In response to those comments, amendments were drafted to clarify the intent of legislation.

Chairperson Veale stated that during the committee meeting members were advised that this bill passed out of the Senate Appropriations committee as a consent item. He added that board staff anticipates that the language will be amended on the Senate Floor.

3. *SB 619 (Morrell) Outsourcing Facilities: Licensure*

Chairperson Lippe explained that SB 619 would establish the regulatory framework for licensure of outsourcing facilities that will compound non-patient specific medications for administration to California patients.

Ms. Herold reported that the bill will be heard in the Senate Business and Professions Committee on April 27, 2015.

Dr. Gray noted that the proposed legislation does not allow a facility to be both an outsourcing facility and a pharmacy. He recommended that the board reconsider this position.

Ms. Herold noted that the board may need to make this a two-year bill if the FDA releases guidance that contradicts the boards proposed licensure requirements.

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

1. *AB 45 (Mullin) Household Hazardous Waste*

Chairperson Lippe explained that this bill would require each jurisdiction that provides residential collection and disposal of solid waste to increase the collection and diversion of household hazardous waste by a yet to be specified percentage.

Chairperson Lippe reported that prior versions of this bill allowed for curbside pickup of household hazardous waste (including prescription drugs). Although such an approach is convenient for residents, such an allowance is contrary to the board's position on the issue and could significantly undermine the efforts of not only our board, but several other entities working diligently to reduce prescription drug abuse.

Chairperson Lippe stated that during the committee meeting it was noted that the bill in its current form is vague and does not provide details explaining what safety measures would be in place to ensure the security of the home-generated pharmaceutical waste as part of the comprehensive program, given the various components allowed in the measure.

Brian Warren with the California Pharmacist Association (CPHA), explained that while pharmacists, want to provide take-back for their patients, bringing the drugs back into the pharmacy is not ideal. He stated that CPHA has been working with the author and the sponsor

of this bill and they have discussed amending the language to utilize a mail-back program. Mr. Warren asked the board to take a support if amended position.

Note: Mr. Brooks left the meeting at 2:56 p.m.

Ms. Herold said that if the bill stated that the collection would occur via a mail-back program she would recommend the board support the bill; however, the bill does not currently reflect this.

Committee Recommendation: Oppose unless amended and suggest that home-generated pharmaceutical waste be disposed of through authorized mail-back programs.

Support: 7 Oppose: 0 Abstain: 0

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

2. *AB 333 (Melendez) Healing Arts, Continuing Education*

Chairperson Lippe explained that AB 333 would allow specified healing arts licensees to apply one unit of continuing education credit for attending a course that results in the licensee becoming a certified instructor of cardiopulmonary resuscitation (CPR) or the proper use of an automated external defibrillator (AED); and it would allow to up two units of continuing education credit for conducting CPR or AED training sessions as specified.

Chairperson Lippe stated that the committee did not take a position on the bill.

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

3. *AB 463 (Chiu) Pharmaceutical Cost Transparency Act of 2015*

Chairperson Lippe reported that AB 463 would establish an annual reporting requirement for each manufacturer of a prescription drug, made available in California, that has wholesale acquisition cost of \$10,000 or more annually or per course of treatment.

Chairperson Lippe explained that during the committee meeting members discussed this measure, but decided not to take a position.

Ms. Sodergren noted that this measure was heard in Assembly Health Committee. She noted

that staff listened to the committee hearing and reported that the measure appears very controversial. Ms. Sodergren added that the author requested that the Health Committee hold the bill for one week to allow him time to work with those who expressed concerns.

4. *AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies: Medication Labels*

Chairperson Lippe explained that AB 486 would provide an alternative method to maintain certain medication information that shall be readable at the patient’s bedside, either via a barcode scan or human-readable, for unit dose medications prepared in a centralized hospital packaging facility.

Chairperson Lippe reported that the committee discussed this measure and noted the board’s prior history on similar proposals, including the board’s support of the initial legislation that allowed for the licensure of CHPs as a way to reduce medication errors through the use of barcode technology (these provisions were included in SB 377, Solorio, Statutes of 2012). Chairperson Lippe explained that after the passage of SB 377 the board learned that the technology was not yet available to facilitate full implementation of all of the law’s requirements. Thus the board has approved waivers of some of the provisions of the current law to allow for licensure of these CHPs.

Chairperson Lippe stated that AB 486 will allow for CHPs to continue providing unit dose medications which will reduce medication errors by ensuring that the right patient gets the right medication.

Chairperson Lippe reported that the committee is recommending a support position given the board’s prior support of similar measures.

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

Committee Recommendation: Support AB 486.

Support: 7		Oppose: 0		Abstain: 0	
Name	Support	Oppose	Abstain	Not Present	
Brooks				x	
Butler	X				
Castellblanch				x	
Gutierrez	X				
Hackworth				x	
Law	X				
Lippe	X				
Murphy				x	
Sanchez				x	
Schaad	x				
Veale	X				
Weisser	X				
Wong				x	

5. *AB 611 (Dahle) Controlled Substances: Prescriptions: Reporting*

Chairperson Lippe explained that AB 611 would authorize an individual designated to investigate a holder of a professional license to apply to the Department of Justice to obtain approval to access information contained in the CURES PDMP regarding the controlled

substance history of an applicant or licensee for the purpose of investigating the alleged substance abuse of a licensee.

Chairperson Lippe reported that during the committee meeting members discussed that as the law is currently structured, H&SC 11165 establishes the CURES program and grants the board the authority to use the program for disciplinary, civil or criminal purposes, as specified. He noted that board staff questions the need for this legislation, given the authority currently established in the Health & Safety Code.

Chairperson Lippe concluded that the committee did not take a position on this measure, as staff was advised yesterday afternoon this this measure is now a two-year bill.

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

6. *AB 623 (Wood) Abuse-Deterrent Opioid Analgesic Drug Products*

Chairperson Lippe reported that AB 623 would require a pharmacist to inform a patient receiving an opioid analgesic drug product on the proper storage and disposal of the drug. Further, this measure would prohibit a health care service plan from requiring the use of opioid analgesic drug products without the abuse-deterrent properties.

Chairperson Lippe explained that the committee discussed this measure quite significantly at their meeting. During the committee meeting, it was noted that the wording of the measure is awkward. Chairperson Lippe noted that during the committee meeting they heard comments indicating that similar provisions are being introduced in several jurisdictions.

Chairperson Lippe stated that the committee questioned if the measure was sponsored by a manufacturer that would force a brand name to remain on a drug formulary. Staff subsequently learned that this measure is sponsored by Power of Pain Foundation.

Chairperson Lippe reported that the committee recommended an oppose position.

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

Committee Recommendation: Oppose AB 623.

Support: 7	Oppose: 0	Abstain: 0		
Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	X			
Castellblanch				x
Gutierrez	X			
Hackworth				x
Law	X			
Lippe	X			
Murphy				x
Sanchez				x
Schaad	X			
Veale	X			
Weisser	X			
Wong				x

7. *AB 684 (Bonilla) Pharmacy*

Chairperson Lippe stated that this is currently a spot bill making changes to section 4200.3 of the Business and Professions Code. Thus, the committee took no action on this item.

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

8. *AB 750 (Low) Business and Professions: Licenses*

Chairperson Lippe reported that this measure would allow boards and bureaus within the DCA to establish, by regulation, a system for a retired category of licensure for persons who are not actively engaged in the practice or profession or vocation.

Chairperson Lippe stated that the committee noted during their discussion that the board has provisions to establish a retired pharmacist license; however, it does not have similar provisions for any additional license types.

Chairperson Lippe explained that if this measure is enacted as currently drafted, the board would have the option to determine if other categories of licensure under the board's jurisdiction should be provided the option of a retired license and if so, under what conditions.

Chairperson Lippe concluded that the committee did not make a recommendation on this bill.

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

9. *AB 788 (Chu) Prescriptions*

Chairperson Lippe reported that AB 788 would have provided provisions to require for the condition or purpose of a medication to be included on a prescription.

Chairperson Lippe stated that board staff was advised that the measure will not be moving forward. As such, neither a copy of the bill nor a bill analysis is provided.

Chairperson Lippe noted that although this bill is not moving, the committee briefly discussed prior legislative attempts to secure the condition or purpose on the prescription label. He added that as part of the public comment received, it was suggested that the board consider clarifying that a pharmacist could, as part of his or her professional judgment, include the condition or purpose.

10. *AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program*

Chairperson Lippe explained that AB 1069 would expand the provisions under which a county- established repository and distribution program could allow the transfer of drugs to other counties, not just to adjacent counties (as currently allowed). It would also allow for the advance repackaging of the donated medications. Further, this measure would define "tamper-evident packaging" for purposes of a county-established repository and distribution program and would require policies and procedures to address how to handle manufacturer recalls for medications without lot numbers.

Chairperson Lippe reported that the bill analysis identifies significant concerns. He added that it also appears that the provisions conflicts with federal law in several areas.

Chairperson Lippe stated that the committee took an oppose position on AB 1069.

Ellen Hou, from Assemblyman Gordon’s office (author of the bill), provided the statement below:

“AB 1069 makes several changes to a county established drug repository and distribution program. Assemblyman Gordon could not be here today and asked me to attend on his behalf. I understand that the Legislation and Regulation Committee met yesterday and is making a recommendation that the Board oppose AB 1069. I am here today to ask that the Board wait to take a position on the bill as Assemblyman Gordon is committed to working with you to try to address all of your concerns. In fact, the sponsors of the bill and I will be discussing these concerns with Board of Pharmacy staff tomorrow and hope to fine a workable solution to address the concerns. If however, we are not able to address all of your concerns we welcome you to take a position on the bill. I just ask that the author’s office is able to engage with the Board of Pharmacy first. Thank you for your consideration.”

Ms. Herold explained that if the board does not take a position at this meeting or at the June board meeting, they will not have the opportunity to provide any amendments.

Ms. Veale stated that the committee’s concerns were significant and recommended the board take an “oppose unless amended” position.

Mr. Room noted that one of the main purposes of the bill is to allow repackaging without placing lot numbers on the repackaged item. He explained that this is a significant departure from current law.

Dr. Gutierrez asked if the bill would allow the program to expand beyond the one county where it currently operates. Ms. Sodergren responded that current law allows for the transfer of drugs between adjacent counties, AB 1069 would expand this to allow transfer between any county.

Mr. Room stated that the bill also defines tamper evident packaging as pharmacy packaging, while federal law defines it as the manufacturer’s packaging.

Ms. Butler asked why the board would oppose a program that facilitates unused drugs being redistributed rather than destroyed. Mr. Room clarified that the board is not opposing such a program, as it is already in existence. The board is considering whether to allow the program to expand to redistribute medication that has been removed from blister packs and thus has no lot number.

Committee Recommendation: Oppose AB 1069.

Support: 0

Oppose: 7

Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler		X		
Castellblanch				x
Gutierrez		X		
Hackworth				x
Law		X		

Lippe		X		
Murphy				X
Sanchez				x
Schaad		X		
Veale		X		
Weisser		X		
Wong				x

The board asked staff to work with the author's office to see if there were any amendments which could be made to bring the bill into line with federal law.

Dr. Gutierrez asked how many counties currently participate in the program. Mr. Room responded that there is currently only one county participating in the program.

Motion: Oppose AB 1069 unless amended.

M/S: Veale/Law

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

11. *AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion*

Chairperson Lippe explained that AB 1351 would change the deferred entry of judgment program into a pretrial diversion program.

Chairperson Lippe reported that this measure was amended last week. He noted that this measure would significantly impede the board's ability to prove in disciplinary proceedings that a licensee or applicant is engaged in illicit drug activities. Chairperson Lippe added that this measure seems to run contrary to the board's consumer protection mandate and the profession the board regulates.

Chairperson Lippe stated that the committee recommended an oppose position.

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

Committee Recommendation: Oppose AB 1351.

Support: 7		Oppose: 0		Abstain: 0	
Name	Support	Oppose	Abstain	Not Present	
Brooks				x	
Butler	X				
Castellblanch				x	
Gutierrez	X				
Hackworth				x	
Law	X				
Lippe	X				
Murphy				x	
Sanchez				x	
Schaad	X				
Veale	X				
Weisser	X				
Wong				x	

12. *AB 1352 (Eggman) Deferred Entry of Judgment: Withdrawal of Plea*

Chairperson Lippe reported that AB 1352 would require a court to allow a defendant who was granted deferred entry of judgment to withdraw his or her plea and enter a plea of not guilty if the changes were dismissed upon successful completion of the program and the defendant shows that the plea may result in the denial or loss of the defendant’s employment, benefit, license or certificate.

Chairperson Lippe explained that similar to the previous measure, this measure would also significantly impede the board’s ability to prove in disciplinary proceedings that a licensee or applicant is engaged in illicit drug activities.

Chairperson Lippe stated that the committee recommended an oppose position.

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

Committee Recommendation: Oppose AB 1352.

Support: 7		Oppose: 0		Abstain: 0	
Name	Support	Oppose	Abstain	Not Present	
Brooks				x	
Butler	X				
Castellblanch				x	
Gutierrez	X				
Hackworth				x	
Law	X				
Lippe	X				
Murphy				x	
Sanchez				x	
Schaad	X				
Veale	X				
Weisser	X				

Wong				x
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13. *SB 396 (Hill) Health and Care Facilities, Outpatient Settings and Surgical Clinics*
 Chairperson Lippe explained that SB 396 would clarify that a surgical clinic is eligible for licensure by the State Department of Public Health regardless of physician or dentist ownership.

Chairperson Lippe stated that this measure is being brought to the board for information only as it will allow for a podiatrist-owned surgical center, which would then allow the board to issue a clinic license.

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

14. *SB 423 (Bates) Pharmaceutical Waste: Over-the-Counter Drugs and Nutritional Supplements*
 Chairperson Lippe stated that SB 423 would exclude from the definition of “pharmaceutical waste” for purposes of regulation under the Medical Waste Management Act, any over-the-counter human or veterinary drug or dietary supplement that is characterized and managed as a hazardous or solid waste.

This measure is being brought to the board for information only, and the committee did not take a position on the bill.

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

15. *SB 587 (Stone) Pharmacy Compounding*
 Chairperson Lippe reported that SB 587 would specify that a pharmacist may initiate or adjust the drug regimen of a patient undergoing treatment for hypertension or hyperlipidemia.

Chairperson Lippe explained that the committee discussed the proposal and expressed concern about the intent of the legislation versus the placement of the proposed amendment.

Chairperson Lippe stated that the committee recommended that the board remain neutral on this measure, but express concern to the author with the current placement of the proposed change.

Ms. Sodergren added that board staff would be reaching out to the author to determine the intent of the legislation.

Ms. Veale stated that the committee was concerned that placing the language in 4052.2 might actually limit the pharmacist’s scope of practice, which the committee did not think the author intended to do.

Ms. Sodergren asked if the board would like to suggest that the author move the bill to 4052. Dr. Gutierrez stated that an advanced practice pharmacist could already adjust drug regimens for any disease state. The board clarified that this bill would expand this to allow for all pharmacists to adjust the drug regimen of a patient undergoing treatment for hypertension or hyperlipidemia.

Mr. Warren, from CPHA, reported that Senator Stone is looking to expand the scope of practice of pharmacists.

Committee Recommendation: Take no position on SB 587.

Support: 7

Oppose: 0

Abstain: 0

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

16. *SB 671 (Hill) Biological Products*

Chairperson Lippe stated that SB 671 would authorize a pharmacist to select an alternative biological product when filling a prescription order for a prescribed biological product if the alternative biological product is interchangeable (as approved by the FDA) and the prescriber does not personally indicate “Do not substitute.”

Chairperson Lippe explained that the board opposed this type of legislation last year, as the list from the FDA (to which the bill referred) did not exist. He noted that the FDA now maintains a list of interchangeable biosimilars (there is one currently approved drug on it, and others in the pipeline).

Chairperson Lippe reported that the committee received many comments on this bill – some in opposition to, and others in support of the prescriber notification provision. He added that the committee heard from a member of the Arizona Board of Pharmacy who stated that their board did not take a position on a similar bill in their state.

Chairperson Lippe stated that the committee recommends that the board take an oppose unless amended position, and request an amendment that strikes the prescriber notification provisions in the bill.

Chairperson Lippe reminded the board that earlier in the meeting Mr. McAllister, from Express Scripts, asked the board to take a support position. Express Scripts believes that the physician’s ability to check Surescripts or to use an application program fulfills the pharmacist’s duty to report substitutions to the physician; even if the pharmacist does not confirm that the physician actually uses these programs.

The board expressed concern that not all physicians may use Surescripts or have the ability to download an application program. Ms. Herold noted that the bill states that if there is no electronic interoperability of systems between the pharmacy and the prescriber’s office then the pharmacist must find another way to communicate with the prescriber’s office.

Mr. Warren stated that CPHA has an oppose unless amended position. He added that they are asking the author to amend the language to clarify the pharmacist’s reporting obligation.

A representative from CVS Health reported that not all independent pharmacies and prescribers use Surescripts and stated that they also had an oppose unless amended position.

Dr. Gray stated that Kaiser is concerned that the requirement to notify the prescriber of any substitution will discourage pharmacists from even considering using interchangeable biosimilars.

Committee Recommendation: Oppose SB 671 unless amended.

Support: 7		Oppose: 0		Abstain: 0	
Name	Support	Oppose	Abstain	Not Present	
Brooks					x
Butler	X				
Castellblanch					x
Gutierrez	X				
Hackworth					x
Law	X				
Lippe	X				
Murphy					x
Sanchez					x
Schaad	X				
Veale	X				
Weisser	X				
Wong					x

c. Legislation Impacting Board Operations

1. *AB 85 (Wilk) Open Meetings*

Chairperson Lippe explained that according to the author, this measure is intended to clarify language within the Bagey-Keene Open Meeting Act by stating that when an advisory board, advisory commission, advisory committee, advisory subcommittee, or similar multimember advisory body is acting in an official capacity of a state body, the entity (regardless of the committee size) is subject to the Open Meeting Act.

Chairperson Lippe stated that as the analysis indicates, the provisions in this bill would significantly impact how the board uses an advisory committee to thoroughly vet an issue and report to the board. He noted that the Governor vetoed a similar bill last year.

Chairperson Lippe concluded that the committee is recommending an oppose position.

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

Committee Recommendation: Oppose AB 85.

Support: 7

Oppose: 0

Abstain: 0

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

2. *AB 1060 (Bonilla) Professions and Vocations: Licensure*

Chairperson Lippe stated that AB 1060 would require the board to advise a former licensee with certain information pertaining to rehabilitation, reinstatement, or reduction of penalty by first-class mail and by email if the board has an email address on file for the ex-licensee.

Chairperson Lippe explained that board staff has confirmed with the author's office that the intent is to require boards to send this notification to *any* email address *ever* on file with the board, which could require significant research on behalf of board staff.

Chairperson Lippe noted that current computer systems used by the board do not have a specified area to store such information. As such, modifications to computer systems may be necessary to comply with these provisions.

Chairperson Lippe stated that the committee is recommending an oppose position.

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

Committee Recommendation: Oppose AB 1060.

Support: 7

Oppose: 0

Abstain: 0

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

Wong				x
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Part 2: Regulation Report

a. For Board Action: Proposal to Amend Title 16 California Code of Regulations Section 1793.5 Pharmacy Technician Application

Chairperson Lippe reported that at the July 2014 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations Section 1793.5 to change the wording of the criminal conviction question on the Pharmacy Technician Application, which is incorporated by reference in the regulation.

Chairperson Lippe stated that the 45-day comment period ran from February 20, 2015 to April 6, 2015. No comments were received during the 45-day comment period.

Chairperson Lippe explained that board approval is necessary for minor amendments to the application to conform to statute.

Chairperson Lippe stated that the committee recommends that the board approve the incorporation of the proposed changes, as specified in the meeting materials, into the pending rulemaking; that the board initiate a 15-day comment period and, absent any negative comments, delegate to the executive officer the authority to make any nonsubstantive changes and adopt the regulation; and to file the adopted regulation with the Office of Administrative Law.

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

Committee Recommendation: Approve the incorporation of the proposed changes as specified in the board meeting materials into the pending rulemaking; initiate a 15-day comment period and, absent any negative comments, delegate to the executive officer the authority to make any nonsubstantive changes and adopt the regulation; and to file the adopted regulation with the Office of Administrative Law.

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

XX. Executive Officer’s Report

Ms. Herold provided the Executive Officer’s report as follows.

a. Medical Board Update

Ms. Herold reported that Kim Kirchmeyer, Executive Director of the Medical Board, was unable to attend the meeting in person and asked that the following statement be read.

The Medical Board of California held a Prescribing Task Force Meeting on April 13, 2015 to discuss best practices. The Task Force heard from Jason Smith on the "Lost Generation." The Task Force also heard an update from the California Department of Public Health on the Prescription Opioid Misuse and Overdose Prevention Workgroup, an update from the Division of Workers Compensation on the process and status of their new guidelines, and an update on the CURES system upgrade. The Task Force then took comments from all interested parties on ways to eliminate opioid misuse and abuse. Several suggestions were made, including using algorithms within databases to identify misuse, guidelines for emergency rooms and emergency rooms working together to share data, more education information on the Board's website for physicians, and other tracking systems for monitoring prescribing patterns. It was also recommended that all parties review the National Pain Strategy that is currently available for public comment. The meeting was very informative and the Task Force will be reviewing ways to get this valuable information to its licensees and to consumers.

b. General Board Update

Ms. Herold reported that she traveled to Washington D.C. to attend a meeting convened by the DEA on e-prescribing. Ms. Herold provided a brief overview of the meeting.

Ms. Herold stated that she also traveled to Washington D.C. to attend a meeting on sterile compounding convened by the FDA. She noted that she was able to share the board's progress in the area of sterile compounding.

Ms. Herold reported that she attended a .PHARMACY committee meeting convened by NABP. Ms. Herold provided a brief update on the progress of the .PHARMACY program.

Ms. Veale and Ms. Butler left the meeting at 3:58 p.m.

c. Duty Inspector Update

Ms. Herold provided a brief report to the board on the duty inspector program. A PowerPoint presentation with statistics on the number of inquiries received and the type of questions received was provided in the meeting materials.

XXI. Adjournment

President Weisser stated that while the board is comprised of individuals with many different viewpoints, the members come together to work collaboratively to protect the consumers of California. President Weisser concluded by thanking the board members and staff for their hard work during his terms as President.

President Weisser adjourned the meeting at 4:09 p.m.

Title 16. Board of Pharmacy. Adopt §1746.3, which is new regulation text, as follows:

§1746.3 Protocol for Pharmacists Furnishing Naloxone Hydrochloride

A pharmacist furnishing naloxone hydrochloride pursuant to Section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

~~(12)~~ "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

~~(23)~~ "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride. Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:

~~(A*i*)~~ Whether the potential recipient currently uses or has a history of using illicit or prescription opioids? (If the recipient answers yes, the pharmacist may skip screening question ii.);

~~(B*ii*)~~ Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. If the recipient answers yes, the pharmacist may continue.

~~(C*iii*)~~ Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to Naloxone. If the recipient answers yes, the pharmacist may not provide the Naloxone. If the recipient responds no, the pharmacist may continue.

~~The screening questions shall be made available in alternate languages for~~
~~whose primary language is not English.~~

These screening questions shall be made available on the Board of Pharmacy's website in alternate languages for recipients whose primary language is not English.

(2)- Provide the recipient training in opioid overdose prevention, recognition,

response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(~~A~~i) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(~~B~~ii) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(~~C~~iii) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient to how to choose the ~~and~~ route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. The pharmacists may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector, or other FDA approved products. The pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) ~~Kit~~-Labeling: A pharmacist shall label the ~~kit~~ naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the

drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Authority and Reference: Section 4052.01, Business and Professions Code.

For the Board of Pharmacy's website:

Naloxone

Suggested ~~Kit~~ Labeling (by route of administration):

Intramuscular	Intranasal	Auto-Injector
<p>Naloxone 0.4mg/1ml single dose vial, # 2 vials SIG: Inject 1 ml intramuscularly upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Syringe 3ml 25G X 1" # 2 SIG: Use as directed for naloxone administration.</p> <p>Kits should contain 2 vials and 2 syringes.</p>	<p>Naloxone needleless prefilled syringe (1mg/1ml concentration) 2ml, # 2 syringes SIG: Spray one-half (1ml) of the naloxone into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.</p> <p>Kits should contain 2 prefilled needleless syringes and 2 atomizers.</p>	<p>Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Kit is commercially available as a twin pack with directions for administration included.</p>

Title 16. Board of Pharmacy. Adopt §1746.X, which is new regulation text, as follows:

§1746.X Pharmacists Initiating and Administering Vaccines

(a) A pharmacist initiating and/or administering vaccines pursuant to Section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

- (1) Completion of an **approved immunization training program**;
- (2) ~~BCurrent~~ basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 3 months of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall ~~provide the patient with a vaccine administration record and~~ advise the patient to consult an appropriate health care provider of the patient's choice.

Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within ~~15 days~~ 3 months of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization recordsharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code, ~~and under title 16, sections 1717 and 1707.1 of the California Code of Regulations~~ is readily retrievable during the pharmacy or facility's normal operating hours.

A pharmacist shall provide the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Authority and Reference: Sections 4052(a)(11), 4052.8, Business and Professions Code.

Title 16. Board of Pharmacy. Adopt §1746.X, which is new regulation text, as follows:

§1746.X Pharmacists Furnishing Travel Medications

(a) For purposes of section 4052(a)(10)(A)(3), “not requiring a diagnosis” means either
(1) a self-diagnosable and self-treatable condition under the federal Centers for Disease Control and Prevention’s (CDC) Health Information for International Travel (commonly called the Yellow Book); or
(2) a prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to Section 4052(a)(10) of the Business and Professions Code shall follow the requirements specified in subdivisions (c) through (f) of this section.

(c) Training: A pharmacist who ~~initiates and/or administers any vaccine~~furnishes travel medications shall keep documentation of:

- (1) ~~Current~~ completion of an approved ~~immunization-travel medicine~~ training program, which must consist of at least ~~230~~ hours and cover the International Society of Travel Medicine’s body of knowledge;
- (2) Completion of the CDC Yellow Fever Vaccine Course;
- (3) ~~BCurrent~~ basic life support certification.

This documentation shall be kept on site and available for inspection.

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

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith ~~examination, though not necessary a physical examination~~evaluation, of the patient, including evaluation of a patient travel history form using a destination-specific travel database. The travel history form must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history form is available on the Board of Pharmacy’s website.

(f) Notifications: The pharmacist shall notify the patient’s primary care provider of any drugs and/or devices furnished to the patient within 3 months of the date of dispense, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient’s choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code, and title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility’s normal operating hours.

A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel plan. An example of an appropriate and comprehensive progress note is available on the Board of Pharmacy's website.

Authority and Reference: Sections 4052(a)(10)(A)(3), 4052(a)(10)(B), Business and Professions Code.