



California State Board of Pharmacy

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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

**LEGISLATION AND REGULATION COMMITTEE
MINUTES**

Date: Thursday, April 11, 2013
Location: Department of Consumer Affairs
Headquarters Building II
1747 North Market Blvd., Suite 186
Sacramento, CA 95834

Committee Members Present (all):

Greg Lippe, CPA, Chair, Public Member
Ramón Castellblanch, PhD, Public Member
Randy Kajioka, PharmD, Professional Member
Victor Law, PharmD, Professional Member
Amy Gutierrez, PharmD, Professional Member
Tappan Zee, Esq., Public Member

Board Members Present in the Audience:

Stan Weisser, President

Staff Present:

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kristy Shellans, DCA Sr. Staff Counsel
Carolyn Klein, Manager
Laura Hendricks, Administrative Analyst

Chairman Greg Lippe called the meeting to order at 9:13 a.m. and roll was taken. Dr. Randy Kajioka arrived at 9:20 a.m. and Dr. Amy Gutierrez arrived at 9:25 a.m.

Part I - LEGISLATION

1. Board Sponsored Legislation for 2013

a. SB 294 (Emmerson) Compounding Sterile Drug Products

Background: SB 294 contains board-sponsored provisions to strengthen board's ability to regulate and monitor pharmacies that compound sterile drug products and distribute or ship into California sterile products for injection, for administration to the eye, or for inhalation.

A letter of support was provided to the author and to the Senate committee members in advance of the policy committee hearing on April 2. The committee was provided with a copy of the Board's letter of support, a staff analysis, and the current bill text. Additionally, the committee was provided with a copy of a letter of concern from the California Hospital Association; and a letter from the California Society of Health-System Pharmacists noting its position of Support if Amended. In addition to seeking clarification on the board's proposal to amend Section 4127.1(a)(c), CSHP is seeking to amend the bill to expand the bill to amend other Pharmacy Law sections, as specified in its letter. The committee was also provided with a copy of written testimony of Sarah Sellers, PharmD, which was provided by Fred S. Mayer, PPSI/Gray Panthers.

Ms. Herold advised the committee of the status of the measure and provided an update on recent policy committee votes. She also addressed some of the comments received by interested parties.

Public Comment:

Jonathan Nelson representing the California Society of Health System Pharmacists (CSHP) requested amendments to clarify how schools of pharmacy can acquire drugs used for teaching. Ms. Herold noted that existing statute at Sections 4031 and 4059 are viewed to provide this authority.

Ms. Shellans offered comments to clarify the language at new Section 4400(v) of the measure, that could restrict a license from being reinstated until the required fee is paid, and to specify how such reinstatement would be effected.

Dr. Steve Gray, speaking as an individual, discussed concerns about the travel expense reimbursement provisions that it may interfere with federal law. Ms. Sodergren noted there is existing case law regarding the charging of a fee to perform the actual service.

Ms. Herold advised the board that current law allows for compounding of prescriber office use in addition to that which is compounded pursuant to a prescription. Ms. Herold indicated that there are clearly entities that have carried over into manufacturing and reminded the committee that the board needs to walk a fine line to ensure that decisions made by the board do not further exacerbate drug shortages.

b. Board-Approved Proposals for 2013-2014

Mr. Lippe provided a summary of the board's approved proposals for this legislative session:

Amendment to Business and Professions Code 4107 – One Site License per Premises; Exception

Business and Professions Code Section 4107 provides that the board may not issue more than one site license to a single premises, unless there is a specific exemption to do so. Following the passage of AB 377 (Hospital Central Packaging Pharmacy), the board approved language that would provide for a specific exemption to issue the central packaging pharmacy permit to a premise that also holds a hospital permit. The board's proposal has been provided to the Senate Committee on Business, Professions and Economic Development and staff has been advised that the language will be amended into the Committee's Omnibus bill, SB 821. There was no additional committee or public comment.

Addition of Business and Professions Code Section 4008.5 – Requirement to Provide Arrest and Court Documents as Requested by the Board

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; these agencies cite the board's lack of authority to receive these documents. At the October 2012 Board Meeting, draft language was approved to add Section 4008.5 to provide the board with the express authority to receive certified records for this purpose. In lieu of adding this provision to the Senate Committee on Business, Professions and Economic Development's omnibus measure, the committee has developed draft amendments to add a general BPC code that would be applicable to all DCA boards. Staff will continue to monitor legislation and advise the committee when this language has been amended into a bill. Ms. Klein advised the committee that a like provision, applicable to all DCA boards, is expected to be added as a new Section 144.5, and amended into the Senate Omnibus bill for health boards.

Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative

Mr. Lippe summarized that existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. At the October 2012 Board Meeting, the board approved a draft amendment that would clearly specify that the one year of paid work experience shall be earned in a licensed facility, as specified. The board's proposal has been provided to the Senate Committee on Business, Professions and Economic Development and staff has been advised that the language will be amended into the Committee's Omnibus bill, SB 821.

Ms. Klein advised the committee that the board approved an additional proposal for sponsorship this session that would authorize the board to issue a letter of public reprimand at the time an application was approved. She noted that staff had been working with an author, but the proposal was later declined and that staff is seeking additional authors. Ms. Sodergren provided the committee with a brief overview of the provision and the need for the provision.

In response to a question about the role of a Designated Representative, Ms. Herold provided a brief description of the role that such an individual serves in a wholesaler, as defined in Section 4053. She indicated this person is responsible for ensuring the safe selection and distribution of drugs in a wholesaler.

Public Comment

Dr. Steve Gray expressed concern with the one-year experience requirement. He noted that Kaiser has a hard time finding staff to fill these positions, and he felt the one year experience requirement was appropriate for the Designated Representative-in-Charge. Ms. Sodergren clarified that the proposal is intended to require an applicant as a designated representative have one year experience in any board-licensed facility – not just a warehouse setting.

With regard to the letter of reprimand proposal, Dr. Gray recommended that the board call it a “letter of concern” because the term ‘reprimand’ may be too harsh.

c. Board Proposal to Define “Correctional Pharmacy” at Section 4046

Background: A proposal to add Section 4066 BPC to define the term “Correctional Pharmacy” has been provided to the Senate Committee on Business, Professions and Economic Development, and staff has been advised that this will be amended into one of the committee’s omnibus measures, as noted below. Staff recommended that the board approve/ratify the language for inclusion in an omnibus measure.

4046. “Correctional Pharmacy” means a pharmacy, licensed by the board, located within any ~~state~~ correctional facility for the purpose of providing pharmaceutical care to inmates of the ~~state~~ correctional facility.

Mr. Lippe sought the committee’s input on the proposal. Mr. Zee spoke in support of the proposal, suggesting that the word “state” be stricken, as there are other government owned correctional facilities in addition to those owned by the state (such as county facilities). Dr. Kajioka asked how this provision would impact remote data entry and if remote entry would still be allowed, given the new definition. Ms. Herold indicated that additional discussion may be necessary and that there will need to be follow-up regulations to better clarify requirements for these settings.

Public Comment:

Dr. Gray indicated that current pharmacy law allows for remote data entry if prior authorization is received and if the individual is appropriately licensed. Dr. Gray indicated that there may be questions as to how this proposal would impact ratios.

M/S (Zee/Gutierrez): Recommend Support, as amended to strike the word “state” in two instances.

Support: 6 Oppose: 0 Abstain: 0

d. Omnibus – SB 822, SB 821

Mr. Lippe summarized that the Senate Committee on Business, Professions and Economic Development sponsors omnibus measures each year. He noted that as previously stated, several of the board’s sponsored provisions are expected to be amended into SB 821. There was no board or public comment.

2. Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction

Dangerous Drugs and Devices

a. AB 396 (Fox) Prescription Label – Condition or Purpose

Mr. Lippe noted that as reflected in the chair report, the author’s office indicated they are not moving forward with this provision.

Dr. Gray commented that data supports the value in providing the purpose on a drug label and commented that it is disappointing that the proposal is not moving forward. Dr. Gray indicated that previously the board had discussed if a pharmacist already has the authority to do this given the duties a pharmacist fulfills in its patient care role. Dr. Gray indicated that such a discussion by the board could remind pharmacists that they are professionally authorized to provide the purpose on the label because it is in the patient’s best interest. Dr. Gray reiterated that this information is very important especially for individuals that live in assisted living. Ms. Herold indicated that the board cannot mandate inclusion on the label under existing statute, but there are several other elements not required on the label but are currently included at the option of either the pharmacy or the patient. Dr. Kajioka indicated that consumers need to be educated to request that a physician include the information on the prescription label.

Chair Lippe requested that a discussion to address the condition or purpose being placed on a prescription container label be placed on a future committee agenda.

b. AB 670 (Atkins) Pharmacy: Incentive Payments

Background: The author's office is addressing the issue where pharmacists or pharmacy employers receive incentives to substitute a patient's medication therapy. AB 670 is intended to eliminate specific financial inducements that encourage pharmacists to change one drug product for another that does not have the same active ingredient. The committee was provided with a staff analysis, the author's Fact Sheet and a copy of the bill as amended April 2, 2013.

Dr. Castellblanch commented that he did not feel this measure was necessary – and he asked for clarification on how the bill would apply to formularies. Ms. Shellans stated her concern that the bill is too broadly drafted. She noted that under current law, a pharmacist can substitute -a drug.

Public Comment:

Tony Long, RPh, expressed concerns that this proposal could potentially be contrary to patient care. Mr. Brian Warren, CPhA indicated that the association has been working with the author's office. Mr. Warren provided some of the background on the proposal relating to MTM services that are provided for some patients. He shared that they continue to work with the author's office, but are unclear if they are going to be able to resolve their concerns. Dr. Gray cautioned that the bill is worded too broadly, that it does not differentiate the various pharmacy settings, including when the pharmacist is working in a health system. Dr. Gray spoke in support of the committee's recommendation to oppose AB 670. Ms. Herold added that the board does not see consumer complaints in this area, but – if it did – such a complaint would be investigated and a pharmacist which could result in a violation of unprofessional conduct.

M/S (Castellblanch/Law): Recommend Oppose AB 670 as Amended April 2, 2013
Support: 6 Oppose: 0 Abstain: 0

c. AB 1136 (Levine) Pharmacists: Drug Disclosures (Drug Warning Labels)

Background: AB 1136 is intended to address drug warning labels related to dispensed prescriptions where the drug may impair a person's ability to operate a vehicle or vessel. Existing pharmacy law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a dangerous drug if the drug poses substantial risk to the person when the drug is taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle. The board's regulation at 16 CCR 1744 requires a pharmacist to inform a patient of the harmful effects of certain drugs dispensed by prescription. A pharmacist utilizes professional judgment when adhering drug warning labels to a dispensed prescription. AB 1136 would remove such discretion when it involves a drug that may impair a person's ability to operate a vehicle or vessel.

Staff attended the Assembly Health Committee hearing and answered the committee's questions regarding current requirements. As noted in the staff analysis the board's regulation specifies substances for which a pharmacist shall orally or in writing provide such warnings. AB 1136 seeks to mandate a drug warning label for these types of substances.

Ms. Klein provided the committee with a copy of the bill as recently amended, as well as a brief synopsis of the changes. Dr. Kajioka expressed concern that the bill is taking away the professional discretion of a licensed professional. Ms. Shellans added her concern that the proposal would limit a pharmacist's discretion in how a drug container is labeled.

Public Comment:

Dr. Gray shared some of the motivations of the bill, which includes there are no current statutory provisions that address driving under the influence of prescription drugs.

Ms. Sodergren noted that the board sees a number of applicants that are pulled over for being under the influence of drugs but when it is determined they have a prescription, they don't get prosecuted.

M/S (Law/Castellblanch): Recommend Oppose AB 1136 as Amended

Support: 5 Oppose: 0 Abstain: 0

Note: Mr. Zee was not in the room at the time the vote was taken

d. AB 1139 (Lowenthal) Prescriptions: Biosimilar Products

Background: AB 1139 seeks to amend Section 4073 to specify that a pharmacist filling a prescription order for a biological product, as specified, may select a biosimilar product, provided that the substituted biosimilar product is deemed by the FDA to be interchangeable with the prescribed product. The amendments would prohibit a pharmacist from making such a substitution if the prescriber indicates "Do not substitute" or words of similar meaning. As with current law, the pharmacist would be required to communicate to the patient the name of the drug dispensed, and ensure the drug container is appropriately labeled.

Additional legislation (SB 598, Hill) also seeks to amend Pharmacy Law as it relates to the substitution and dispensing of a biosimilar product, where a biological product is prescribed.

Mr. Lippe invited the committee's comments, and that of the public.

Public Comment:

Mandy Lee, California Retailers Association, stated this proposal was introduced as an alternative to another piece of legislation, and that this proposal is preferred by CRA's members. Ms. Lee indicated that they are unclear when the FDA will act. Dr. Gutierrez indicated that FDA currently provides a list of drugs that are under review which indicates that there is work being done in this area.

Dr. Gray provided the committee with an explanation of the difference between biosimilar substitutions versus generic substitutions. Dr. Gray indicated that Kaiser is concerned because this proposal is premature. Dr. Gray indicated that there are two processes, determining that the drugs are similar, and then determining which drugs are interchangeable. Dr. Gray noted that between the two bills, this is the preferred proposal.

Ms. Herold advised the committee that given that this is an essential function of the board, she encouraged the board and committee to discuss the policy behind it. Ms. Shellans asked if there are concerns about how a biosimilar would work. Ms. Herold indicated that the FDA will be making the determination if the drug is equivalent, not the pharmacist. She indicated that such a substitution may be in the best interest of patient care.

M/S (Castellblanch/Gutierrez): Recommend Neutral, but express concerns about the proposal being premature, and the role a pharmacist plays in drug substitution.

Support: 5 Oppose: 0 Abstain: 1 (*Zee*)

e. SB 204 (Corbett) Prescription Drugs: Labeling (Translations)

Background: Existing Pharmacy Law requires that a prescription container dispensed to a patient include the directions for use of the drug (Section 4076). Board regulation at 16 CCR 1707.5 specifies standardized “directions for use” that shall be used, if they are applicable to the prescription. In addition, the board maintains on its website translations in five languages of the “directions for use” that are found at 16 CCR 1707.5(a)(4).

SB 204 would add Section 4076.5 to require a pharmacist to use the translations for the “directions for use” available on the board’s website, as applicable, when labeling a prescription. The section would also authorize a pharmacist to translate the directions for use into additional non-English languages if certified translation services are utilized to complete the translations.

Mr. Lippe provided an overview of the proposal and added that staff has requested a Fact Sheet from the author’s office and has reached out to the author’s staff to seek clarification on some of the components of the measure. Dr. Kajioka indicated concern about who would be liable for the required translations. Ms. Shellans noted that if statute mandates the use of translations on the board’s web site, the liability becomes the boards. Dr. Kajioka expressed concern on the financial impact to small businesses, speaking in opposition to mandating that all pharmacies provide translations that may not be needed in their communities – he noted these requirements may be cost prohibitive. Dr. Kajioka stated that pharmacies take care of their patients without such a mandate. Mr. Law stated he does not feel the proposal is necessary. He commented that he provides translations to take care of his patients, and he is also concerned about liability to the board. Mr. Law made a motion to oppose the bill; Mr. Zee seconded the motion.

Dr. Castellblanch said it is unclear why we need to oppose the bill – and he is not clear as to the board’s liability. Mr. Law stated that the board needs to address the fact that these translations are a mandate on the board. Mr. Zee spoke in support of Mr. Law’s comments, expressing concern that the bill may impede care. Dr. Gutierrez expressed similar concerns regarding the measure. Dr. Castellblanch added that the board did not agree to allow the free market to solve these problems.

Public Comment:

Mr. Brian Warren advised the board that CPhA has taken an Oppose position. He said they believe the proposal is premature given that the board is currently evaluating the patient-centered label requirements. He stated that the interpreter requirement is better for consumers.

M/S (Law/Zee): Recommend Oppose SB 204

Support: 5 Oppose: 1 (*Castellblanch*) Abstain: 0

f. SB 205 (Corbett) Prescription Drugs: Labeling (12-point Font)

Background: SB 205 would amend Section 4076 to require that any prescription dispensed meets the requirements of state and federal law, and is correctly labeled in at least a 12-point sans serif typeface. Existing regulation at 16 CCR 1707.5 requires that specified “patient-centered” information on a prescription drug label be printed in a minimum 10-point sans serif typeface, but that the pharmacy shall print the drug label in 12-point sans serif typeface if requested by the patient.

Mr. Lippe provided a summary of the proposal, adding that staff has requested a Fact Sheet from the author’s office. Ms. Herold noted that under the current construct, the proposal would require that the entire prescription label be printed in 12-point font, not just the patient-centered items. Dr. Castellblanch spoke in support of mandating a larger font on the label, and that if the bill language mandates that requirement for all elements, it is likely a drafting error. Dr. Kajioka stated his concern that mandating 12-point font will limit the flexibility for pharmacists. He stated the board has not heard any remarks that the font size isn’t big enough. Mr. Zee made a motion to recommend that the board oppose the bill; Mr. Law seconded the motion.

Public Comment:

Dr. Gray agreed that the bill currently requires everything on the label to be printed in 12-point font. He stated that with the current requirements, the description of the product is now too small and that is becoming a safety concern for some patients. Dr. Gray added that if the author is addressing what is important to be larger, the description of the product may need to be considered.

M/S (Zee/Law): Recommend Oppose SB 205

Support: 5 Oppose: 1 (*Castellblanch*) Abstain: 0

g. SB 506 (Hill) Ephedrine: Retail Sale

Background: Until January 1, 2019, SB 506 would restrict the furnishing of ephedrine products without a valid prescription. SB 506 would eliminate the current reporting of specified ephedrine products to the California Department of Justice (DOJ) and, instead, provide for the collection and reporting into a single web-based database operated by the National Precursor Log Exchange (NPLEx) specified proposed transactions of those products.

The web-based single database would be available to a retailer at no charge, but would require a retailer to access this web-based system via the internet. Retailers would be required to submit specified information prior to completing a transaction, and the retailer would be prohibited from completing the transaction if an alert is generated by the system.

While the measure addresses the recordkeeping of these transactions during a mechanical or electronic failure of the system, the measure does not specify whether a retailer would be authorized to complete a transaction under those circumstances.

Mr. Zee discussed current restrictions on purchasing ephedrine products and stated he feels SB 506 would place a further burden on a consumer. He indicated it is unclear what problem this bill is trying to solve. Dr. Gutierrez sought clarification on point-of-sale transactions. Dr. Kajioka said the bill does not address what a pharmacy is to do in the case of a system failure. The committee discussed the pros and cons of such a system.

Public Comment:

Ms. Lee, CRA, commented that the issue of ‘smurfing’ is well documented. She said that paper logs as currently required have privacy implications and does not stop illegal behavior. She commented on previous measures and other proposed solutions that were previously attempted. In response to a committee question, Mr. Lee indicated that funding for the new system would be from the OTC manufacturers. Dr. Gray commented that the proposal solves the problem of insuring that all retailers share information; he added that Kaiser supports the bill.

M/S (Zee/Law): Recommend Oppose SB 506

Support: 2 Oppose: 2 Abstain: 2

Motion Fails

h. SB 598 (Hill) Biosimilars

Background: SB 598 would add Section 4052.55 to the Business and Professions Code to specify conditions under which a pharmacist may exercise professional discretion to substitute a **biosimilar** for a prescribed **biological** product, if certain requirements are met.

Mr. Lippe provided an overview of the proposal, and reflected on the committee’s discussion of AB 1139. Dr. Castellblanch motioned that the committee recommend a Neutral position, and send a letter to the author denoting the committee’s comments as it relates to biosimilars. Dr. Castellblanch made a motion to recommend a position of Neutral on SB 598 and that the board send the author a letter (similar to AB 1139) reflecting the committee’s concerns and the possible infringement on the practice of pharmacy this bill places. Mr. Law seconded the motion.

Public Comment:

Ms. Lee, CRA, noted that SB 598 is different from the other proposal (AB 1139) in that once approved by the FDA, the pharmacist would be required to notify the prescriber of a biosimilar substitution within five days. She stated that right now retailers dispense small amounts of biosimilar products, and this requirement would place an undue burden on the pharmacy. She added that requiring a pharmacy to keep a record of all biosimilar products dispensed is another burden, and that CRA opposes this bill.

M/S (Castellblanch/Law): Recommend position of Neutral on SB 598
Support: 6 Oppose: 0 Abstain: 0

i. SB 669 (Huff) Emergency Medical Care: Epinephrine Auto-Injectors

Background: SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors, make them available to trained individuals (as specified) and allow those individuals to administer these devices, without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction.

Mr. Lippe provided a summary of the measure, noting that staff has sought clarification from the author's office on various components of the measure, as specified in the analysis. Mr. Zee made a motion that the committee recommends a Support position; Mr. Law seconded the motion.

Public Comment:

Dr. Gray, speaking as an individual, stated the bill places a burden on a physician to check a certificate and that with no exam, be required to write a prescription. Mr. Gray recommended that a pharmacist is an appropriate health care professional to handle these types of transactions. Dr. Gray encouraged the committee to consider a Support if Amended position, to **also** allow a licensed pharmacist be authorized to dispense epinephrine auto-injectors and approve the related training certificates. Mr. Doug Hillblom, stated that there is a new product for an injectable that actually talks to the user and provides verbal instructions on the safe administration of the device. Ms. Herold asked, what happens if an individual receives an injection that did not need one. She asked the committee to consider if the benefits were greater than any risk to the public. Mr. Zee spoke in support of Dr. Gray's comments, amending his motion to **Support if Amended**, with the amendment that the physician or a pharmacist be authorized to approve the training certification and issue the prescription. Mr. Law agreed to the amended motion.

M/S (Zee/Law): Recommend position of Support if Amended
Support: 6 Oppose: 0 Abstain: 0

j. SB 809 (DeSaulnier) CURES

Background: Health and Safety Code Sections 11165 – 11165.3 establishes and defines the parameters and use of the CURES Program within the California Department of Justice. Under current law, prescribers and pharmacies are required to report each week to DOJ every Schedule II, III and IV prescription dispensed.

Following substantial funding reductions that were part of the 2011-2012 Governor's Budget, the Department of Justice has been maintaining the program with limited resources. In 2009 DOJ launched an automated Prescription Drug Monitoring Program (PDMP) within CURES. This program allows authorized users, including pharmacists, prescribers, and others, to access at the point of care patient controlled substance prescription information. This information allows prescribers and pharmacists to make informed decisions about patient care and to detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners.

SB 809 would establish permanent funding for CURES by increasing fees for specified health care practitioners and also to wholesalers, nonresident wholesalers and veterinary food-animal drug retailers.

Mr. Lippe provided a summary of the proposal. Ms. Herold made a suggestion that the committee consider a requirement that Schedule V controlled substances be required to be reported to CURES. Dr. Castellblanch spoke in support of making the CURES system more user friendly. Dr. Castellblanch made a motion that the committee recommend a position of Support, and add comments that would reflect that the fee required to fund CURES be added on top of the licensing fees already specified in Pharmacy Law, that dispensed Schedule V substances be reported to CURES, and that the system be more user friendly. Dr. Kajioka seconded the motion. Ms. Shellans noted that the fee could be clarified by amending Section 4400.

Public Comment:

Dr. Gray discussed some of the concerns Kaiser has with this provision as it relates to the performance of the CURES system prior to requiring dispensing a medicine. Kaiser would be in support of including schedule V drugs.

John Valencia, indicated that he spoke in support of CURES and ongoing funding; however, he commented that they believe ongoing funding should come from the general fund. The question posed to the committee is: what is the board, in fact, supporting – funding of CURES as a repository, or also for funding additional staff, SWAT teams etc.

M/S (Castellblanch/Kajioka): Recommendation that the board Support SB 809, noting the required fee is on top of those already authorized by the board; that the system be more user friendly, and in support of adding Schedule V to those substances that shall be reported to CURE.

Support: 6 Oppose: 0 Abstain: 0

Enforcement Legislation

k. 62 (Price) Coroners Reports

Background: Under existing law, Section 802.5 of the Business and Professions Code, when a coroner receives information that a death may be the result of gross negligence or incompetence, as specified, the coroner shall file a report with the Medical Board of California and other entities. The bill, *as introduced*, would amend Section 802.5 to require that when a coroner receives information indicating that a death may be the result of prescription drug use, the coroner shall file a report with the Medical Board of California and other specified entities, *and the California State Board of Pharmacy*. The bill specifies what information that must be reported, and further specifies that within 90 days of the initial report, the coroner's report, autopsy protocol, and other relevant information shall follow. As introduced, staff estimated that an additional six inspectors and three associate analysts would be needed to receive, review, analyze and inspect violations of Pharmacy Law, related to the received reports. The board voted to SUPPORT SB 62, as introduced, at the February Board Meeting.

Staff provided the committee with a copy of SB 62, as Amended April 9, 2013 – which struck the Board of Pharmacy from those entities that would receive the coroner's reports. Ms. Herold advised that it appears the change was made at the request of coroners. She added that staff is reaching out to the author's office to acquire additional information.

Licensing Legislation

I. AB 186 (Maienschein) Professions and Vocations: Military Spouses: Temporary Licenses

Background: AB 186, as Amended 4/1/13, would a Amend Section 115.5 to require a board to issue a provisional license to an applicant who meets specified requirements, provided the application

- Includes an affidavit that the information submitted in the application is accurate and
- Where verification from the other jurisdiction has been *requested*.

The bill further provides that the applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under the BPC at the time the act was committed, as specified. Of concern is the requirement that the board issue a provisional license based on limited information. For example, for a Pharmacist applicant, the board requires that in addition to passing the NAPLEX, an applicant must also pass the CPJE as a condition of licensure. Staff indicated that the board may wish to consider if – through the provisional licensing of an individual – placing such an individual in a pharmacy setting before it is able to ensure the individual meets the requirements for licensure in California is in the best interest of the public safety.

The staff analysis noted that the board faces challenges in implementing such provisional licenses because the board is unable to modify its current applicant tracking system to

accommodate the new license types. Staff noted that the board will be migrating to the new DCA BreZE system in 2013 and possibly into 2014, and provided the committee with application processing times as of December 2012.

Mr. Lippe provided an overview of the legislative proposal. Ms. Shellans recommended that the board should not be giving out licenses if the underlying permit is being disciplined; she recommended that the language at proposed Section 115.5(b)(2)(B), “at the time the act was committee” be stricken. Ms. Sodergren commented on the legislative history, in that in the last session, the section was amended to require boards to “expedite” a license application – this bill requires boards to issue a provisional license. Ms. Herold spoke of situations where minimum requirements are not or cannot be met, yet – under the bill – the board would have someone practicing under a provisional license. For example, what if a spouse takes the pharmacists exam four times in 18 months and fails – what is the board to do with the provisional license? The board would need additional authority to revoke such a license. Under current requirements, an individual who fails the pharmacists examination four times would be required to take additional coursework before taking the examination again and would not meet the minimum requirements for licensure as a pharmacist. Dr. Gutierrez inquired as to why the existing language is not sufficient.

Public Comment:

Dr. Gray discussed some of the challenges with the current construct of the legislative proposal.

M/S (Gutierrez/Lippe): Neutral position; and staff to work with the author’s office to address concerns.

Support: 5 Oppose: 0 Abstain: 0

Note: Dr. Castellblanch was not in the room at the time the vote was taken

m. AB 213 (Logue) Healing Arts: Licensure and Certification Requirements: Military Experience

Background: Existing Pharmacy provides for the licensure of Pharmacists, Pharmacist Interns, Pharmacy Technicians and other individuals and representatives related to its site licenses, and specifies the minimum requirements for licensure of these individuals. For Pharmacy Technicians, board regulation (16 CCR 1793.6(b)) specifies that a course of training provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, shall meet the requirements of Section 4202(a) for a Pharmacy Technician applicant.

AB 213 would specify that not later than 7/1/14, if a board accredits or otherwise approves schools offering educational course credit for meeting licensure qualification, the board shall require a school seeking accreditation or approval to submit to the board proof that the school has procedures in place to evaluate, upon presentation of satisfactory evidence by the applicant, the applicant’s military education, training, and practical experience toward the completion of a program that would qualify a person for licensure, as specified.

Mr. Lippe provided an overview of the proposal. Ms. Sodergren clarified that the intent of the measure is to consider relative military experience as part of the path to licensure. Mr. Lippe noted that staff will continue to watch this measure.

n. **AB 258 (Chavez) State Agencies: Veterans**

Background: SB 258 would standardize the way any state government organization would ask an individual as to their veteran status. The author states that individuals who may not identify themselves as a veteran because the way a question is asked may lose out on many Federal benefits to which they are entitled.

Mr. Lippe briefly summarized the measure. Ms. Herold stated if such a question is mandated, a second question should indicate how the individual was discharged. Mr. Lippe noted that staff will continue to watch this measure.

o. **AB 512 (Rendon) Healing Arts: Licensure Exemption**

Background: Existing law provides that until 1/1/14, an individual may be exempt from the licensure and regulation requirements for defined health care practitioners, to offer or provide health care services for which he or she is licensed or certified, through a sponsored event, as defined. This section also requires an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other requirements, including the payment of a fee as determined by a board. The board does not have regulations to specify requirements for pharmacists from other states to serve at sponsored healthcare events, as allowed by Section 901 BPC.

Mr. Lippe summarized the measure, noting that AB 512 would extend the sunset provisions of Section 901 BPC from 2014 to 2018. Mr. Herold provided historical information related to health care events. The committee discussed the dispensing of drugs at these events. Mr. Zee spoke in support of providing the public health care through these events, and it is in the board's best interest to enforce matters related to the practice of pharmacy at these events. There was no public comment.

M/S (Zee/Lippe): Recommend Support AB 512

Support: 4 Oppose: 0 Abstain: 1 (*Law*)

Note: Dr. Castellblanch was not in the room at the time the vote was taken

p. **AB 555 (Salas) Professions and Vocations: Military and Veterans**

Background: Existing law provides for the licensure and regulation of various professions and vocations by DCA boards, and that boards may adopt rules and regulations to provide for methods of evaluating education, training, and experience obtained in the armed services, if applicable to the requirements of the profession to which they are applying.

For Pharmacy Technicians, board regulation (16 CCR 1793.6(b)) specifies that a course of training provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, shall meet the requirements of Section 4202(a) for a Pharmacy Technician applicant.

AB 555 would require a board to consider, and that a board may accept, any relevant training received while serving in the armed services of the United States for purposes of satisfying the requirements for a license, as specified. The measure authorizes a board to consult with the Department of Veterans Affairs and the Military Department when evaluating whether training acquired during military service is applicable to the requirements for the license being sought.

Mr. Lippe provided an overview of the measure, noting staff will continue to watch the bill. There was no public comment.

q. AB 1057 (Medina) Professions and Vocations: License: Military Experience

Background: Existing law provides for the licensure and regulation of various professions and vocations by DCA boards, and that boards may adopt rules and regulations to provide for methods of evaluating education, training, and experience obtained in the armed services, if applicable to the requirements of the profession to which they are applying.

AB 1057 would require every board to inquire on every application for licensure if the applicant is serving in, or has previously served in the military.

The board will be migrating to the new DCA BreZE system in 2013 and possibly into 2014. Board staff will communicate with the DCA on how the department may plan to implement the provisions of the measure, if enacted.

Mr. Lippe provided a brief overview of the proposal. Ms. Klein provided the committee with an amended version of the bill (4/9/13), noting the amendment will delay implementation to 2015 to address issues related to BreZE. Mr. Lippe indicated that staff will continue to watch this bill. There was no public comment.

r. AB 1003 (Maienschein) Professional Corporations: Healing Arts Practitioners

The committee did not discuss this bill. Mr. Lippe noted that AB 1003 is related specifically to the Physical Therapy Board and, as such, no staff analysis is provided.

s. AB 299 (Holden) Health Care Service Plans / Insurer: Mail Order

Background: SB 299 is a bill sponsored by the California Pharmacists Association, which would amend Section 4112 BPC to prohibit a resident or nonresident pharmacy that delivers prescriptions via mail from entering into, or being a party to, an agreement with a

health care service plan or disability insurer that requires a plan enrollee to utilize mail order services, or that requires a plan enrollee or insured to opt out of a mail order process.

Mr. Lippe provided an overview of the proposal. Ms. Shellans noted that the proposal is not in the business of regulating private party agreements – and that is beyond the scope of the board’s authority. She added that the bill does not address what happens with those who are already in such third-party contractual agreements. Ms. Herold stated the issue is whether or not a patient should be required to use mail order to get their prescription medications. Dr. Kajioka spoke in support of patient access to prescription medications without having to get them through mail order. Dr. Gutierrez commented on the high cost of specialized drugs, and that some patients are required to use mail order to keep costs down. She said there is a financial motive for insurers. Ms. Shellans stated that if the proposal continued to be in the Pharmacy Law, that there be continuity by placing like requirements with the Health and Safety and Insurance Codes. Dr. Castellblanch stated he feels the law was fine the way it is.

Public Comment:

Mr. Warren commented on the genesis of the proposal. In response to committee comments, he noted that the amendments were placed in Pharmacy Law by Legislative Counsel, and that the provisions may be moved to the Health and Safety and Insurance Codes.

M/S (Gutierrez/Lippe): Recommend Support if Amended, to place the provisions in the Health and Safety and/or Insurance Codes.

Support: 5 Oppose: 0 Abstain: 0

Note: Mr. Zee was not in the room at the time the vote was taken

t. AB 804 (Lowenthal) Medi-Cal Pharmacy Providers: Invoices

Background: To safeguard the confidentiality of proprietary information that retail pharmacies are required to submit to the Department of Health Care Services as part of establishing a new Medi-Cal Fee-For-Service reimbursement methodology, AB 804 would provide that pharmacy invoice information provided for this purpose be confidential and exempt from disclosure under the California Public Records Act.

Mr. Lippe provided a brief overview of the proposal. There was no committee or public comment.

u. SB 146 (Lara) Workers’ Compensation: Medical Treatment: Billing

Background: Existing law provides that any provider of services, as defined, shall submit with a request for payment an itemization of services to include a copy of the prescription. As introduced 1/31/13, the measure struck the requirement for a copy of a prescription to be submitted with such a request for payment. As amended, the bill does allow specified

entities to request a copy of the prescription document during a review of records of prescription drugs dispensed by a pharmacy.

Mr. Lippe provided a brief overview of the proposal. There was no committee or public discussion.

v. SB 445 (Price) Pharmacies: Advertising: Controlled Substances

Background: Existing Pharmacy Law requires that an advertisement of the retail price of a drug shall be limited to quantities of the drug that are consistent with good medical practice, and specifies information required for such an advertisement. There is no section that restricts the advertising of controlled substances. Additionally, existing law requires every pharmacy to post a notice concerning the availability of prescription price information; the notice may be provided to consumers via a written receipt with the required information, and allows an individual to receive price information, as specified. SB 445 would specify that under no circumstances may an advertisement from a pharmacy specifically promote the sale or dispensing of controlled substances.

Mr. Lippe provided a brief overview of the proposal. Ms. Shellans expressed concerns about the constitutionality of the bill as it may impede free speech and could leave the board in a very precarious position of enforcing provisions that are unconstitutional. Ms. Herold noted that she has never seen a drug add for controlled substances, and said she is unclear as to the need for this proposal.

Public Comment:

Dr. Gray indicated that as part of a Part D program, Kaiser is required by federal law that requires them to post process, even for controlled substances. He noted the proposal may conflict with these federal requirements.

The committee did not recommend any position on this measure.

w. SB 727 (Jackson) Medical Waste: Pharmaceutical Product Stewardship Program

Background: Current law defines pharmacy waste as bio hazardous waste, which in turn (in another code section) is designated as medical waste. The Medical Waste Management Act (MWMA) prescribes the methods for treating such waste because of the potential harm to public health and safety and the environment if not managed properly. The MWMA establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements. Regulation of the MWMA is performed by the California Department of Public Health.

SB 727 would add the “Drug Abuse Prevention and Safe Disposal Program” to the Public Resources Code. This article would set forth definitions, requirements for stewardship plans, to include the minimum number of collection sites for each plan submitted. The

program would require that a stewardship plan include the number of collection services, and that there shall be on and after January 1, 2016 one collection service within 10 miles per person in the state, with a 20 percent increase in the number of collection services one year thereafter, and other information. The plan shall also include a description of the methods to be used to **collect, transport and process** home-generated pharmaceuticals in this state.

Mr. Lippe provided an overview of the bill.

Public Comment:

Heidi Sanborne spoke as a co-sponsor of the proposal. She indicated they are seeking a statewide solution to handle the disposal of prescription drugs. She further indicated that some of the language in the bill was included to specifically address the board's diversion concerns. Ms. Sanborn highlighted provisions of the bill that addressed the collection and security of the disposed drugs (Section 3 of the bill – Proposed Section 47125(h)). She stressed their willingness to work with the board to find solutions.

Ms. Nan Brasmer of the California Alliance for Retired Persons (CARA) stated that CARA supports SB 727, noting it is very important that individuals have a safe and legal way of disposing of their unwanted prescription medications.

Dr. Gray, representing Kaiser and CSHP, stated both organizations support the intent of SB 727. He noted that the way the bill is drafted, the burden is on the producers. He asked the committee to consider if returned drugs should be counted in order to meet reporting requirements, as such handling would be required to meet the current reporting requirements within the bill.

Ms. Herold indicated this is an opportunity for the board to work on a system by which these drugs can be taken back. Ms. Sanborne stressed her willingness to work with the board to accomplish the intent of the bill. The committee did not recommend a position on SB 727 but encouraged staff to work with the author's office to address the board's concerns about drug safety.

Other Legislation

x. **SB 493 (Hernandez) Pharmacy Practice**

Background: Article 3 of the Business and Professions Code provides for the scope of practice, and exemptions, for a pharmacist licensed by the board.

SB 493 would create a board designation of "Advanced Practice Pharmacist" to be recognized by the Board of Pharmacy; would declare that pharmacists are health care providers who have the authority to provide health care services. Additionally, SB 493 would specify expand the types of services that may be provided by a pharmacist to include immunizations and other functions, as specified; and make conforming changes to Sections 4052 and 4060 to effect the provisions of the bill.

Mr. Lippe provided an overview of the proposal, noting that the proposal was amended on April 1. Dr. Gutierrez spoke in support of the measure, indicating that as health care needs change, and with the expansion of health coverage, pharmacists need to play an integral role. The committee members discussed the requirements for the advanced practice designation. Ms. Shellans noted that the bill does not contain an enforcement provision to remove such a designation, if necessary.

Public Comment:

Mr. Doug Hillblom, CPhA and CSHP, stated the proposal represents collaboration between the CPhA and the CSHP. Dr. Gray, CSHP, spoke of the work of a taskforce and that this effort was put forth at the request of the author. He stated the author intends to address the shortage of primary health care practitioners by allowing a pharmacist to manage a patient's drug therapy – health care that some pharmacists currently provide in specified settings; and that SB 493 provides a pathway for such a designation.

Dr. Gutierrez indicated she would like to see the board support the bill, to allow for the expanded scope of practice for these pharmacists. Dr. Castellblanch spoke in support of the bill, noting this should be a top priority for the board.

M/S (Gutierrez/Kajioka): Recommend Support SB 493
Support: 6 Oppose: 0 Abstain: 0

Part II - REGULATION

1. Regulations Approved by the Office of Administrative Law

Mr. Lippe summarized that on March 13, 2013, the Office of Administrative Law approved the board's rulemaking to amend Section 1746 of Title 16 of the California Code of Regulations related to the Emergency Contraception Protocol. The regulation goes into effect on July 1, 2013. He noted that the Fact Sheet utilized by pharmacists when dispensing emergency contraceptives pursuant to this protocol is being updated and should be available when the regulation goes into effect. There was no further committee or public comment.

2. Regulations Approved – Recently Noticed

Mr. Lippe provided an update on the board's combined rulemaking to amend Sections 1745 and 1769, and to add Section 1762 to Title 16 of the California Code of Regulations, summarizing dates of previous public comment periods. Mr. Lippe noted that at the February 5, 2013, Board meeting, the board voted to modify the proposed language at Section 1762 (to strike subdivision (b)) and that staff is preparing a notice of modified text for a 15-day public comment period. There was no additional committee or public comment.

3. Board Approved – Undergoing Administrative Review

Mr. Lippe provided an update on the board's proposal to add a new Article 5.5 to Title 16 of the California Code of Regulations related to Pedigree Requirement. He summarized that the board's proposal to add a new Section 1747 would establish requirements for the "unique identification number" required by Section 4034 of the Business and Professions Code, and the board's proposal to add a new Section 1747.1 would establish requirements for declarations that must be filed with the board, as required by Sections 4163.2 and 4163.5 of the Business and Professions Code. Mr. Lippe noted that following the board's adoption of the modified language, staff has compiled the rulemaking file and has submitted it to the Department of Consumer Affairs to begin the review process. There was no further committee or public comment.

4. Board Approved – Awaiting Notice

Mr. Lippe provided an update of the four board-approved proposals awaiting public notice, three of which are related to continuing education requirements, and one proposal to amend Section 1751.9 related to standards for agencies that accredit sterile injectable compounding pharmacies.

With regard to Section 1751.9 he noted that staff is recommending that the notice to Amend Section 1751.9 be held and not noticed at this time, in light of the board's sponsored legislation related to sterile drug products. There was no public comment on this item.

M/S (Lippe/Castellblanch): Recommend the notice to amend Section 1751.9 be held until a later time, and that staff issue for public notice the three proposals related to continuing education (as previously approved by the board for notice).

Support: 6 Oppose: 0 Abstain: 0

Part III – THIRD QUARTERLY REPORT – COMMITTEE GOALS 2013/2014

Mr. Lippe reported that since the adoption of the board's new Strategic Plan, the committee has not met to review and determine what goals shall be reported. The committee tabled this discussion and asked that staff to bring back to a future committee meeting suggested goals for the committee's consideration.