



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

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

DATE: June 3-4, 2015

LOCATION: University of Southern California – *Orange County Center*
2300 Michelson Drive
Irvine, CA 92612

BOARD MEMBERS

PRESENT: Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasure
Stanley C. Weisser, RPh Greg
Lippe, Public Member Ricardo
Sanchez, Public Member
Ramón Castellblanch, PhD, Public Member (6/4/15 only)
Albert Wong, PharmD
Lavanza Butler, RPh

**BOARD MEMBERS
NOT PRESENT:** Rosalyn Hackworth, Public Member
Ryan Brooks, Public Member
Gregory Murphy, Public Member
Allen Schaad, RPh

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Joan Coyne, Supervising Inspector (6/3/15)
Janice Dang, Supervising Inspector (6/4/15)
Joshua Room, Deputy Attorney General
Laura Hendricks, Staff Analyst
Liz, McCaman, Researcher (6/4/15)

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

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

Wednesday, June 3, 2015

Call to Order

9:07 a.m.

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

President Amy Gutierrez called the meeting to order and established a quorum of the board. Board members present: Lavanza Butler, Albert Wong, Greg Lippe, Deborah Veale, Amy Gutierrez, Stanley Weisser, and Ricardo Sanchez.

Board members not present: Rosalyn Hackworth, Ramon Castellblanch, Ryan Brooks, Gregory Murphy and Allen Schaad.

Note: Victor Law arrived at 9:25 a.m.

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 the April 21-22, 2015 Meeting Minutes

Laura Freedman, DCA staff counsel, noted that there were minor edits the she would work with staff to correct.

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

Motion: Approve the April 21-22, 2015 board meeting minutes including corrections from Ms. Freedman.

M/S: Weisser/Veale

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			

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

The board recognized Ralph Beale.

V. **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 and Possible Future Action by the Board**

Victor Law arrived at 9:25 a.m.

Anne Sodergren, assistant executive officer, provided a presentation which highlighted the uniform standards and implementation recommendations from staff. The entire presentation has been provided immediately following these minutes.

Upon the completion of Ms. Sodergren presentation, the board formed a committee to review and modify the board's disciplinary guidelines, procedure manual and probation monitoring contracts in order to incorporate the uniform standards. President Gutierrez assigned Stanley Weisser, Ricardo Sanchez and Victor Law to the committee.

The board recessed for a break at 9:43 a.m. and resumed at 9:53 a.m.

VI. **Petition for Early Termination of Probation**

Administrative Law Judge Adam Berg presided over the petition for early termination of probation for Lawrence (Larry) Bell, RPh 40966.

VII. **Petition for Reinstatement**

Administrative Law Judge Adam Berg presided over the petitions for early termination of probation for the following pharmacy technicians.

- a. **Eduardo Rivera, TCH 70498**
- b. **Denise Eaves, TCH 50501**
- c. **Jennifer Ortiz (York), TCH 43949**
- d. **Wilfredo Deollas, TCH 63786**

VIII. **Closed Session**

Pursuant to Government Code Section 11126(c)(3), the board convened to closed session at 1:18 p.m. to deliberate on the petition for reinstatement and early terminations of probation.

IX. **Reconvene Open Session**

The board reconvened to open session at 2:30 p.m.

X. **New Content Outline for the California Jurisprudence Exam (CPJE)**

President Gutierrez explained that the board is required to complete an occupational analysis periodically, which serves as the basis for the CPJE examination. To complete this analysis, the committee recently developed a job analysis survey with the board's contracted psychometric firm. President Gutierrez noted that the survey was offered to randomly selected California pharmacists (via postcard and a link to the board's website) in June 2014. **Note:** 524 pharmacists provided responses.

President Gutierrez reported that after reviewing the results of this survey it became apparent that the content outline for the CPJE needed to change slightly to ensure it remains valid for California. Under the leadership of the board's psychometric consultant, the Competency Committee revised the content outline. The revised content outline can be found in the board meeting materials using the following link. http://www.pharmacy.ca.gov/meetings/agendas/2015/15_jun_bd_content_outline.pdf

President Gutierrez explained that upon board approval of the revised content outline, the Competency Committee will work with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2016. She noted that staff will also begin updating the Candidate's Handbook to incorporate the revised content outline to ensure it is available when appropriate.

President Gutierrez and Ms. Herold reviewed the proposed changes to the content outline.

Ms. Herold noted that the Competency Committee also reviews the North American Pharmacist Licensure Examination (NAPLEX) to ensure that the CPJE is not testing items already covered by the NAPLEX, because Pharmacist applicants must pass both the NAPLEX and CPJE prior to licensure in California.

President Gutierrez stated that with the Affordable Care Act and the new advanced practice pharmacist licensure, it is important that the exam evolve to reflect the increase in pharmacists' responsibility and scope of practice.

The board discussed the perceived lack of law questions on the exam. Ms. Herold explained that the questions are formulated in a way that tests the student's knowledge of the law by having them apply it to a situation, rather than simply asking them to recall the law verbatim.

Mr. Weisser expressed concern with the lack of patient consultations occurring in California. The board agreed with his concern and discussed ways that this important function could be included in the CPJE. Ms. Herold reminded the board that at the July 2015 Board Meeting there would be a forum on patient consultation. During this forum the deans of California schools of pharmacy will present to the board their school's curriculum on patient consultation.

The board recessed for a break at 2:59 p.m. and resumed at 3:23 p.m.

The chairperson of the Competency Committee provided the board with a high-level review of the committee's work to update the CPJE. The chairperson also addressed the board's concerns with the perceived lack of law questions on the exam. It was noted that this is something that the committee has been discussing at their meetings.

Motion: Approve the new content outline for the California Jurisprudence Exam (CPJE).

M/S: Law/Veale

Support: 7 Oppose: 0 Abstain: 0

Note: Mr. Sanchez was not present for the vote.

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 Gutierrez adjourned the meeting at 3:56 p.m.

Thursday, June 4, 2015

Call to Order

9:09 a.m.

President Gutierrez called the meeting to order and established a quorum of the board. Board members present: Lavanza Butler, Albert Wong, Greg Lippe, Deborah Veale, Amy Gutierrez, Stanley Weisser, Victor Law and Ricardo Sanchez.

Board members not present: Rosalyn Hackworth, Ryan Brooks, Gregory Murphy and Allen Schaad.

Note: Ramon Castellblanch arrived at 9:38 a.m.

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

The board recognized Allen Gordon.

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

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

XIII. Oral Argument Upon Reconsideration of Decision – Vy Khanh Thi (Nguyen) Tarr, RPH 64465

The board heard oral arguments for the petition to reconsider the decision for Vy Khanh Thi (Nguyen) Tarr.

The board recessed to closed session at 10:25 a.m. to discuss the petition for reconsideration. The board resumed open session at 11:00 a.m.

XIV. SB 493 Implementation

a. Regulations Detailing Licensure Requirements for Advanced Practice Pharmacists (APP)

Chairperson Weisser reported that at the April 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 advance practice pharmacist. Additionally, a fee of \$300 was selected as the application and renewal fee for this license.

President Weisser noted that at the April board meeting, the board made several modifications in the text and referred the matter to the next SB 493 committee meeting. However, there has been no meeting of the committee and therefore the following items are being brought to the board for discussion and action at this meeting.

Chairperson Weisser explained that the following text was brought back to the board for its review and approval.

Note: The text modified by staff since the April board meeting is indicated in red and double underscore.

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 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 **(or confirming)** 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 composed of no fewer than 1,500 hours **of experience providing clinical services to patients**, earned over a period of no longer than four years. **If the qualifying experience was earned under a protocol, the experience must include initiating, adjusting or discontinuing drug therapy of a patient as authorized by law. The applicant shall demonstrate possession of such experience by providing both:** ~~The documentation of this experience that shall be provided to the board shall include both:~~

- ~~(1) An attestation~~ **A written statement** from the applicant pharmacist attesting under penalty of perjury that he or she has earned this experience **within the appropriate time frames**, and:
- ~~(2) An attestation or letter~~ **A written statement** 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.

Chairperson Weisser reviewed the changes to the language (in red) and opened the floor for discussion.

Upon recommendation from legal counsel, the board agreed to change “attesting” to “confirming” in section (a)(2).

Ms. Veale asked if the board should discuss the proposal from CPhA and NACDS to amend 1730 so that their changes could be incorporated in this rulemaking. President Gutierrez responded that CPhA and NACDS are proposing changes to the definitions in 1730 that the committee has not yet reviewed; therefore she would like the board to move forward with the rulemaking language (provided above) and allow the committee to further discuss the proposal from CPhA and NACDS at a future meeting.

President Gutierrez expressed concern that the proposed language does not include cross references to 4052.1 and 4052.2 to provide clarity on the term “clinical services.” Ms. McCaman explained that during the April board meeting, the board decided not to reference specific statutes, rather use the term “as authorized by law.” She also noted that she had reviewed the webcast to ensure that she drafted the language based on the board’s discussion.

President Gutierrez again expressed concern that the language was too broad and did not clearly define the experience providing clinical services a pharmacist must have prior to applying to becoming licensed as an APP. She further explained that she was concerned a pharmacist may apply for APP licensure with experience doing only *one* of the following clinical services: initiating, adjusting or discontinuing drug therapy. President Gutierrez stated that an APP should have experience providing *all three* of the services.

Dr. Castellblanch asked if staff reviewing the applications for the required clinical services would be pharmacists. Ms. Herold responded that the staff reviewing the applications would not be pharmacists; however if there was a question regarding the experience, it would be reviewed by a pharmacist staff member.

To address President Gutierrez’s concerns, Ms. Freedman suggested amending section (c) as follows: “...the experience must include initiating, adjusting ~~or~~ **and** discontinuing drug therapy of a patient as authorized by law.”

Brian Warren, with California Pharmacist Association, agreed with the suggestion from Ms. Freedman.

The board discussed the need to have clearly defined requirements in the regulation language as other states will be looking to see how California implements this program.

Kathy Besinque and Steve Gray asked the board to consider removing the requirement for the 1,500 hours to be earned over a period of no longer than four years. They explained that the time limit may eliminate those in academia and experienced pharmacists who are supervising other pharmacists who provide clinical services.

A representative from CSHP also expressed concern with the four-year time limit.

Chairperson Weisser explained that the committee discussed this portion of the language in detail at previous meetings; and the reason for the four year limit was to ensure that the applicant has current experience providing clinical services. Ms. Herold added that the board also wanted to be sure that the experience was gained during a concentrated period of time, rather than a few hours a month over numerous years.

As the board was unwilling to remove the four-year time period, Dr. Besinque and Dr. Gray asked the board to allow supervision of other pharmacists who provide clinical services to count towards the 1,500 hours. They said this would allow more experienced pharmacists who supervise others to fulfill the 1,500 hours of experience.

Sarah McBane, a pharmacist, noted that in North Carolina applicants have to submit either copies of the protocols to the board or fill out a form attesting to their experience. Ms. Herold reminded the board that the committee has looked at what other states are doing when drafting the regulation language.

Mr. Law stated that it is the board's duty to protect the public and therefore the board needs to ensure that applicants have up-to-date knowledge and current patient care experience.

President Gutierrez stated that the many of the items being discussed had been deliberated at previous committee meetings. She asked the board to move forward with the regulation process and allow stakeholders to make comments and recommendations as part of the 45-day comment period. The board agreed that it would be more efficient to move forward in the regulation process and allow comments to be provided during the rulemaking process.

The board agreed with Ms. Freedman's previous suggestion to amending section (c) as follows: "...the experience must include initiating, adjusting ~~or~~ and discontinuing drug therapy of a patient as authorized by law."

In addition to the attestation required in 1730.1 (c)(1), the board decided to require a protocol be provided whenever available. If the protocol is unavailable, then the applicant must provide a description of the activities.

Ms. Freedman asked if the board would also want a copy of a collaborative practice agreement. The board confirmed that the requirement would be to provide a copy of the protocol *or* the collaborative practice agreement.

Dr. Gray recommended that board use the term "collaborative practice authorization." Ms. Herold replied that the statute uses the term "collaborative practice agreement."

Motion: Direct staff to modify the language based on the board’s discussion and provide the modified language to the board president and SB 493 Committee chairperson to review. After the board president and committee chair have confirmed that the modified language conforms to the board’s discussion, direct staff to initiate a rulemaking and release the text for the 45- day comment period, and to return to the board with any negative comments, or otherwise prepare and submit the rulemaking file for approval by the Office of Administrative Law.

M/S: Weisser/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			

b. Future Qualifying Methods for APP Licensure

Chairperson Weisser explained that very recently, CPhA and NACDS provided the board with text that would establish a new process under which pharmacists could qualify for APP licensure. This text is provided below.

1730 Acceptable Certification Programs

- (a) In addition to certification programs recognized by the Accreditation Council for Pharmacy Education (ACPE) as described in Section 4210(a)(2)(A), 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).
- (b) For purposes of this section and Business and Professions Code Section 4210(a)(2)(A), a “certification program” means a program that meets one of the following criteria:
 - (1) The certification is granted to an individual to designate to the public that the individual has attained the requisite level of knowledge, skill, and/or experience in a well-defined area of pharmacy.
 - (2) The certification is issued to an individual after the successful achievement of performance in an accredited education or training program.
- (c) Further, certification programs recognized under this definition must meet all of the following criteria:
 - (1) Is aligned with the services permitted to be provided by an advanced practice pharmacist
 - (2) Is designed to measure advanced knowledge and skills in one or more areas of pharmacy practice through the use of written or practical knowledge assessments or examinations.
 - (3) Is developed and directed by recognized educational or pharmacy experts.

Chairperson Weisser stated that this would be the first opportunity for the board to discuss this language.

Note: At previous committee and board meetings the members discussed in detail the difference between a *certificate* program and a *certification* program. After much discussion and public comment the board elected to only accept *certification* programs that are certified by NCCA.

Jon Roth, from CPhA, and Alex Adams, with NACDS, provided a presentation on their proposal to establish a pathway for a pharmacist to satisfy the ‘certification’ criterion using *certificate* programs. A copy of the presentation is provided following these minutes.

Mr. Law asked if Dr. Adams or Mr. Roth had a specific certificate program in mind for the board to recognize as an additional pathway to licensure. Mr. Roth responded that they anticipate new programs to be created in response to this new licensure category. He noted that their proposed language would allow for the development of future programs.

Ms. McCaman stated that the statute specifically requires completion of a *certification* program. She also reminded the board that there are significant differences between *certificate* programs and a *certification* program.

Chairperson Weisser asked that this item be placed on the agenda of the next SB 493 Committee meeting so that it could be discussed in greater detail.

Motion: Place this item on the agenda of the next SB 493 Committee meeting.

M/S: Castellblanch/Sanchez

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			

c. Regulations to Implement the Non-Emergency Protocol for Pharmacists Who Furnish Naloxone, Including Labeling Requirements

Chairperson Weisser reported that on April 10, the board’s naloxone protocol became effective under emergency provisions that will last 180 days. The board used a subscriber email alert to

advise pharmacists and others that pharmacists who possess the one hour of training could provide naloxone to anyone requesting it. Chairperson Weisser noted that a fact sheet was also released that provides patient information about naloxone. He added that these items are also highlighted on the board's website.

President Weisser explained that the board now has until early October to notice and promulgate a naloxone protocol regulation to replace the emergency adoption version of the protocol.

Dr. Castellblanch commented that he would like the board to do more to promote the furnishing of naloxone by pharmacists.

Rebecca Cupp, from Ralph's, commented that Ralph's has finalized their protocol for furnishing naloxone and it will be rolling it out to all of their pharmacies soon.

President Gutierrez asked if the board could post on its website pharmacies that furnish naloxone. Dr. Wong added that the board could create a poster for pharmacies to display notifying patients that they can receive naloxone in the pharmacy.

A representative from Walgreens reported that they are reviewing their implementation plan for their California pharmacies to begin providing naloxone.

Al Carter from CVS reported that they are finalizing their training program so that CVS pharmacists in California can begin furnishing naloxone.

d. Requirements for Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices

Chairperson 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.

Chairperson Weisser stated that based on the discussions during the February and April board meetings, staff drafted language to establish parameters for those pharmacists who provide immunizations. One requirement is to mandate required reporting into an immunization registry. Chairperson Weisser reported that the current language requires reporting to the registry with 90 days. However, recently board staff received comments that 90 days is too long.

Ms. McCaman reported that she has been working with representatives from Los Angeles County Department of Public Health, and they have expressed concern with the 90-day reporting requirement. They asked the board to consider changing the language to require immunizations be reported into the appropriate database within 30 days. Ms. McCaman explained that reducing

the reporting time frame would help eliminate duplicate vaccines, provide accurate immunization records for school aged children, and ensure that patients are receiving their vaccines within the proper interval time-frames.

The board agreed to modify the language to require the reporting of vaccines into the immunization database within 30 days of administration. The board also agreed to require the pharmacist to report the immunization to the patient’s primary care provider within 30 days of administration.

Motion: Modify 1746.4 as provided below. Direct staff to initiate a rulemaking and release the text for the 45 day comment period.

M/S: Castellblanch/Butler

§1746.4 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, and
 - (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~~ 30 days 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~~ 30 days 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.

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			

Motion: Approve and adopt the rulemaking as prepared (above), and assuming that there are no negative comments, delegate to the executive officer the authority to make non-substantive changes to the language.

M/S: Lippe/Butler

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			

e. Development of Proposed Requirements for Pharmacists to Provide Prescription Medications Not Requiring a Diagnosis that Are Recommended by the CDC for Travel Outside the US

Chairperson Weisser reported that at the April committee meeting, the committee reviewed a draft regulation establishing requirements for pharmacists providing prescription medications not requiring a diagnosis as recommended by the CDC for travel outside the US.

Ms. McCaman recommended amending the language to require the pharmacist to notify the patient’s primary care provider of any drugs and or devices within 30 days. The board agreed to change the reporting requirements from 90 days to 30 days.

Motion: Modify 1746.5 as provided below. Direct staff to initiate a rulemaking and release the text for the 45 day comment period.

M/S: Castellblanch/Butler

§1746.5 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, and
 - (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~~ 30 days 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.

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			

Motion: Approve and adopt the rulemaking as prepared (above), and assuming that there are no negative comments, delegate to the executive officer the authority to make non-substantive changes to the language.

M/S: Weisser/Law

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			

The board thanked Ms. McCaman for her work on drafting the regulation language.

The board recessed for a break at 1:45 p.m. and resumed at 2:08 p.m.

XV. Legislation and Regulation

a. Board Sponsored Legislation

1. AB 1073 (Ting) Pharmacy: Prescription Drug Labels

Status: Double-referred to Senate Business Professions and Economic Development, and to Senate Judiciary

Chairperson Lippe explained that this bill would require dispensers to use a standardized direction for use on a label of a prescription container when applicable and would permit a dispenser, upon request, to select the appropriate translated directions for use to include on the prescription label or supplemental information. This bill also allows for a dispenser to provide his or her own translated directions. Chairperson Lippe 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 transcription of the translated directions.

Chairperson Lippe reported that the bill passed out of the Assembly on May 14, 2015. To date, there have been no nay votes on the measure. Board staff recently received possible amendments for consideration from interested parties. Chairperson Lippe concluded that staff will be working with the author's office to secure any additional amendments.

Dr. Castellblanch asked who would be held liable for a translation error when a pharmacy uses a vendor to translate materials. Chairperson Lippe responded that the pharmacy and the vendor would be liable. He noted that waiver of liability only applies to pharmacies who use the board-provided translated directions for use.

2. SB 590 (Stone) Pharmacy: Intern Licenses

Status: Hearing not yet scheduled.

Chairperson Lippe explained that this measure would 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 the measure was amended April 22, 2015 to address some concerns from the California Pharmacy Council. On April 30 the bill passed out of the Senate. Chairperson Lippe noted that to date there have been no "NAY" votes, and staff continues to address concerns and respond to inquiries regarding the measure.

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

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

Status: Held on suspense for appropriations in the Senate.

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

Ms. Herold reported that the bill has been held on suspense for appropriations in the Senate. She explained that because of this, the bill will be moved in January or reintroduced.

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

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

1. AB 45 (Mullin) Household Hazardous Waste

Status: Hearing postponed by Appropriations

Board Position: Oppose Unless Amended

Chairperson Lippe explained that the intent of AB 45 is to enact legislation that would

establish various household hazardous waste collection programs, including curbside, door-to-door and residential pickup services as a principal means of collection such waste and diverting it from California's landfills and waterways. This measure would require each jurisdiction that provides for residential collection and disposal of solid waste, including household pharmaceutical waste, to increase its collection and diversion of such waste by 15% by July 1, 2020 unless otherwise specified.

Chairperson Lippe reported that following the April board meeting, staff offered amendments to require the use of mail-back programs unless the jurisdiction complies with the provisions of federal law related to the safe collection and disposal of such waste. However those amendments were not accepted.

Chairperson Lippe stated that in its current form, it is unclear to staff what safety measures would be in place to ensure the security of the home-generated pharmaceutical waste, given the various components allowed in the bill.

President Gutierrez noted that the Enforcement committee will be discussing drug take-back at their next committee meeting.

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

Status: Senate Business Professions and Economic Development.

Board Position: Support

Chairperson Lippe reported 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. He added that this bill contains an urgency clause, which would enact the provisions upon signature by the Governor and the filing with the Secretary of State.

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

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

Status: Died in Appropriations.

Board Position: Oppose

Chairperson Lippe explained that AB 623 would have required a pharmacist to inform a patient receiving an opioid analgesic drug product on the proper storage and disposal of the drug. Also, it would have prohibited a health care service plan from requiring the use of opioid analgesic drug products without the abuse-deterrent properties.

Chairperson Lippe reported that this bill did not make it off the Suspense File in Assembly Appropriations. However, the author's office did say that it is very likely they will reintroduce something similar in the second half of the session. Chairperson Lippe concluded that staff plans to stay in touch with the author's office and address any questions they may have.

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

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

Status: Third reading

Board Position: Oppose Unless Amended

Chairperson Lippe explained that AB 1069 would expand the provisions under which a county established repository and distribution program allows the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

Chairperson Lippe reported that since the April board meeting, staff has been working with the author's office to address many of the legal conflicts the measure initially contained – and the amended version is significantly scaled back from the prior version. Staff believes there are still some concerns with the current language and the author's office has indicated that they would like to explore some additional possible amendments and that they will work with the board.

Ms. Sodergren stated that there are three main issues that staff is working to address:

- The bill would allow a participating pharmacy to transfer donated drugs to another county – not just an adjacent county. Staff determined that this provision would be acceptable so long as it doesn't delay a patient's access to therapy, and so long as the transfer is consistent with other Pharmacy Law provisions.
- The bill would allow the advance repackaging of the donated drugs. Staff has conveyed to the author's office that the board would entertain amendments that would further define restrictions on repackaging, but staff has yet to see language to address this.
- Staff is concerned that the lot number will not be on the prescription container. Staff has told the author that so long as the receiving pharmacy can verify the chain of custody of the drug the board would consider such an amendment. However, the author's office had not yet provided any language to formally consider.

Chairperson Lippe concluded that board staff will continue to work with the author's office.

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

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

Status: Passed out of Assembly Appropriations

Board Position: Oppose

Chairperson Lippe reported that AB 1351 would significantly change the deferred entry of judgment program into a pretrial diversion program, expand the conditions under which an individual could be granted deferred entry of judgment, and reduce the duration of the program to as little as six months.

Ms. Sodergren explained that SB 1351 will significantly impact the board's ability to take appropriate action against an applicant or licensee.

Chairperson Lippe concluded that staff has advised the author's office of the board's concerns.

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

Note: Dr. Castellblanch left the meeting at 2:20 p.m.

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

Status: Re-referred to Senate Public Safety Committee

Board Position: Oppose

Chairperson Lippe stated 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 defendant performed satisfactorily during the deferred entry of judgment period, and if the defendant attests on a form developed by the Judicial Council that the plea may result in the denial or loss of the defendant's employment, benefit, license or certificate.

Chairperson Lippe reported that board staff advised the author's office of the board's concerns with this measure including the concern that this bill would eliminate the board's discretion in making licensing decisions based upon prior criminal convictions that have been withdrawn.

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

7. SB 671 (Hill) Pharmacy: Biological Product

Status: Held at desk.

Board Position: Oppose Unless Amended

Chairperson Lippe explained 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 and the prescriber does not personally indicate "Do not substitute."

Ms. Sodergren reported that at the April board meeting the board discussed this bill and determined that the notification back to the prescriber was unnecessary and may cause delays in patients getting their medications. She added that staff conveyed the board's position to the author's office and requested that the pharmacist notification requirement be removed from the bill. The author's office indicated that this requirement is a core component of the bill and will not be eliminated.

Dr. Law asked if there was a similar bill last year. Ms. Herold confirmed that there was a similar bill vetoed the year before.

c. Legislation Impacting Board Operations

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

Status: Passed out of Appropriations

Board Position: No position. This is the first time the board has discussed the bill.

Ms. Sodergren explained that AB 12 would require state agencies and departments to review, adopt, amend or repeal any application regulations that are duplicative, overlapping, inconsistent, or out of date by January 1, 2018. This measure also would establish notice and reporting requirements. Ms. Sodergren stated that staff is recommending an oppose position.

Ms. Herold noted that as part of the Sunset Review process the board does much of the review that this bill is seeking.

Motion: Oppose AB 12.

M/S: Weisser/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			

2. AB 85 (Wilk) Open Meetings

Status: Passed out of Assembly Appropriations

Board Position: Oppose

Chairperson Lippe reported 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 following the April board meeting, staff advised the author's office of our position as well as the reason for the opposition. The author asked staff for input or technical changes to address the board's concerns, but ideas and options offered by staff were not accepted.

Chairperson Lippe concluded that the author's office has indicated a willingness to address the board's concerns, but a solution has not been identified.

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

3. AB 1060 (Bonilla) Professions and Vocations: Licensure

Status: Awaiting Hearing Date

Board Position: Oppose

Chairperson Lippe reported that this measure would require the board to advise an ex-licensure about 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-licensure.

Ms. Sodergren explained that at the April board meeting the board took an oppose position due to the ambiguity of the email reporting requirements. Following the April meeting, board staff advised the author's office of our concerns. She noted that the author's office indicated it is working on possible amendments that may address the board's concerns (as well as comments from other DCA boards).

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

4. SB 467(Hill) Professions and Vocations: Administrative Expenses

Status: On the Senate 3rd Reading File

Board Position: No position. This is the first time the board has discussed the bill.

Ms. Sodergren reported that this bill would require pro rata assessed by the Department of Consumer Affairs to be approved by the legislature, would require the Attorney General to submit an annual report on various workload measures and would direct the director of DCA to work with healing arts boards to standardize referral of complaints consistent with a memo issued under a prior DCA director.

Ms. Sodergren explained each board within DCA regulates a unique practice setting and therefore has different priorities when reviewing complaints. Staff is concerned that this bill would require all DCA board's to use a standard set of priorities when reviewing complaints. Ms. Sodergren asked the board to allow staff to work with the department and the author's office to address the concerns. The board directed staff to work with the author's office and the department (no position was taken).

XVI. Organizational Development

a. Fee Audit Update

President Gutierrez reported that the board secured a contract with a company to conduct an independent audit of the board's fee structure to determine the costs to deliver services. The intent of the audit was to address the structural imbalance of the board's current budget and to determine the appropriate fees that should be assessed for various application and renewal fees.

President Gutierrez stated that unfortunately, after consultation with the DCA’s budget office, it is clear that the board is unable to use the draft information provided by the contractor. The board has severed its contractual relationship with the vendor.

President Gutierrez concluded that the DCA’s budget office will complete the necessary independent assessment and provide written recommendations on the appropriate fees necessary to ensure the board receives full recovery for the costs it incurs to deliver services.

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

b. Determination of Reimbursement Rates for Specified Inspector Duties

President Gutierrez explained that Business and Professions Code Section 125.3 provides the authority for an administrative law judge to direct a licensee to pay a cost recovery fee, including the reasonable costs of the investigation and enforcement of the case. Additionally, Business and Professions Code Section 4400(v) provides the authority for the board to collect the costs necessary to cover the board’s expenses relating to performing the inspection of a nonresident sterile compounding pharmacy.

President Gutierrez stated that the board uses an internal activity tracker to manage the activities completed by field staff. The information from this activity tracker is then used to demonstrate the inspector’s time related to a case.

President Gutierrez reported that the board currently assesses a reimbursement rate of \$102/hour for inspector’s time, which was the recommended rate provided during the last independent fee audit of the board.

President Gutierrez explained that at the board’s request the DCA budget office has completed an assessment and determined \$121/hour and \$127/hour would be appropriate hourly rates for inspectors and supervising inspectors respectively.

Motion: Approve the new rates of \$121/hour for inspectors and \$127/hour for supervising inspectors. The new rates will become effective July 1, 2015.

M/S: Weisser/Law

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			

c. Request for the Board to Award Continuing Education Credit for Critical Point USP Chapter 797 Compliance Training

President Gutierrez reported that on May 27 to 28, 2015, board inspectors as well as pharmacists employed by the Department of Public Health, received two days of intensive sterile compounding training. This training was designed to provide board inspectors with the opportunity to secure the knowledge and skills necessary to facilitate regulatory inspections of pharmacies that compound sterile injectable products. President Gutierrez noted that she and Allen Schaad had attended the training, as well.

Note: This training meets the criteria for continuing education coursework established in California Code of Regulations Section 1732.3.

President Gutierrez reported that the training had been very helpful to her and Mr. Schaad.

Motion: Approve 14 hours of continuing education for all pharmacists who completed the training (board inspectors, Department of Public Health pharmacists and two pharmacist board members).

M/S: Veale/Weisser

Support: 7 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			

d. Sunset Oversight Review of the Board of Pharmacy 2015-2016

President Gutierrez reported that on April 30, 2014, board staff received notice that the Senate Committee on Business, Professions and Economic Development and the Assembly Committee on Business and Professions will begin its Sunset Oversight Review this fall.

President Gutierrez explained that as part of the review process, board staff will prepare a report that addresses 13 specific content areas requested by the committee. The report is due December 1, 2015.

Ms. Herold explained that historically the development of this report has been a significant undertaking by board staff. Because of the due date of the report, board staff would request board consideration to delegate review of the report to either an ad hoc committee of the board or the board’s organizational development committee. Ms. Herold stated that the committee would review the draft and provide general direction to staff as necessary.

President Gutierrez stated that she would like the Organizational Development Committee to review the report and provide general direction to staff as necessary.

Ms. Herold added that the final report would be provided to the board during the January 2016 meeting.

Motion: Direct staff to complete the Sunset Review Report and provide it to the Organizational Development Committee for review and general direction, as necessary.

M/S: Weisser/Lippe

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			

XVI. Organizational Development

President 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 added that the board submitted comments under three categories, under President Weisser’s signature.

a. Draft Guidance: For Entities Considering Whether to Register As Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act

President Gutierrez explained that this guidance states that entities registered with the FDA as outsourcing facilities will be regulated as outsourcing facilities according to current good

manufacturing practice requirements (cGMP) for all products they produce or compound. (Federal law allows outsourcing facilities to be sterile compounding pharmacies, as well.) President Gutierrez noted that there are approximately 50 FDA-registered outsourcing facilities, including one in Switzerland.

President Gutierrez reported that the outsourcing guidance states that if a facility does not intend to compound all drugs under cGMPs, then the facility should not be registered as an outsourcing facility. Additionally, the facility:

- Must be engaged in the production of compounding sterile human drugs.
- Does not repackage drugs (except as discussed in other guidance documents)
- Does not produce biologic drugs
- Does not produce animal drugs

The board's comments on this guidance can be found in the board meeting materials using the following link. http://www.pharmacy.ca.gov/meetings/agendas/2015/15_jun_bd_fda.pdf

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

b. Draft Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act

President Gutierrez explained that this guidance provides that outsourcing facilities are required to report adverse drug events to the FDA within 15 days. Specifically, all serious, unexpected adverse drug experiences associated with the use of their compounded prescription drug products must be reported and the FDA "strongly recommends" that outsourcing facilities report all serious adverse drug experiences generally.

President Gutierrez stated that the guidance lists four elements for the investigation to include: the patient, the reporter, the suspect drug, the serious adverse event. It then describes the specific details about each element to include in the report.

Ms. Herold noted that the 15-day reporting requirement for adverse events in the guidance document is longer than the 12-hour requirement in existing California law for compounding pharmacies to report to the board any drug recalled.

The board's comments on this guidance can be found in the board meeting materials using the following link. http://www.pharmacy.ca.gov/meetings/agendas/2015/15_jun_bd_fda.pdf

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

c. Draft Memorandum of Understanding Between a State and the U.S. Food and Drug Administration Addressing Certain Distributions of Compounded Human Drug Products

President Gutierrez read the following paragraph from page 1 of the guidance document:

"This Memorandum of Understanding (MOU) establishes an agreement between the State of [insert State] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug

products interstate and the appropriate investigation by the State of [insert State] of complaints relating to compounded human drug products distributed outside the state. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 353a), and does not apply to drugs that are compounded by registered outsourcing facilities.”

President Gutierrez explained that the MOU exempts the compounded products of pharmacies under specific circumstances, including providing the state has entered into the MOU, from:

- Complying with cGMPs
- Labeling with adequate directions for use
- Possessing FDA prior approval of the drug product

President Gutierrez explained that if the state has entered into the MOU, then the MOU:

- Requires the home state to investigate issues arising from the interstate distribution of compounded drugs by a pharmacy and to identify the root cause of the problem, and take response to the action
- Requires the state to review compounding records during the inspections of compounding pharmacies to ensure the compounding pharmacy has not distributed an inordinate amount of compounded drug product interstate.
- Defines an inordinate amount as not more than 30 percent of the total number of compounded and non-compounded drug products distributed or dispensed (both in-state and interstate).

The board’s comments on this guidance can be found in the board meeting materials using the following link. http://www.pharmacy.ca.gov/meetings/agendas/2015/15_jun_bd_fda.pdf

Ms. Herold noted that at some point in the future, once finalized, the board will need to determine whether it wishes to enter into such an agreement with the FDA. She added that the FDA has extended the deadline to submit comments on this guidance document because they have received so many comments from stakeholders. Ms. Herold also stated that many states have provided negative feedback on the document.

The board discussed their concerns with the 30 percent cap on the total number of compounded and non-compounded drug products distributed or dispensed (both in-state and interstate).

Dr. Gray, from Kaiser, recommended working with other states to negotiate with the FDA for better terms in the MOU.

d. Draft Guidance for Industry: Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

President Gutierrez reported that the board has not yet submitted comments on this guidance document, but staff intends to provide comments on the guidance document before the July Board Meeting.

President Gutierrez read the following paragraph from Page 3 of this guidance:

“When a drug product is prepackaged, its characteristics may change in ways that have not been evaluated during the FDA approval process and that could affect the safety and efficacy of the drug product. Improper repackaging of drug products can cause serious adverse events. Of particular concern is repackaging of sterile drug products which are susceptible to contamination and degradation. For example, failure to properly manipulate sterile drug products under appropriate aseptic conditions could introduce contaminants that could cause serious patient injury or death. Repackaging practices that conflict with approved product labeling could result in drug product degradation and adverse events associated with impurities in the product or lack of efficacy because the active ingredient has deteriorated.”

President Gutierrez explained that drugs that are repackaged are not regulated by the FDA under provisions dealing with pharmacy or outsourcing facilities. The guidance states that the FDA does not intend to take action for certain violations of federal requirements for entities that repackage drugs, provided:

1. The facility is licensed by a state as a pharmacy or holds an outsourcing facility license
2. If the repackaging occurs in a pharmacy or federal institution only: 1. after receipt of a patient-specific prescription or written chart order, or 2. Repackaged in advance of receipt of a patient-specific order based on prior demand for a previous, consecutive 14-day period AND history for prior 14-day periods.
3. The repackaging is done by or under the supervision of a licensed pharmacist
4. For single dose vials, the repackaging does not conflict with drug product labeling
5. For single dose vials repackaged into multiple units, the product is repackaged in a way that does not conflict with drug product labeling
6. The repackaged drug product conforms to specific beyond use dating (BUD)
7. Provides different requirements for BUD for an outsourcing facility, and requires CGPMs for the repackaging processes. Additionally the guidance provides labeling requirements for the repackaged product.
8. The repackaged product is not sold or transferred by an entity other than the one that repackaged the product.
9. The repackaged drug product is distributed only in states in which the facility repackaging the product meets all applicable state requirements.
10. Addresses guidance for repacking drugs on the FDA’s drug shortage list.

Ms. Herold reported that staff would draft the guidance document for signature by the board president and submit it to the FDA.

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

President Gutierrez adjourned the meeting at 3:08 p.m.

Testimony regarding proposed CCR Section 1730

June 4, 2015

California Pharmacists Association

National Association of Chain Drug Stores

Advanced practice pharmacist

- Section 1730 “Acceptable Certification Programs”, as proposed:
 - Requires additional clarification for all statutorily allowable certification programs.
 - Can be better-aligned with the Council on Credentialing in Pharmacy by adding a definition.
 - Requires specificity to provide the Board of Pharmacy with protections against programs that do not meet the rigor for assessing advanced practice pharmacist skills.

California Pharmacists Association

National Association of Chain Drug Stores

Advanced practice pharmacist

- 4210(a)(2)(A) - A person who seeks recognition as an Advanced Practice Pharmacist shall meet **any two** of the following requirements:
 1. Earn certification in a relevant area of practice
 2. Complete a postgraduate residency
 3. Provide clinical services to patients for at least one year under a collaborative practice agreement

Advanced practice pharmacist

- A person who seeks recognition as an Advanced Practice Pharmacist shall meet any two of the following requirements:
 1. **Earn certification in a relevant area of practice**
 2. Complete a postgraduate residency
 3. Provide clinical services to patients for at least one year under a collaborative practice agreement

Certification

Section 4210(a)(2)(A):

“Earn certification in a relevant area of practice from...”

1. ... an organization recognized by the Accreditation Council for Pharmacy Education (ACPE), **or**
2. ... another entity recognized by the board.”

These are the two methods by which certification can be achieved to meet criterion #1 of the Advanced Practice Pharmacist credential in 4210(a)(2)(A).

Draft Regulations Sec 1730

- The proposed draft regulations for CCR Section 1730 only addresses “... *or another entity recognized by the Board.*”
- The draft regulations requires additional guidance as to the quality and nature of a certification program being offered under the other statutorily-permitted pathways.
- Additional regulatory language is necessary to ensure that those program qualifying under ACPE meet the rigor and assessment of pharmacist’s skills for performing Advanced Practice Pharmacist scope of practice.

Certification

Section 4210(a)(2)(A):

“Earn **certification** in a relevant area of practice from...”

- The term “certification” is not defined in law.
- Certification is a term of art in the credentialing industry that refers to the confirmation of certain characteristics of a person after some form of external review, education, assessment, or audit*.

*Institute for Credentialing Excellence, accessed 5/27/15

California Pharmacists Association

National Association of Chain Drug Stores

Certificate

- According to the Institute for Credentialing Excellence, assessment-based **certificate programs**:
 1. Provide instruction and training to aid participants in **acquiring specific knowledge, skills, and/or competencies** associated with intended learning outcomes;
 2. **Evaluate participants' achievement** of the intended learning outcomes; and
 3. Award a certificate only to those participants who meet the **performance, proficiency or passing standard** for the assessment(s)

California Pharmacists Association

National Association of Chain Drug Stores

Certification

- According to the Institute for Credentialing Excellence, **certification**:
 1. Provides an independent **assessment of the knowledge, skills, and/or competencies** required for competent performance of an occupational or professional role;
 2. Is intended to **measure or enhance continued competence** through recertification or renewal requirements;
 3. Certification designates that participants have **demonstrated the requisite, work-related knowledge, skills, or competencies** and met other requirements established by the certification program provider.

Certificate and Certification

Under these universally-accepted definitions there is commonality among both certificate and certification:

1. Acquiring or possessing specific knowledge, skills, and/or competencies; and
 2. A demonstration/assessment of participants' achievement of those skills;
- Thus the statute clearly intends to permits multiple pathways for pharmacists to meet criterion #1 for the Advanced Practice Pharmacist under 4210(a)(2)(A).

Certificate and Certification

Examples of the multiple pathways for pharmacists to meet criterion #1 for the Advanced Practice Pharmacist.

- ACPE accredited, assessment-based Certificate Programs
 - Example: Canadian/APhA ADAPT Program
- NCCA accredited Certification Programs
 - Examples: Board of Pharmacy Specialties; Commission for Certification in Geriatric Pharmacy
- Multidisciplinary Certifications
 - Examples: Certified Diabetes Educator, Certified Asthma Educator

Certificate and Certification

Institute for Credentialing Excellence summarizes the difference in assessment-based certificate and certification this way:

“One program type is not more or less rigorous than another. They simply serve different purposes and may require different business approaches, governance structures, development processes, etc.”

Suggested Revisions to CCR 1730

- 1730 (a): Remains as drafted with substantive clarification added to reference all permitted pathways under 4210(a)(2)(A).
 - ACPE recognized organizations, or
 - Another entity recognized by the board
- Three technical corrections:
 - NCCA accredits programs, it does not certify programs.
 - The name of NCCA includes Certifying, not Certification Agencies.
 - Adds 'post graduate' to b(2) to clarify the type of programs.

Suggested Revisions to CCR 1730

- 1730 (b): Adds a definition of 'certification' into law to ensure any certification offered for satisfying 4210(a)(2)(A):
 - (1) Utilizes the ICE and Council on Credentialing in Pharmacy (CCP) definitions for attaining the requisite level of knowledge, skill and/or experience in pharmacy practice, and;
 - (2) The certification can only be issued after successful achievement of a performance assessment.

Provides important clarity to program providers regarding the distinction in both types of qualifying certification programs.

Suggested Revisions to CCR 1730

- 1730 (c): Defines the criteria for all certification programs as needing to be:
 - (1) Aligned with the services permitted to be provided by an advanced practice pharmacist
 - (2) Designed to measure advanced knowledge and skills using written or practical knowledge assessments or examinations
 - (3) Developed and directed by recognized educational or pharmacy experts.

These criteria assure the BoP that only programs related to the scope of APP practice would be qualified (e.g. not immunization certificate).

Concluding Remarks

- As the sponsors of SB493, it is clear in the statutory language that the intent behind Sec. 4210(a)(2)(A) was to:
 - Provide multiple pathways for a pharmacist to satisfy the 'certification' criterion using certificate programs accredited by ACPE as well as certification programs from other providers "recognized by the Board";
 - However, additional regulatory language ensures clarity in the use of the term 'certification' by defining the term in law; and
 - Adds important protections to the BoP with regard to the types of criteria that any ACPE or other entity approved by the Board must include in their certification programs.


Thank you

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SB 1441

Uniform Standards Regarding
Substance-Abusing Healing
Arts Licensees



Uniform Standard

- Diagnostic Evaluation
- Temporary Removal from Practice
- Communication with Employer
- Drug Testing
- Support Group Meetings
- Types of Treatment
- Worksite Monitors



Standards Continued

- Positive Drug Test
- Ingestion of Banned Substance
- Major and Minor Violations
- Petitions to Return to Practice on a Full Time Basis
- Petition for Reinstatement of a Full and Unrestricted License
- Private Sector Vendor Requirements



Standards Continued

- Confidentiality
- External Audit of Contractor
- Measurable Criteria for Standards



Implementation Recommendation

- Disciplinary Guidelines
- Procedure Manual
- Contractual Requirements



Standard Four

- Requirements on the participant
- Requirements on the board
- Requirements on contractor



Implementation Timeline

- June 2015: Staff work with ad hoc committee
- July 2015: Board considers regulation language
- August 2015: Initiate Rulemaking
- October 2015: Adopt regulation language
- November 2015: Submit rulemaking



Implementation Timeline Con't

- November 2015: Submit rulemaking for review
- January 2016: Submit rulemaking to OAL
- April 2016: New regulation takes effect