



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
LICENSING COMMITTEE MEETING MINUTES**

DATE: June 18, 2014

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Deborah Veale, RPh, Chair
Lavanza Butler, PharmD
Victor Law, RPh
Albert Wong, PharmD

COMMITTEE MEMBERS

NOT PRESENT: None

STAFF

PRESENT: Virginia Herold, Executive Officer
Rob Buckner, Manager

Call to Order

Chair Veale called the meeting to order at 10:10 a.m.

Chair Veale provided instructions for meeting attendees interested in receiving continuing education credit to sign in at the back of the room.

Chair Veale conducted a roll call. Committee Members Lavanza Butler, Victor Law, and Albert Wong were present. Board member Alan Schaad was present in the audience.

1. Presentation by Pharmacist Planning Service, Inc. on a Proposal to Eliminate Tobacco Products from Pharmacies

In early February 2014, CVS announced that it would move to stop selling tobacco products from its stores in the fall. At this meeting, Pharmacist Planning Services Inc. presented information and spoke in support of eliminating tobacco product sales from pharmacies.

Ms. Herold explained the Board does not have the authority to restrict tobacco sales in pharmacies and that any move to eliminate tobacco sales would probably need to be done legislatively. She

indicated the Board could, however, create a policy statement regarding the adverse health effects of tobacco.

The Committee heard public comment in support of creating a policy. Steve Gray provided background on The California Pharmacist's Association's (CPhA) policy of supporting the restrictions of tobacco sales in any facility that houses a pharmacy and the American Pharmacist's Association' (APhA) policy which states that government should not allow a pharmacy that sells tobacco products to participate in government health networks (Medi-Cal, etc.).

A representative of the California Society of Health System Pharmacists (CSHP) provided background into CSHP's policy supporting the elimination of tobacco sales from all California pharmacies and establishments that house a pharmacy.

A representative from the California Retailer's Association spoke in opposition.

Committee Recommendation

Motion: Recommend that the Board adopt a policy in support of eliminating tobacco and e-cigarette sales from California Pharmacies.

M/S: Butler/Law

Support: 4 Oppose: 0 Abstain: 0

2. **Request from California Health Sciences University Possessing ACPE "Pre-Candidate" Accreditation for Recognition by the Board of Pharmacy Under 16 CCR § 1719 for Purposes of Issuing Intern Licenses**

Current regulation, Title 16 CCR 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE). Specifically:

1719. Recognized Schools of Pharmacy.

As used in this division, "recognized school of pharmacy" means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

There are three levels to full ACPE accreditation status for new schools or pharmacy: pre-candidate status, candidate status and full accreditation. A school may be granted candidate status once the school has produced its first class of graduates. At this point, section 1719 allows the board to issue intern licenses to current and future students. However, before possessing candidate status and while students are moving through the program at a new school, the school may have pre-candidate status with ACPE. This means that the school is progressing to meet the ACPE accreditation standards but has neither completed the process nor graduated its first class. In such cases, the board must recognize the school for purposes of issuing an intern license. In order to secure the training expected by ACPE, students need intern licenses.

ACPE does not award pre-candidate status to new schools that are not adequately progressing towards full accreditation.

There are at least three new schools of pharmacy seeking to establish themselves in California. Only one possesses pre-candidate status at the time of this June 18 meeting.

The California Health Sciences University School of Pharmacy, Fresno, CA, (CHSU) has been granted pre-candidate status by the ACPE. The first class of students will be admitted in the fall of 2014. In order for the school's students to secure the training they need, the students need intern licenses. Lacking ACPE candidate status, the board cannot currently issue these licenses to students.

Recently, CHSU requested board recognition of its program for purposes of issuing intern pharmacist licenses to students attending their program.

Typically pharmacy programs that advance to candidate status do achieve full accreditation status, but ACPE cannot guarantee that any particular school will do so in the future.

Staff recommends that the board recognize CHSU for purposes of issuing intern licenses to its students. Staff will maintain contact with ACPE to ensure the school continues to move towards full ACPE accreditation status in the future.

At this meeting, the Committee discussed many scenarios for students of CHSU. There were no representatives from CHSU and there was no public comment.

Committee Recommendation

Motion: Recommend that the Board recognize the California Health Sciences University School of Pharmacy.

M/S: Butler/Law

Support: 3 Oppose: 0 Abstain: 1 (Wong)

3. Results of Continuing Education Audits of Pharmacists in California

Periodically, the board reviews statistics regarding the status of continuing education (CE) audits conducted on pharmacists who state under penalty of perjury on their license renewals that they have earned 30 hours of CE as required.

At this meeting, Ms. Herold stated approximately 20 percent of those who are audited are not able to provide proof they have completed 30 hours of CE. She also spoke of the need for Pharmacists to safely store their CE certificates for four years in case they are audited. There was no public comment.

4. Request for a Waiver Under California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Sections 4128 et seq.

- a) Mercy Hospital of Folsom**
- b) Loma Linda University Medical Center**

In 2012, CSHP and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are barcoded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012).

Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read. The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals. Specifically, the board's letter to the governor included the following:

“...Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient's chart and a patient's wristband the right medication, in the right dose will be ensured at the patient's bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events...”

At the January 2014 Board Meeting, Sharp Hospital and Scripps Health San Diego appeared before the board seeking an exemption to allow them to secure a centralized packaging license, but limitations in their software that prohibit full compliance with the barcode requirements specified in Section 4128.4. The items listed in section 4128.4 appear on the label but not in the barcode. Instead Scripps Health System and Sharp Hospital requested that the board interpret the meaning of those provisions more broadly to allow additional time following licensure for the hospitals to fully comply with the requirements in statute.

Section 4128.4 requires:

4128.4. Barcode Required; Information Retrievable Upon Reading Barcode

Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

- (a) The date the medication was prepared.
- (b) The components used in the drug product.
- (c) The lot number or control number.
- (d) The expiration date.
- (e) The National Drug Code Directory number.
- (f) The name of the centralized hospital packaging pharmacy.

The board approved both waivers.

Mercy Hospital of Folsom and Loma Linda University are requesting similar waivers from the board.

At this meeting, representatives from Mercy Hospital of Folsom provided information about their current barcoding system and spoke in support of obtaining a waiver. There were no representatives from Loma Linda University Medical Center.

A representative from CSHP stated that CSHP is working with the board to write legislation to clarify the language in Business and Professions Code section 4128.4.

Committee Recommendation

Motion: Recommend that the board approve a five-year waiver for Mercy Hospital of Folsom. As long as the lot number is provided on the label and the required data elements are otherwise retrievable, waive the requirement that the data elements in section 4128.4 be retrievable at the patient's bedside by way of a barcode.

M/S: Law/Wong

Support: 4 Oppose: 0 Abstain: 0

5. Discussion on Reporting of Intern Hours Earned for Interns in ACPE Accredited Schools

At the March Licensing Committee and the April Board Meeting, the board discussed the topic of the reporting of intern hours for purposes of qualifying to take the CPJE. At the April Board Meeting, the board agreed to revise the current process used by the board.

To secure this action, a statute and regulation will need modification. Additionally this committee needs to recommend to the board a new process for validating the intern hours earned by students in ACPE-approved schools. Existing provisions will remain for foreign-educated pharmacists who possess FPGEC certification, but need 1,500 hours of intern experience to qualify to take the CPJE.

California Business and Professions Code section 4209 provides:

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an

applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

Board regulations provide additional requirements for earning intern hours:

1728. Requirements for Examination.

- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
- (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
 - (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
 - (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
 - (C) Experience in both community pharmacy and institutional pharmacy practice settings.
 - (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

There are two areas where the intern hours completed can be recorded: (1) Number of hours of pharmacy practice experience obtained in a pharmacy, and (2) Number of hours of pharmacy practice experience substantially related to the practice of Pharmacy.

Staff recommendations:

1. For California Pharmacist Applicants who Graduated After June 2010:
 - (a) If not licensed in any state in the US:
 - Accept a certified copy of a transcript from the ACPE-approved school of pharmacy identifying that the student has fulfilled all requirements and earned a doctor of pharmacy degree
 - OR
 - Require a letter from the ACPE-approved school of pharmacy that the student has completed at least 1500 hours of intern experience while completing the PharmD curriculum
 - (b) If licensed for one year in any state in the US -- no change—accept licensure for one year as fulfilling the intern hours requirement
 - (c) If a graduate of a foreign school of pharmacy, possessing FPGEC certification
 - No change --must submit intern hours on the intern hours affidavit forms. If hours earned outside California, must provide proof of licensure as an intern in that state and still require intern hours forms to total 1,500 hours. The state will not have to certify the forms nor collect the hours to transfer to CA.

Chair Veale provided background information and the committee reviewed staff recommendations and made additional suggestions for proposed amendments to current Pharmacy Law to address changes to the intern hours process. There was no public comment.

Committee Recommendations

Motion: Recommend that the board sponsor amendments to section 4209 of the Business and Professions Code in the 2015 legislative session as follows:

(a) (1) An intern pharmacist shall complete at least 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.
(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist who has graduated from a school of pharmacy on or after January 1, 2016, which has been accredited by the Accreditation Council for Pharmacy Education as provided in section 4200 shall be deemed to have complied with the intern experience requirements specified in subdivision (a) upon award of a PharmD degree. The board shall accept fulfillment of at least 1,500 hours of intern experience upon receipt of a certified transcript from the school of pharmacy which posts the PharmD degree.

(c) Applicants seeking intern experience outside of the PharmD curricula in a school of pharmacy accredited by the Accreditation Council for Pharmacy Education shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.

~~(e)~~ (d) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience, provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

M/S: Law/Butler

Support: 4 Oppose: 0 Abstain: 0

Motion: Recommend that the board adopt the revisions to CCR 1728 for the 2015 legislative session, as follows:

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of at least 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) [Proof of completing at least 1,500 hours of pharmacy practice experience by graduates of a school of pharmacy accredited by the Accreditation Council for Pharmacy Education on or after January 1, 2010, shall be deemed to have fulfilled this requirement by the award of a PharmD degree posted to the graduate's transcript.](#)

~~(2)~~ (3) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

~~(3)~~ (4) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

~~(4)~~ (5) A signed copy of the examination security acknowledgment.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

M/S: Law/Wong

Support: 4 Oppose: 0 Abstain: 0

6. Review and Discussion of Questions on Applications to Collect Prior Conviction Information

At the request of the DCA legal office, the committee in December 2013 began a discussion to revise the 'conviction questions' on the board's individual applications. This was requested by the department in an effort to provide uniformity throughout the boards and bureaus.

Unlike other professions, working in a pharmacy or drug wholesaler gives individuals direct access to dangerous drugs, including controlled substances. The board needs to determine how it will address prior convictions involving drugs.

The committee discussed the language proposed by the department, as well as the current language on the Pharmacist, Pharmacy Technician and other personal license applications.

The 'conviction question' language discussed was:

"Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?"

Check the box next to **"YES"** if you have ever been convicted or plead guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanor, and felonies. You do not need to report a

conviction for an infraction with a fine of less than \$300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea of no contest and any convictions that were subsequently set aside pursuant or deferred pursuant to sections 1000 or 1203.4 of the Penal Code.

Check the box next to "NO" if you have not been convicted of a crime.

You may wish to provide the following information in order to assist in the process of your application: 1) certified copies of the arresting agency report; 2) certified copies of the court documents; 3) and a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required. **Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary."**

Chair Veale provided background and read opinions from various attorneys regarding the proposed changes to the conviction questions.

Via telephone, Supervising Deputy Attorney General, Joshua Room, provided additional information and reviewed his proposed language. The Committee asked questions and made recommended revisions.

Dr. Law asked whether the application could include a list of convictions for which an applicant would most likely be denied. Mr. Room thought it would be a good idea to create a list in regulation to define those crimes which the board feels are substantially related to the duties and functions of a licensee.

Steve Gray suggested the application be updated to further explain the definition of an infraction for the benefit of applicants and limit the period of inquiry to five years.

The committee also discussed adding question #2 from the Pharmacy Technician application (17A-5 Rev. 01/11) to the Pharmacist, Intern Pharmacist, and Designated Representative applications.

Committee Recommendations

Motion: Recommend that the Board amend question #7 on the Pharmacy Technician Application (17A-5) Rev. 01/11; and question #19 on the Pharmacist application as follows:

Have you ever been convicted of, or pleaded guilty or nolo contendere/no contest to, any crime, in any state, the United States or its territories, a military court, or any foreign country?

Include any felony or misdemeanor offense, and any infraction involving drugs or alcohol or with a fine of \$500 or more. You must disclose a conviction even if it was (1) later dismissed or expunged pursuant to Penal Code section 1203.4 et seq., or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210 et seq., or an equivalent post-conviction drug treatment diversion dismissal provision from a non-California jurisdiction. Failure to answer truthfully and completely may result in the denial of your application.

NOTE: You may answer "NO" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; (3) convictions more than two years old on the date you submit your application for violations of California Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or California Health and Safety Code section 11360, subdivision (b); and (4) infractions or traffic violations with a fine of less than \$500 that do not involve drugs or alcohol.

M/S: Wong/Law

Support: 4 Oppose: 0 Abstain: 0

Motion: Recommend that the Board add Question #2 from the Pharmacy Technician application to the Pharmacist, Intern, and Designated Representative applications.

M/S: Wong/Law

Support: 4 Oppose: 0 Abstain: 0

7. Competency Committee Report

- a) Recruitment of New Members for the Board's Competency Committee**
- b) Job Analysis Design of the California Pharmacist Practice for the Practice Standards and Jurisprudence Examination (CPJE) for 2015-2020**

(a) Recruitment of New Members for the Board's Competency Committee

The board's Competency Committee develops and oversees the administration of the California Pharmacist Jurisprudence Examination or CPJE. This exam consists of 90 multiple-choice items that assess minimal competency in patient communication skills, pharmacy law and clinical knowledge in practice situations in California.

The board is looking to recruit new members for the Northern Competency Committee who are specialized in Institutional settings.

Besides the main functions of the committee described above, related duties of the committee include the oversight of a job analysis of the pharmacist profession every five years to assure that the exam remains valid for entry-level pharmacist practice. From this analysis, the committee develops the content outline for the examination. Appointment to the committee is an honor, but the work required is demanding. There are three two day meetings annually in the north annually. Attendance at the committee meetings is a necessity.

The board's president appoints all committee members to terms of four years, with reappointment possible. Practicing California pharmacists who have been licensed within the last five years are especially encouraged to apply. Applications must include a curriculum vitae, a cover letter describing the pharmacist's area of pharmacy experience or practice, and three letters of reference from pharmacists who are familiar with the pharmacist's work.

(b) California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Effective April 1, 2014, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means that there is currently a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. The board expects to release the scores in late June 2014, however, will release exam scores more quickly if the review is completed.

(c) Examination Development

The Competency Committee workgroups continues to meet throughout 2014 for examination development. Both Competency Committee workgroups will meet for the annual meeting in August to discuss examination development.

Occupational Analysis of the Pharmacist's Duties

The committee has also developed a job analysis survey to be used to complete an occupational analysis with the board's contracted psychometric firm. Pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the examination. We released this survey to a random sample of pharmacists June 6, 2014. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE. Pharmacists who complete the job analysis survey will be awarded three hours of CE credit as approved by the board at a prior meeting.

At this meeting, Chair Veale and Ms. Herold provided background information and asked everyone to consider serving on the Competency Committee. There was no public comment.

8. Licensing Statistics

Chair Veale provided a summary of some of the licensing statistics for July 2013-May 2014. During the first eleven months of fiscal year, the board received over 14,000 applications and issued just under 11,500 licenses. The number of applications received decreased when compared to the same period last year by about 6 percent. Additionally, there was a 6.4 percent decrease in the number of licenses issued.

Ms. Herold cautioned that the statistics are preliminary and that final statistics will be available at the July 30-31 board meeting.

No additional committee or public comment was provided.

9. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Steve Gray requested the Licensing Committee add an item to a future agenda to clarify the licensing of hospital pharmacies that:

- May or may not be on the same campus of the hospital licensed by the California Department of Public Health
- May or not have an actual pharmacy in the separate facility
- And may or may not have a pharmacist inside the separate facility

No additional committee or public comment was provided.

Chair Veale adjourned the meeting at 12:45 p.m.