



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: December 11, 2013

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

**COMMITTEE MEMBERS
PRESENT:** Deborah Veale, RPh, Chair
Victor Law, RPh
Lavanza Butler, PharmD
Stanley C. Weisser, RPh, Board President

**COMMITTEE MEMBERS
NOT PRESENT:** Greg Lippe, Public Member
Albert C.M. Wong, PharmD

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Manager
Kristy Shellans, DCA Staff Counsel
Michael Santiago, DCA Staff Counsel
Debbie Damoth, Administration and Regulation Manager
Amber Dillon, Licensing Manager
Laura Hendricks, Associate Analyst

Call to Order

Chair Veale called the meeting to order at 10:01 a.m.

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

Chair Veale conducted a roll call. Committee Members Lavanza Butler and Victor Law were present. President Weisser attended and participated in the meeting.

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1. Text for Criminal Conviction Questions on Board Applications

Background

The board's applications for individual licenses (e.g., pharmacists, pharmacy technicians) ask:

"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."**

The Legal Office requested the committee review these questions and modify the verbiage to conform to the format used by other boards and bureaus in the department.

Discussion

Chair Veale reviewed and referenced the language provided in the meeting materials and asked committee members for comments.

Department of Consumer Affairs (DCA) Staff Counsel Kristy Shellans further explained a letter was sent to DCA clients regarding the conviction related questions. There was some concern with the scope and breadth of the questions used. Specifically, the questions do not identify the questions that the board cannot consider when making a licensing decision. The committee discussed concerns of ensuring the language is clear and easy for all applicants to read and understand.

Board staff indicated it would be beneficial to work with both DCA counsel and Attorney General (AG) counsel as the later would be defending board licensing decisions when an appeal of an application denial occurred.

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Chair Veale requested board staff continue to work with counsel to bring a draft back to the committee.

Chair Veal asked for public comment. No public comment was provided.

Agenda Items 2 and 3 Combined

2. **Pharmacist Intern Hours Requirements from Business and Professions Code Section 4209 and 16 California Code of Regulations Section 1728**
3. **Pharmacy Intern Hours Affidavit Form 17A-29**

Relevant Statutes and Regulations

Business and Professions Code section 4209:

- (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 at 16 California Code of Regulations Section 1728 then goes on to specify:

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.

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

Background

Periodically, usually in response to inquiries from the public, the board has scheduled discussions on the number of intern hours earned and reported to the board as a requirement for admission to the California pharmacist licensure examination. At October 2013 Board Meeting, President Weisser requested that intern hours be added to the agenda of the Licensing Committee at the request of Board Member Victor Law.

The Pharmacy Intern Hours Affidavit (form 17A-29) has two areas where the intern hours earned 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. NOTE: A maximum of 600 hours may be granted at the discretion of the board.

The board requests that the hours earned by a pharmacist intern while in school that are not obtained in a pharmacy but substantially related to pharmacy be recorded on line two of the Pharmacy Intern Hour Affidavit form. The board will also accept a letter from the School of Pharmacy on school letterhead "certifying that the student has accumulated 600 hours of internship through the experiential activities of the Doctor of Pharmacy curriculum in the School of Pharmacy" signed by the dean.

California Northstate University has expressed concern to the board's licensing staff about the appropriateness of the forms being completed by the colleges in California. However, there is no written statement from the school.

Discussion

Chair Veale referenced the language provided in the meeting materials and suggested that item 2 and 3 be discussed together then asked if committee members or the public had any questions or concerns.

Mr. Victor Law stated that the concern was brought forth by California Northstate University. Committee members discussed the issue. Some members of the committee indicated that changes to the current requirements are not required and indicated that the intent of the requirements are to protect the consumers and pharmacy students need real life experience such as consultation with the patients. Executive Officer Virginia Herold indicated she would like to hear from the California schools of pharmacy. Ms. Herold also reminded the committee of the requirement for the foreign graduates to complete 1500 hours of intern experience.

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Chair Veale asked for public comment.

Dennis McAllister, representing the Accreditation Council for Pharmacy Education (ACPE), provided the committee with the intern requirements for accredited pharmacy degree programs and shared that as part of their process the ACPE also requires that the preceptors obtain annual training.

Chief Executive Officer John Roth for California Pharmacist Association (CPhA) expressed concern of the requirement for the intern hour affidavit and asked that the form be rescinded for all the hours required by the board.

Chair Veale recommended that the board place the topic on the agenda for the next meeting and invite the California schools of pharmacy to discuss the regulation and affidavit requirements. Board staff was directed to contact the NABP and survey intern hour requirements for other states.

4. Implementation Schedule for SB 809 (DeSaulnier, Chapter 400, Statutes of 2013)

Relevant Statutes

Health and Safety Code Sections 11165 – 11165.3 establish and define the parameters and use of the CURES Program within the California Department of Justice. For a number of years, prescribers and pharmacies have been required to report each week to DOJ every Schedule II, III, and IV prescription dispensed.

Background

In 2013, the CURES Program received additional funding through SB 809 to rebuild and replace its aging computer system and provide minimal but essential staffing to support the program in the future. This support was needed because CURES had been housed in the Department of Justice's (DOJ) Bureau of Narcotic Enforcement, a unit that was totally defunded several years ago in response to General Fund budget cuts made by Governor Brown in response to the state's fiscal crisis.

The new CURES funding source is now the regulatory boards in the Department of Consumer Affairs that license prescribers and dispensers. Beginning in April 2014, every practitioner eligible to prescribe (e.g., physicians, nurse practitioners, optometrists, veterinarians, dentists) or dispense (pharmacists, pharmacies), wholesalers and clinics will pay an ongoing fee of \$6 per year fee as part of their renewal. Additionally before January 1, 2016, every pharmacist (and each of the prescriber classifications) will be required to submit an application to obtain approval to access CURES data as part of the renewal process. This process is intended to ensure widespread eligibility for prescribers and pharmacists to access CURES data on an individual patient -- when the practitioners so choose -- at the time of prescribing or dispensing.

Additionally, due to a trailer bill to the 2013/14 California State Budget, the board is funding for two years (2013/14 and 2014/15) an additional \$215,000 (in addition to ongoing annual funding of \$92,000 that we have been providing for approximately 10 years) that will be used to replace the aging CURES computer and replace it with a more robust system, capable of providing better access to the state's prescribers and dispensers who are checking the controlled substances dispensed to specific patients as part of the

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prescription drug monitoring program (PDMP). The dispenser boards are also contributing sizeable amounts to secure a new computer system.

Specifically, SB 809 provides the following goals for this computer system:

- (1) Upgrading the CURES PDMP so that it is capable of accepting real-time updates and is accessible in real-time, 24 hours a day, seven days a week.
- (2) Upgrading the CURES PDMP in California so that it is capable of operating in conjunction with all national prescription drug monitoring programs.
- (3) Providing subscribers to prescription drug monitoring programs access to information relating to controlled substances dispensed in California, including those dispensed through the United States Department of Veterans Affairs, the Indian Health Service, the Department of Defense, and any other entity with authority to dispense controlled substances in California.
- (4) Upgrading the CURES PDMP so that it is capable of accepting the reporting of electronic prescription data, thereby enabling more reliable, complete, and timely prescription monitoring.

Board staff is participating in development of the parameters for the new CURES computer system. They are also involved in establishing a simplified mechanism by which pharmacists will be able to sign up for CURES without having to have documents certified by notary publics as part of the approval process.

Discussion

Chair Veale reviewed and referenced the language provided in the meeting materials.

Virginia Herold stated the intent is to make a more user friendly Prescription Drug Monitoring Program and advised the committee that the board will start collecting fees April 2014 consistent with the legislation. Ms. Herold noted that an upgraded system is necessary to fully implement the provisions of SB 809.

Mr. Law underscored the need for the new system to be user friendly and was advised that board staff is participating in the development along with the Department of Justice. Ms. Herold also noted that the DOJ will also be seeking input from stakeholders on system requirements as part of the development effort for the new system.

Chair Veale asked for public comment.

Darlene Fujimoto with the American Society of Consultant Pharmacists questioned whether the provisions of SB 809 apply to nurses as well. Ms. Herold recommended that Dr. Fujimoto consult with the Board of Registered Nursing.

5. Implementation Schedule for SB 493 (Hernandez, Chapter 469, Statutes of 2013)

Background

Senate Bill 493 establishes an “advanced practice pharmacist” category of licensure, allowing such pharmacists to perform advanced patient care functions, such as to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue

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medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers.

Specifically: SB 493:

- Creates a new license category of Advanced Practice Pharmacist who may practice advanced practice pharmacy within or outside a pharmacy (*CA B&P 4016.5*)
- Allows an APP to write or issue a prescription in specific settings under 4052.2(a) (*CA B&P 4040, 4051, 4076*)
- Allows an APP to issue an order for controlled substances in specific settings (*CA B&P 4060*)
- Also, an APP may:
 - Perform patient assessments
 - Order and interpret drug therapy related tests
 - Refer patients to other health care providers
 - Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers
 - Initiate, adjust or discontinue drug therapy; must provide notification back to diagnosing prescriber or enter info into patient record shared with the prescriber
 - require registration with DEA for prescribing APP
 - tests ordered by APP in coordination with and notification to patient’s diagnosing physician (*CA B&P Code section 4052.6*)
- APP Requirements:
 - Hold an active CA pharmacist license – in good standing -- as a pharmacist
 - File an application with the board & pay fee (\$300 max)
 - License good for 2 years, and will be linked to RPh renewal
 - An additional 10 units of CE each renewal cycle is required in an area of practice relevant to the pharmacist’s clinical practice (*CA B&P 4210, 4233*)

Regulations will be needed to implement multiple provisions in SB 493: for example

To qualify as an APP, a licensed pharmacist must possess 2 of the 3 below:

1. Earn certification in relevant area of practice (ambulatory care, critical care, geriatric, nuclear, nutrition support, oncology, pediatric, pharmacotherapy, psychiatric practice recognized by ACPE or another entity recognized by the board)
2. Complete postgraduate residency in accredited postgraduate institution where 50 percent of experience includes direct patient care with interdisciplinary teams
3. Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, APP, a pharmacist practicing collaborative drug therapy management, or health system (*CA B&P 4210*)

Additional provisions of the bill affect all pharmacists, including those who do not become licensed as APPs. Some of these provisions will also require the board to implement regulations. Senate Bill 493:

- Allows a pharmacist to administer drugs and biological products that have been ordered by a prescriber (*CA B&P Code section 4052*)

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- Allows a pharmacist to independently initiate and administer vaccines listed on routine immunization schedules of the CDC for persons three years of age or older. 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 info to patient's primary care physician and into the CDPH's immunization registry.
 - Be able to initiate and administer epinephrine or diphenhydramine by injection (*CA B&P 4052.8*)
- Permits a pharmacist to furnish nicotine replacement products in accordance with a state treatment protocol to be developed jointly by the Board and Medical Board, provided:
 - Records are retained of drugs and devices furnished for at least 3 years so as to notify health providers or monitoring of the patient
 - The pharmacist notifies the patients primary care provider of drugs and devices furnished or into a patient record -- the pharmacist must complete 1 hour of CE on smoking cessation therapy biennially
(*CA B&P sections 4052 and 4052.9*)
- Permits a pharmacist to furnish self-administered hormonal contraceptives in accordance with a state protocol developed by the Board and the Medical Board of California pursuant to the guidelines of the CDC. (*CA B&P Section 4052, 4052.3*)
- Also a pharmacist may furnish prescription medications not requiring a diagnosis recommended by the CDC for individuals traveling outside the US (travel medications) (*CA B&P section 4052*)

The California Pharmacists Association and California Society of Health System Pharmacists have joined together with some of their members and multiple California schools of pharmacy to develop components to comply with some of the provisions in SB 493. The board was not involved in this process.

Discussion

Chair Veale reviewed the agenda item. Ms. Veale iterated that the board will work with the public and stakeholders. Ms. Herold advised the committee that the Medical Board will also have a designee to assist with the development of some protocols required by this legislation. Ms. Herold suggested that a draft protocol could be provided for the Medical Board for consideration during is May 2014 Board Meeting if the draft is ready.

Ms. Veale suggested that the board identified existing protocols and programs that may already exist, to leverage that information and identified the Centers for Disease Control as one possible source.

The committee also heard a brief presentation by representatives of CPhA and CSHP. The presentation discussed a collaborative effort being undertaken by the two associations to develop a certificate program that would comply with the requirements of SB 493. The representatives also expressed interest in working with the board to develop the necessary elements to achieve full implementation of SB 493.

Several meeting attendees also expressed interest in working with the board.

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Chair Debbie Veale requests that the committee reconvene early February 2014 to allow groups the opportunity to bring forward protocols for committee review as well as allow board staff to complete research.

6. Implementation Schedule for SB 294 (Emmerson, Chapter 565, Statutes 2013)

Background

SB 294 is the board's sponsored legislation to strengthen the board's ability to regulate specialized pharmacies within and outside California that compound sterile drug products – that is, those that are compounded for injection, administration to the eye or for inhalation. The provisions provide for implementation of the requirements beginning 7/1/2014.

Discussion

Chair Veale provided an overview of the agenda item. Virginia Herold informed the committee that the board has a go live date of July 1, 2014. The board is not authorized to hire staff or have the funds to implement SB 294. The board is working with legal for implementing. Board inspectors have undergone training for at least 53 hours. The board is still completing inspections as this continues to be a public health issue. The board would like to have the hospitals licensed as soon as possible or they will not be able to compound as of 7/1/14 without a board license for sterile compounding. If they are licensed as outsourcing, they will still need to be licensed with the board.

Chair Veale asked for public comment.

Public comment on this item included an inquiry about the board's ability to inspect nonresident sterile compounding pharmacies that are shipping products in to California. Ms. Herold advised all present that the board will be inspecting such facilities.

7. New Pharmacy Technician Accreditation Commission

Relevant Statutes

4202. Pharmacy Technician: License Requirements for Education, Experience; Board Regulations; Criminal Background Check; Discipline

(a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:

- (1) Has obtained an associate's degree in pharmacy technology.
- (2) Has completed a course of training specified by the board.**
- (3) Has graduated from a school of pharmacy recognized by the board.
- (4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a).

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Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(e) Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.

1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health-System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(1) Knowledge and understanding of different pharmacy practice settings.

(2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Background

The board has learned from an outside source that the American Society of Health-System Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education (ACPE) have announced their collaboration to accredit pharmacy technician education and training programs, beginning in late 2014. The collaboration will result in the creation of the Pharmacy Technician Accreditation Commission (PTAC), which will be tasked with assuring and advancing the quality of pharmacy technician education and training programs.

The PTAC will conduct document reviews and site surveys and advise the ASHP/ ACPE boards of directors, which will then agree on final accreditation actions. The establishment of the PTAC expands upon ASHP's 31-

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year history as a national accrediting body for pharmacy technician training programs. The ACPE also accredits educational programs involving pharmacy – specifically all schools of pharmacy in the US are accredited by ACPE.

According to information provided to the board, there are currently 258 programs in the ASHP accreditation process. Through the work of its Commission on Credentialing, ASHP will continue to accredit pharmacy technician programs until the PTAC officially begins its work in the fall of 2014. ASHP will also provide ongoing accreditation support for the PTAC.

The formation of the new review structure will require the need for the board to reevaluate and possibly modify its regulation at 16 California Code of Regulation section 1793.6 regarding approved courses of training for pharmacy.

Discussion

Chair Veale provided an overview of the agenda item.

No public comment was provided.

Chair Veale requested that this item be placed on a future meeting agenda of this committee for staff to provide more information on the new ASHP technician program approval process so the committee can make a decision about how to proceed.

8. Pharmacy Compounding Accreditation Board (PCAB) Pharmacy Technician Certification Requirement Changes

Background

The board has been advised by the Pharmacy Compounding Accreditation Board that as a result of concerns raised by their applicants regarding technician certification, the PCAB's Standards Committee reviewed the interpretation of PCAB Standard 1.20.

After review the Standards Committee recommended no change in Standard 1.20 to the PCAB Board of Directors. Instead the recommendation was to continue with the current interpretation of Standard 1.20 and cancel the pending January 1, 2015, recommended change.

Consequently, a proposed requirement for pharmacy technician certification that had been slated to begin on January 1, 2015, has been eliminated. Thus PCAB will continue with their current interpretation of Standard 1.20 directing that pharmacy technicians will be certified or otherwise credentialed by an appropriate certifying agency only when required by the state(s) in which they practice.

Discussion

Chair Veale provided an overview of the agenda item and determined that the proposed changes have been eliminated.

No committee or public comment was provided.

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9. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Effective December 1, 2013, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This means there will be 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 February 2014.

Examination Development

The Competency Committee workgroups continued to meet throughout 2013 for examination development. Both Competency Committee workgroups met once during the fall to discuss examination development.

No additional committee or public comment was provided.

10. Licensing Statistics

Chair Veale provided a summary of some of the licensing statistics for July 2013-October 2013. During the first four months of fiscal year, the board has received over 6,700 applications and issued over 5,600 licenses. The number of applications received has increased when compared to the same period last year by about 7.6 percent. Additionally, there is a slight increase (0.8 percent) in the number of licenses issued.

No additional committee or public comment was provided.

11. Public Comment for Items Not on the Agenda

No public comment was provided.

Chair Veale adjourned the meeting at 1:02 p.m.