



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
MINUTES**

DATE: March 24, 2009

LOCATION: First Floor Hearing Room
Department of Consumer Affairs
Sacramento, CA 95834

**BOARD MEMBERS
PRESENT:**

Stanley C. Weisser, RPh, Acting Chair
James Burgard, Public Member
Susan L. Ravnar, PharmD
Kenneth Schell, PharmD

**STAFF
PRESENT:**

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Schieldge, DCA Staff Counsel
Tessa Fraga, Staff Analyst

Call to Order

Chair Weisser called the meeting to order at 10:04 a.m.

1. Emergency and Disaster Response Planning: EMS Authority Looking for Pharmacists and Other Health Care Volunteers

Chair Weisser provided that the Emergency Medical Services Authority (EMSA) has notified the board and other agencies that it is seeking service providers in three areas:

1. Maintenance of state-owned disaster readiness equipment and state-run warehouses
2. Management and deployment of licensed medical and support personnel for disaster response
3. Development and implementation of disaster response training program.

Chair Weisser explained that the intent is to identify if services are available to the State of California to provide a "turnkey" California Medical Assistance Team (CAL-MAT) program with readiness and response capabilities for disaster medical assistance personnel and equipment.

Chair Weisser indicated that EMSA may subsequently issue either a Request for Proposal (RFP), or an Invitation for Bid (IFB), or both, for various services to begin as early as July 1, 2009.

2. Review of the Professional Competency Statement for Pharmacy

Chair Weisser provided that the competency statement for pharmacy was created in 1969 when clinical pharmacy was under creation and there was no definition of what a pharmacist does. This statement was used by the board in part for what we use the CPJE content outline for: to develop test questions for the licensure examinations. This was used to construct exams prior to the advent of job analyses and content outlines which have been in use since the late 1980s.

Chair Weisser directed the committee to evaluate this statement with the following questions:

1. Does the board need the competency statement? Why?
2. If yes, does it need revision?

Committee Discussion:

Susan Ravnar indicated that the statement may still serve some benefit.

Kenneth Schell provided that the statement does not seem to be relevant in its current location. He indicated that the statement may be a better fit in an alternative location. Dr. Schell stated that the statement could be reevaluated and possibly included on the board's website.

James Burgard commented that the statement is misplaced and seems to be more of a mission statement. He provided that the document is outdated and is not worth revising.

Kristy Schieldge, DCA Staff Counsel, expressed concern regarding the accuracy of the statement. She also provided that the statement may be constraining when trying to set standards of practice for a dynamic profession.

Motion: To remove the competency statement from the pharmacy lawbook and to discontinue its use.

M/S: JB/KS

Support: 4 Oppose: 0

3. National Association of Boards of Pharmacy's and Accreditation Council for Pharmacy Education's Confirmation of Appropriate Content for Continuing Education Provider Coursework

Chair Weisser provided that on March 12, 2009, the ACPE sent a letter advising all state boards of pharmacy with independent approval authority for continuing education to ensure that pharmacists receive balanced and independent continuing education.

Chair Weisser provided the following from this letter:

It has come to the attention of the Accreditation Council for Pharmacy Education (ACPE) and the National Association of Boards of Pharmacy (NABP) that some individual state-based continuing pharmacy education (CPE) approval processes of non-ACPE CPE that awards credit towards pharmacist relicensure has occurred for content that was commercial in nature (e.g. promotional talks, advisory board slides, pharmaceutical company speakers, etc.)

The ACPE advises that non-accredited CPE activities should be screened to ensure the aspects of the Office of Inspector General (OIG) and Standards for Commercial Support (SCS) guidance are maintained. Without the appropriate screening, state board approval processes could mistakenly allow credit for promotional materials and undermine the accreditation process, as well impact the pharmacist who received relicensure credit for those activities. ACPE and NABP acknowledge the need for independent state board approval processes to permit pharmacists to meet their individual continuing education and learning needs. However, during these times of heightened investigation and evaluation of educational influence for commercial gain, it is paramount that the state boards with independent approval processes implement safeguards to ensure their pharmacists receive balanced and independent education that is applied towards relicensure requirements.

Chair Weisser indicated that the Pharmacy Foundation of California, which is one of two approvers of pharmacist CE in California, has been advised.

4. Request for Board Recognition of a School of Pharmacy with Precandidate Status with the Accreditation Council for Pharmacy Education Pursuant to 16 CCR § 1719 – Jefferson School of Pharmacy, Philadelphia, PA

Chair Weisser provided that 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).

Chair Weisser stated that Jefferson School of Pharmacy (JSP), Philadelphia, PA was granted Pre-Candidate status by the ACPE during its January 2008 meeting and the first class of students was admitted in the Fall of 2008. JSP is undergoing review by the ACPE during 2008/09 Review Period for advancement to Candidate accreditation status. Recently, the Jefferson School of Pharmacy requested board recognition of its program for purposes of issuing intern pharmacist licenses to students attending their program, but who may spend some time and work in CA.

Committee Discussion:

Ms. Herold provided that new schools of pharmacy are emerging throughout the US to meet the demand for pharmacists. She indicated that board staff has worked closely with ACPE to ensure proper accreditation standards for these schools.

Dr. Schell expressed concern regarding the requirement for two 15-week semesters during the first three years of the PharmD program and requested that board staff seek clarification.

Chair Weisser sought clarification regarding the board's authority under Title 16.

Ms. Schieldge responded that the board does have the authority to recognize and provide accreditation. She suggested that the board remain consistent and possibly define criteria for recognition within regulation.

Motion: To recognize the Jefferson School of Pharmacy, Philadelphia, PA, with its precandidate status with the Accreditation Council for Pharmacy Education for purposes of issuing intern permits as authorized in Business and Professions Code § 4208.

M/S: JB/KS

Support: 4 Oppose: 0

5. Assembly Bill 418 (Emmerson): Pharmacy Technician Qualifications

Chair Weisser indicated that during the last legislative cycle, the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licensed in California as a pharmacy technician. This bill was pulled due to concerns expressed by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

Chair Weisser provided a summary of events since that time including that on December 4, 2008, CSHP sponsored another stakeholder meeting. Discussion at this meeting revealed that there is still disagreement within industry about what and if there is a problem with the current existing pharmacy technician qualifications requirements as well as whether the draft legislative proposal correctly addresses the minimum qualifications. At that time, CSHP indicated that they may move forward with their legislative proposal, but scale back the requirements to apply to only pharmacy technicians working in the inpatient setting.

Chair Weisser also discussed AB 418 (Emmerson), which was introduced on February 23, 2009. Chair Weisser stated that this legislation will change the minimum qualifications for licensure as a pharmacy technician as well as require 20 hours of continuing education each renewal cycle.

Chair Weisser stated that existing law authorizes the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent and has either obtained a specified

associate's degree, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board.

Chair Weisser indicated that the bill would authorize the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent, passes a pharmacy technician examination recognized by the National Organization for Competency Assurance and approved by the board, and has either obtained a specified associate's degree, completed a course of training offered by a specified accredited program, or graduated from a specified school of pharmacy.

Chair Weisser provided that the bill identifies an effective date of January 1, 2011, and will also require a pharmacy technician to successfully complete 20 hours of approved courses of continuing pharmacy education (CE) during the 2-years preceding an application for renewal and exempts this requirement for the first renewal cycle. The bill also specifies the form and subject matter content for these CE courses and provides that a pharmacy technician license that is not renewed within 3-years after expiration may not be renewed and shall be canceled at the end of a 3-year period.

Chair Weisser explained that in its current form, the bill would automatically prohibit any application with a felony drug or pharmacy related conviction from seeking licensure. Board staff consulted with staff counsel, who expressed concern that the bill in its current form could constitute a de facto ban from licensure for those with a specified criminal background.

Chair Weisser provided that the bill author's intent is that the technician exam and the completion of an approved continuing education will better protect California consumers.

Committee Discussion:

Ms. Herold explained that the bill would have a fiscal and workload impact on the board.

Chair Weisser sought clarification regarding the legal requirements.

Ms. Schieldge explained that a testing requirement being added prohibits anyone with a felony conviction from taking the exam. She added that under current law, pharmacists can retain their license with a conviction deemed not to be substantially related to the profession or by demonstrating satisfactory rehabilitation. Ms. Schieldge provided that technicians will not have the same opportunity under the new bill.

Bob Ratcliff, Supervising Inspector, sought clarification on the status of technicians who do not complete CE.

Ms. Herold responded that the technician will go into inactive status.

Public Comment:

Bryce Docherty, representing CSHP, reported that CSHP has addressed some of the major philosophical issues with the bill. He added that the bill has some technical issues that will

be addressed. Mr. Docherty provided that the bill is heavily supported and will be heard in the Assembly Business and Professions Committee on March 31, 2009.

Lynn Rolston, representing California Pharmacists Association (CPhA), provided that the bill conforms with CPhA policy. She expressed concern regarding the bill's short timeline and the board's staffing and workload.

Ms. Herold responded that she does anticipate staffing to be an issue. She asked Ms. Schiedge to clarify if regulations will need to be developed to fulfill Section 4202 (a) within Section 3 of the bill.

Ms. Schiedge responded that a regulation is needed.

Discussion continued regarding requirements and necessary regulations.

Mr. Docherty provided that there will be implementation issues. He added that the implementation date is flexible in order to ensure that the process is effective.

Lorie Rice, representing the UCSF School of Pharmacy, expressed concern regarding accrediting bodies having the ability to provide continuing education. Ms. Rice questioned if this was the intent.

Mr. Docherty provided that the intent is to approve an entity to accredit training programs. He indicated that it is the responsibility of the pharmacist technician to obtain continuing education credits in a manner consistent with the bill's requirements.

Ms. Rice suggested that a provision be drafted to address the potential conflict of interest of the approving agency also providing CE.

Chair Weisser provided that the Legislation/Regulation Committee will be discussing this issue at a future meeting.

There was no addition committee or public comment.

6. ExCPT Examination For Pharmacy Technicians

Chair Weisser provided that Business and Professions Code Section 4202 specifies the requirements for licensure as a pharmacist technician in California. Specifically, an applicant must either be a high school graduate or possess a general education certificate equivalent as well as satisfy one of four qualification methods:

1. Possess an associate's degree in pharmacy technology.
2. Complete a course of training specified by the board in regulation.
3. Graduate from a school of pharmacy recognized by the board.
4. Be certified by the Pharmacy Technician Certification Board (PTCB).

Chair Weisser stated that in September 2006, this committee discussed this Exam for the Certification of Pharmacy Technicians (ExCPT). At that time, the board directed a review of the exam to determine if it is job-related. The ExCPT exam is a computer-based test used

to assess the knowledge of pharmacist technicians and is accredited by the National Commission for Certifying Agencies. The examination is accepted by several states as a qualifying method for licensure. The exam is being offered in all 50 states and there are currently 42 test sites available in California. Chair Weisser indicated that because of staffing changes with the Department's Office of Examination Resources as well as legislative proposals which would alter the licensing requirements for pharmacy technicians, this action was tabled.

More recently, board staff met with the Chief Executive Officer at her request to discuss the exam and provided technical input on the process for California law to allow use of this exam as one of the qualification methods for licensure, including an assessment of the exam for job-relatedness as well as a statutory change to B&PC 4202(a)(4).

Chair Weisser highlighted that AB 418 (Emmerson) would alter the requirements for licensure. In its current form, the bill would make the necessary statutory changes to allow the use of the ExCPT in addition to any other exam that is accredited, as specified. If this bill does not pass, as the board so chooses, the board would need to sponsor legislation to allow for the use of this exam.

Chair Weisser also discussed that the board would need an assessment of the examination for compliance with Section 139 of the Business and Professions Code and that board staff recommend that a similar assessment be conducted on the PTCB.

Committee Discussion:

Ms. Herold advised the committee not to take action on this item until more information is gathered.

Ms. Weisser indicated that the committee will not act on this issue at this time.

There was no additional committee discussion.

7. Issue Statement on Pharmacy Workforce Shortage by the California Hospital Association Workforce Committee, December 1, 2008

Chair Weisser provided that in mid-2008, the California Hospital Association (CHA) established a coalition to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. This coalition was comprised of workforce committees, an advisory council and four workgroups. Board executive staff was invited to participate on the pharmacy services workgroup.

Chair Weisser referenced the issue statement provided and stated that the CHA report concludes that, although there has been an increase in the number of pharmacists educated within California over the prior few years, there continues to be a gap in the number of pharmacists that California will need.

Discussion indicated that it appears that the CHA used somewhat dated data regarding the number of pharmacists graduated. A footnote in CHA's report provided board statistics

showing that in fiscal year 2007-08, 2,061 applicants took the board's examination. Of these, 890 were graduates of California schools of pharmacy. Also, in fiscal year 2007-08, a total of 1,385 pharmacists were licensed.

Committee Discussion:

Dr. Ravnan questioned if data is available regarding licensees who have stayed in California to practice and was advised that it is not.

Public Comment:

David Smith expressed concern regarding possible errors and information provided in the report.

Ms. Herold offered to relay Mr. Smith's remarks to the CHA.

There was no additional committee or public comment.

8. US Department of Health and Human Services, Health Resources and Services Administration's Report: *The Adequacy of Pharmacist Supply: 2004-2030*

Chair Weisser stated that the board was provided with a copy of a Health and Human Services Agency report entitled: *The Adequacy of Pharmacist Supply 2004-2030*. This report presents a slightly less dire picture of the supply of future pharmacists than the California Hospital Association's Report; however both predict continued shortages of needed pharmacists.

Chair Weisser highlighted the conclusions from the report, as follows:

- The supply of pharmacists is growing significantly faster than was previously projected.
- The demand for pharmacists continues to grow.
- There is currently a moderate shortfall of pharmacists.
- The future supply of pharmacists is projected to grow at a rate similar to the projected growth in demand from changing demographics.
- Supply and demand are projected with a level of uncertainty. Only under an optimistic supply projection combined with a conservative demand projection is future supply adequate to meet demand.

9. Experiences of an Employer Recruiting Foreign-Trained Pharmacists for Work in the United States

Chair Weisser indicated that documentation of workforce shortages continues to emerge. With a limited number of pharmacy schools in the US and a rising demand for pharmacist services, one potential recruitment source are foreign-trained pharmacists. As recently as the November 2008 Pact Summit, the Department of Consumer Affairs encouraged all attendees to consider foreign-trained professionals to address shortages.

Chair Weisser summarized the requirements for licensure, indicating such individuals must be certified by the Foreign Pharmacy Graduate Examination Committee (FPGEC) before applying for a license in California. The certification process through the FPGEC includes passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE); passing the Test of Spoken English (TSE) and Test of English as a Foreign Language (TOEFL) or iBT TOEFL; and evaluation by the FPGEC of educational curriculum and foreign licensure requirements of each applicant.

In addition, the board is required by law to collect a social security number prior to the issuance of any license.

Presentation to the Committee:

Alan Pope and Kim Guggiana (Safeway):

Mr. Pope provided information regarding Safeway's foreign-trained pharmacist program to combat pharmacist shortages and to fill positions in less desirable areas. He indicated that the program recruits its participants primarily online from India, the Philippines, South Africa, Korea, and Canada. Mr. Pope explained that the program offers assistance to its participants including legal counsel, paid relocation expenses, intern hours, guidance with the visa process, and help with obtaining a position after receiving a license.

Ms. Guggiana provided that the program is faced with several challenges including the number of available visas and costly wage requirements.

Ms. Guggiana indicated that the foreign-trained pharmacists have practiced in their country of origin. She added that despite Safeway's efforts to advertise and employ locally, there are many positions that are still not filled in less desirable areas.

Committee Discussion:

Chair Weisser sought clarification on the number of foreign graduates that have participated in the program and the retention rate.

Ms. Guggiana indicated that Safeway has brought 30-40 foreign graduates into California. She added that the program's retention rate is great and that most participants leave due to family needs, not to work for the competitor.

Chair Weisser asked how the program addresses language issues with its participants.

Mr. Pope provided that the applicants undergo a thorough hiring process. He added that the hires have performed exceptionally well.

Ms. Herold questioned if applicants are encountering any obstacles when obtaining a social security card.

Ms. Guggiana provided that it usually takes 2-4 weeks to obtain a social security card.

Discussion continued regarding the visa and social security card process.

Mr. Burgard commended Mr. Pope and Ms. Guggiana for their presentation.

Public Comment:

David Smith expressed concern regarding the cost per hire, retention rate, and applicant certification.

There was no additional committee or public comment.

10. Pharmacy Access Partnership's Request to Establish a Hormonal Contraception Pilot in Pharmacies

Chair Weisser provided that the Pharmacy Access Partnership is seeking to provide patients with greater pharmacy access to hormonal contraception. To establish support for this practice, they propose a study under the aegis of the board.

The Pharmacy Access Partnership proposes a pilot to establish practice protocols where physicians and pharmacists would collaborate in writing protocols to allow pharmacists in a community pharmacy to provide limited supplies (up to one year) of oral contraceptives, contraceptive patches and vaginal rings, to women who come into the pharmacy and meet the screening criteria. If the pilot is successful, they propose seeking statutory authority to allow such programs permanently.

The request is based on 16 CCR § 1706.5 which allows the board to waive specified provisions of regulations (Title 16) to an accredited school of pharmacy recognized by the board for purposes of an experimental plan or program. However, the board does not have the authority to waive statute (laws enacted by the Legislative).

Presentation to the Committee:

Sharon Landau (Pharmacy Access Partnership) and Belle Taylor-McGhee (Pacific Institute for Women's Health):

Ms. Landau provided that the Pharmacy Access Partnership has been working with a group of high-level experts and interested stakeholders to explore the potential for developing a pharmacy access hormonal contraception model in California, building upon the successes and lessons learned from a pharmacist-initiated provision of a hormonal contraception pilot in Washington State. The goal is to increase capacity for contraceptive access at the pharmacy to better meet women's healthcare needs.

Ms. Landau indicated that the Pharmacy Access Partnership is requesting the board to allow this pilot to use a protocol similar to pharmacist immunization services whereby a protocol between a pharmacist and a physician permits the application of the protocol for qualifying women who want to get hormonal contraception from the pharmacist directly for a set period of time. She provided that the Pharmacy Access Partnership is seeking a waiver for the "prior diagnosis" portion of such a protocol. Further, she stated that since a request

for hormonal contraception does not require a “diagnosis,” the need for a prior relationship between a provider and patient is not relevant.

Ms. Taylor-McGhee provided that recent action to lift restrictions on Medicare Plan B and access to emergency contraceptives increases the need to expand and ensure access to contraception overall.

Committee Discussion:

Dr. Ravnan sought clarification on the standards of care.

Ms. Landau responded that the standards of care have changed. She provided that healthy women require a pelvic exam every 2-3 years. Mrs. Landau indicated that the program receives support from a collaboration of medical physicians.

Dr. Schell questioned if the Medical Board has been approached to participate in the program.

Ms. Landau responded that the partnership has not specifically approached the Medical Board. She added that they are working with organized medicine and various physicians.

Ms. Schieldge provided that the board can not implement the proposal through regulation and indicated that a statutory amendment is required.

Ms. Herold suggested that the Pharmacy Access Partnership implement a patient specific protocol. She also recommended that they discuss their program with potential authors of pharmacy-related bills.

Public Comment:

Ms. Rice sought clarification on whether a pilot program can be implemented under the jurisdiction of a research study with a university. She stated that the pilot program is a great opportunity to expand the scope of practice and increase women’s access to emergency contraception.

Ms. Herold responded that authority is required.

Dr. Schell provided that the support of the Medical Board will increase the likelihood of implementing a pilot program.

There was no additional committee or public comment.

11. Competency Committee Report

Chair Weisser provided that the Competency Committee workgroups have met earlier this year and focused on examination development and item writing and additional workgroup meetings are scheduled throughout the year.

Chair Weisser stated that the committee will also begin to develop a job 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. It is anticipated that distributing the survey to a random sample of pharmacists will begin before the end of year. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

12. Public Comment for Items Not on the Agenda

David Smith expressed concern regarding new graduates and PIC qualifications. He also suggested that the board address the licensure process to ensure a more timely and effective procedure.

There was no additional public comment.

The meeting was adjourned at 11:42 p.m.