



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE Meeting Summary

DATE: March 3, 2004

TIME: 9:30 a.m. – 12 noon

LOCATION: Holiday Inn Oakland Airport
500 Hegenbeger Road
Oakland, CA

BOARD MEMBERS Clarence Hiura, Pharm.D., Chair
Ruth Conroy, Pharm.D.
John Tilley, R.Ph.

**STAFF
PRESENT:** Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Paul Riches, Legislation Chief
Dana Winterrowd, Staff Counsel

Call to Order

Committee Chair Clarence Hiura called the meeting to order at 9:30 a.m. He explained that committee member Richard Benson would not be attending the meeting because of another commitment. He noted that he would not be attending the Board meeting in April and Ruth Conroy agreed to present the Licensing Committee report.

Report on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and the California Specific Examination

Assistant Executive Officer Virginia Herold reported that the board is still waiting for the Department of Consumer Affairs and the Department of General Services to approve the contracts needed to implement the NAPLEX and CPJE in California. It is believed that both contracts are in the final stages of approval.

The board's goal has been to have applicants able to take both the CPJE and NAPLEX, with California as the qualifying state, in March. However, this will depend on when the contracts are finally signed. Both exams will be available six days a week at designated testing locations across the United States. There will be 125 sites for the CPJE.

The board has 611 applicants for the exams as of today. There were 141 applications received before July (most of these individuals postponed taking the June examination), and 470 have been received since July 1.

Application forms and instructions detailing the application process are available on the board's Web site. A Candidates' Guide handbook detailing procedures for taking the CPJE, what to expect at the test site, and how to study for the CPJE (including sample questions) has been developed. The board will place this handbook on its Web site, but Experior Assessments (the test administrator) will send a handbook to each candidate who has been qualified by the board to take the CPJE.

The NABP has a handbook containing similar information on its Web site regarding the NAPLEX that is available for downloading by applicants. Ms. Herold emphasized the changes to the security requirements for admissions to the CPJE examination. Applicants are required to bring a government-issued identification (driver's license, state-issued identification card, military card) containing a recent photograph and a federal Social Security card. The name appearing on both of these identification cards must match exactly the name used to register for the CPJE, including designations such as "Jr." or "III," etc. If the applicant does not have the appropriate identification, then he/she will not be admitted to take the examination and will need to reschedule.

The CPJE has been tested online and is ready to go. The computer administration is very basic and individuals without computer experience (which is very unlikely for pharmacists) can still take the examination online without even typing knowledge. A tutorial will be given at the test site for each applicant before he or she starts the examination.

The board will release examination results within 15 days following the NAPLEX and approximately 30 days following the CPJE.

The board has made proposed regulation changes to its examination procedures to fully implement the NAPLEX and CPJE. The regulations have been noticed and the board will act on them at the April meeting.

Proposal to Restructure the Competency Committee

Ms. Herold reported that the board's Competency Committee has created, overseen the administration of, and graded the California pharmacist licensure examination. Until January 2004, the examination was given twice a year and was comprised of 300 multiple-choice items and a 100-point, short-answer examination that had to be hand-graded.

This year, under the new examination structure created by SB 361, the board still must develop one examination, the 90-item multiple-choice CPJE. However, to prevent exam compromise, many more than 90 questions are being administered at any time. The Competency Committee develops these questions.

Appointment to the committee is an honor, but the work required of the committee is demanding. There is a minimum of seven two-day meetings annually, and additional outside time spent writing questions. Additionally, there are periodic subcommittee meetings to review performance statistics of the examination or perform other specialized tasks. Whereas the committee formerly hand-graded the short answer exam (this accounted for two of the seven two-day meetings), the committee is currently creating new items for the new examination structure.

Later this year, the committee will oversee a job analysis of the pharmacist profession; a survey of 2,000 pharmacists for each duty they perform and the importance of each task. From this job analysis, the committee develops the content outline for the examination. This job analysis must be conducted every three to seven years, to assure that the exam remains valid for entry-level pharmacist practice.

The committee is carefully structured to ensure a balance of practitioners from all practice settings. In the last six months, there have been a number of changes as some members have rotated off the committee (they typically serve for eight years) and several others have resigned early due to other commitments. The current composition of 21 members is:

<p>Schools of Pharmacy</p> <ul style="list-style-type: none"> 1 active member UCSF 1 active member UOP 1 inactive member UOP 1 active member Western 2 active members USC 	<p>Community setting</p> <ul style="list-style-type: none"> 5 active pharmacists 1 inactive pharmacist 2 vacancies
<p>Board of Pharmacy</p> <ul style="list-style-type: none"> Ken Schell Supervising Insp. Ming & Inspector Janice Dang 	<p>Inpatient setting</p> <ul style="list-style-type: none"> 4 active pharmacists 1 inactive pharmacist <p>Managed care</p> <ul style="list-style-type: none"> 1 active pharmacist

Typically the inactive members are those who are unable to attend meetings regularly. Additionally, the new pharmacy schools at Loma Linda and UCSD should be offered the chance to appoint members to the committee. In the past, each school has appointed two members.

Now that the needs of the new exam cycles are established, staff believes it is appropriate to convert to a new structure, a structure similar to the one used by NABP. The proposed structure

would be a two-tier structure, a group of item writers to develop questions for the examination, and the core committee – the group that selects items and refines them for the examination, selects a cut score and oversees issues arising from administration of the examination.

The item writers would meet once annually for an item-writing workshop. Then, throughout the year, assignments to write questions in specific areas of the content outline would be assigned to them. The questions would be sent to the board in a secure manner. There would be no other meeting for this group of individuals.

The core committee would refine and revise the questions submitted by the item writers and review items selected for examinations to assure a balanced exam for any applicant. The committee would establish cut scores and review the performance of questions in the exam pool. When necessary, the members would also write items for the examination. This group would be smaller than the current committee (if the current Competency Committee was fully appointed, there would be 29 members). The proposed structure would be:

<u>Recommended Composition:</u>	<u>19 members</u>
Schools of Pharmacy: 1 member each	6 members
Community Practice:	6 members
Institutional Practice:	5 members
Board Member:	1 member
Inspector:	1 member

Attendance at the meetings would be a requirement, and those who miss a certain number of committee meetings each year would be asked to become item writers because attendance at these meetings would not be necessary. There would continue to be seven meetings annually, but the board’s item bank of usable items would grow greatly, facilitating examination administration. At some point in the future (perhaps two years), it could be possible to reduce the number of annual meetings of this group, perhaps to five or six meetings per year.

Terms would be for four years, with reappointment to another four years. The board’s president would appoint all members. Appointment would require three letters of recommendation in addition to the applicant’s curriculum vitae.

The costs for the new structure (\$99,724) would be about the same as the costs for the current structure if 29 members were appointed to the committee and attendance remained at current levels – about 50 percent attending any full two-day meeting (\$101,810).

Restructuring the committee would reduce the burden placed on the members of the committee to attend 14 meeting days annually and write questions outside of the committee meetings. It would help prevent member “burn-out.” Another benefit of using item writers for new questions would be a broader base of examination questions in the “bank.” And as stated earlier, within two years, the committee could reduce its number of two-day meetings from seven to five each year if a large enough item bank exists.

The Licensing Committee recommended that the Board of Pharmacy approved the proposed restructure of the Competency Committee.

Report Requirement of Business and Professions Code Section 4200.1 – Four Attempts to Pass the Pharmacist Licensure Examination

Ms. Herold reported that since 1999, candidates for the California pharmacist licensure examination who fail the examination four or more times, are required to take 16 units of education in pharmacy in a school approved by ACPE or by the board before they can retake the examinations. This provision will be repealed January 1, 2005, unless the sunset date for this provision is extended.

The board sponsored this provision to remove a number of applicants from the licensure examination who had repeatedly failed the examination – in fact; there were several applicants who had taken the examination more than 25 times. A major concern was that these individuals were taking the examination only to memorize questions that could be provided to preparation course providers.

The provision itself was modeled after a similar provision enacted for the dental examination.

When the provision was enacted in 1997, the board was also mandated to provide a report to the Legislature after June 1, 2004 and before December 31, 2004 on the effect of this provision in four areas. These areas are:

1. The number of applicants taking the examination and the number who fail the examination for the fourth time
2. The number of applicants who, after failing the examination for the fourth time, apply to take the additional 16 semester units of pharmacy education in California, and the number of these applicants who are accepted into the pharmacy education program.
3. The number of applicants who, after filing the examination for the fourth time, apply to participate in any pharmacy studies program, in or out of California, and the number of these applicants accepted by those programs.
4. To the extent possible, the school and country from which applicants graduated and the comparative pass/fail rates on the examination in relation to the school and country.

At the April 2004 Board Meeting, a copy of this report will be provided for review before it is submitted to the Legislature.

However, since the examination structure itself was greatly altered by last year's SB 361, staff requests that an extension in the sunset date for this provision be made. The reason for this is to allow the board time to evaluate the effect of the provision on the new examination structure. Proposed language was provided.

According to a recent legal opinion prepared by Departmental Counsel Dana Winterrowd, the four-time failure provision still affects those who take the CPJE and the NAPLEX. For those

who have never taken the California licensure examination, they will have four opportunities to take and pass the CPJE and four opportunities to take and pass NAPLEX.

If someone had taken the old examination (before January 1, 2004) and failed it one or more times, these attempts do count when determining the four failures. For example, if someone failed the January and June 2003 examinations, he or she would have two more opportunities to pass the CPJE and two opportunities to take the NAPLEX. Once he or she reach four failed attempts, the individual would need to take the 16 units of pharmacy education before he or she could retake the examination.

Some of the schools that provide the pharmacy coursework are Idaho State and Long Island University. In the past, USC also provided the coursework, but discontinued the program several years ago. None of the other pharmacy schools ever established a course.

Some preliminary data:

EXAM	TOTAL CANDIDATES	FOUR-TIME FAILERS	PERCENT
June 2003	1,284	12	0.9 percent
Jan. 2003	675	15	2.2 percent
June 2002	1,156	6	0.5 percent
Jan. 2002	536	21	3.9 percent
June 2001	1,165	12	1.0 percent
Jan. 2001	601	18	3.0 percent
June 2000	1,065	11	1.0 percent
Jan. 2000	537	14	2.6 percent
June 1999	950	9	0.9 percent
Jan. 1999	508	28	5.5 percent
	8,477	146	1.7 percent
	exam attempts	failed 4-times	

The Licensing Committee recommended that the Board of Pharmacy sponsor legislation to extend the provision that requires an applicant who has failed the board's pharmacist licensure examination to take an additional 16 units of pharmacy education. The provision would be extended until the board's next sunset review in 2006.

Proposed Amendment to CCR, title 16, sec. 1719(a) – Board Approval of Pharmacy Schools Pending Accreditation by the Accreditation Council for Pharmacy Education (ACPE)

At the January 2004 Board Meeting, the board agreed to accept “candidate status” accreditation by the ACPE as meeting sufficient standards for the board to issue an intern license to a student at Lake Erie School of Pharmacy.

This was the second time in one year that the board had to consider accreditation of a new pharmacy school because students were seeking California intern licenses. Both schools had limited accreditation status from the ACPE, which required specific board action to assure they could be issued intern licenses. At the board meeting, staff stated that they would suggest a more permanent resolution to the board.

Internship is an integral part of the pharmacy education of students. State licensing agencies look for ACPE accreditation as a means to assure the students are receiving particular (and approved) educational coursework before an intern pharmacist license is issued. This is especially critical for new schools, where there is only provisional ACPE accreditation (full accreditation will not be given until the first students have graduated from the school).

The ACPE Accreditation Manual, 9th Edition has the following definition of “candidate status:”

9.3.2 Candidate. A new program that has students enrolled but has not had a graduating class may be granted Candidate status. The granting of Candidate status denotes a developmental program, which is expected to mature in accord with stated plans and within a defined time period. Reasonable assurances are expected to be provided that the program may become accredited as programmatic experiences are gained, generally, by the time the first class has graduated. Graduates of a class designated as having Candidate status have the same rights and privileges as graduates of an accredited program.

Therefore, staff recommended that the committee consider amending section 1719 regarding the requirements for the admission to the examination to include a school of pharmacy that is accredited or has been “granted” candidate status by the ACPE.

The committee noted that section 1719 relates to the requirements for admission to the pharmacist licensure examination. It does not address the requirements for the issuance of an intern permit. While this section needs to be updated, staff would review the intern sections to include the same provision.

The Licensing Committee recommended that the Board of Pharmacy revise section 1719 and other “intern” provisions to recognize those schools of pharmacy that have been granted “candidate” status by the ACPE. Staff will provide the exact language at the board meeting.

Update on the Development of Statewide Protocol for Pharmacists to Dispense Emergency Contraception and Recommendation to Pursue Adoption of an Emergency Regulation

On January 30, 2004 the Medical Board of California considered the emergency contraception protocol approved by the Board of Pharmacy at its January 21, 2004 meeting. The discussion

focused on the inclusion of a question regarding the last menstrual period in the protocol. Opposition to this question was articulated by the American College of Obstetricians and Gynecologists (the same opposition was indicated in their testimony before the Board of Pharmacy). The Medical Board delegated consideration of the protocol to a committee of its board, and Board of Pharmacy staff will participate in those discussions. It is expected that the Medical Board committee will meet prior to the Board of Pharmacy meeting in April so that the board may consider any changes that are proposed. The Medical Board anticipates having the protocol on its agenda in May as an action item.

In addition, the staff counsel for the Medical Board indicated that the protocol may have to be adopted as a regulation. Staff will be exploring this with counsel and if necessary, the board may want to take action to adopt the protocol as an emergency regulation.

The Licensing Committee requested that the board's staff counsel confer with the Medical Board's counsel to determine the need to adopt the protocol as a regulation. The committee recommended that the board consider the recommendation from Medical Board at its April meeting and then determine if action is necessary to adopt the protocol as an emergency regulation.

Request for Changes to Business and Professions Code section 4232 and CCR, title 16, section 1732 – 1732.7 Relating to Continuing Education (CE)

The California Pharmacists Association submitted a request to the Board of Pharmacy that it consider amendments to the CE regulations. One reason for this request was that in January 2004, the activities of the Accreditation Evaluation Service (AES) moved from the California Pharmacists Association (CPhA) to the CPhA Educational Foundation. In addition the following changes were included:

- Change the term “continuing pharmaceutical education” to “continuing pharmacy education”
- Change AES from a “continuing education provider and coursework review component of the California Pharmacists Association” to “the accreditation agency for providers of continuing pharmacy education in California”
- Change the role of AES and ACPE from “approvers” to “accreditors”
- Change the ownership AES to the CPhA Educational Foundation
- Change the language from “organization” to “accreditation agency”
- Change the review/audit requirement 10%
- Change the term “certificates of completion” to “statements of credit”
- Require the provider to furnish the “statement of credit” to participants who complete the requirements for course completion
- Require that the material be current in order for it to be considered valid CE

While it appeared that many of the proposed changes to the CE regulations were technical and an effort to update the law, concern was expressed that some changes were substantial. The professional associations agreed to review the proposal and resubmit the request.

Request from Cedars-Sinai Medical Center for a Waiver Pursuant to CCR, title 16, sec. 1706.5 to Conduct a Study with UCSF, School of Pharmacy to Determine the Impact of Technician Checking Technician Filled Unit Dose Cassettes on Patient Care

Dr. Ambrose, Professor of Clinical Pharmacy for UCSF, School of Pharmacy requested a waiver of CCR, title 16, sec. 1793.1(f) and 1793.7(b). The purpose of the waiver is to allow a pharmacy technician in a unit-dose drug distribution system to check another technician. Dr. Ambrose stated that this study is a logical sequel to the successful experimental program that evaluated technicians that concluded in December 2003.

This sequel study will evaluate the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. Such functions require special expertise of pharmacists in the management of drug therapy, from which patients will benefit.

The Cedars-Sinai Medical Center (CSMC) is the sponsoring facility. The proposal requests that the board allow the “tech-check-tech” process to continue at CSMC, while UCSF measures the number and types of medication errors prevented during the equivalent time period that pharmacists would be check medication cassettes. Dr. Ambrose requested that the Board of Pharmacy grant the waiver for two years and that an interim report would be provided at one year. Representatives from CSMC also stated that they would continue to seek legislation to allow the “tech-check-tech” process.

The Licensing Committee recommended that the Board of Pharmacy approve the study.

Statutory Proposal for Application Information

Executive Officer Patricia Harris explained that the applications for the board’s 12 regulatory programs require a range of different information from the various applicants. On the advice of counsel, requests for much of the needed information has not been included on applications because of a concern regarding the specific legal authority to request the information. Accordingly, staff developed a legislative proposal for inclusion in the 2004 Omnibus Bill. This proposal is intended to provide the board with clear statutory authority to request information needed to evaluate the qualifications of any applicant. This will allow the board to include necessary information on application forms without adopting regulations to do so.

The proposal is to clarify the basic information that is requested on application forms, which is consistent with the relevant law requirements to obtain a license or permit from the board. Concern was expressed that the proposal may be too broad. Modifications to the proposal would be provided.

The Licensing Committee recommended that the Board of Pharmacy support the legislative proposal, noting that proposed modifications will be provided to address the concern that the language is overly broad.

Overview of Scholarship Process for Pharmacist

At the January meeting, the board agreed to pursue a statutory change to clarify the \$25 contribution that can be made to the pharmacist loan repayment program. During this discussion, clarification was sought about the loan program and how it works. Staff agreed to provide more information at the next meeting. In response, Legislation Chief Paul Riches explained that Assembly Bill 2935 (Chapter 1138, Statutes of 2002) established the California Pharmacist Scholarship and Loan Repayment Program in the Office of Statewide Health Planning and Development (OSHPD). The bill established a mechanism for pharmacists and pharmacies to contribute \$25 to a fund that would provide scholarships or loan forgiveness to pharmacists and pharmacy students who committed to serve in medically underserved communities.

The statute specifies that the program will only be implemented to the extent funding is made available. It permits both the contributions by renewing pharmacists and pharmacies and any other source of funding that can be identified and appropriated by the Legislature.

The bill also specifies that the program shall be administered using the criteria employed by the National Health Service Corps scholarship and loan repayment programs and excerpts from those program bulletins were provided. As a general matter, the programs provide funding to students and graduates who commit to provide health services in medically underserved communities for a two-year period. Funding is capped at \$25,000 per year based on either the actual educational expenses or the total amount of qualified educational loans outstanding for the candidate.

Candidates are selected generally based on financial need and having characteristics that indicate a tendency to remain in the underserved community after their commitment has been completed.

Strategic Plan Review and Update

The Licensing Committee reviewed the strategic plan and did not make any changes.

ACPE Evaluation of the Doctor of Pharmacy Program of Thomas J. Long School of Pharmacy

Ms. Harris reported that the Accreditation Council for Pharmacy Education (ACPE) is responsible for the evaluation of pharmacy education. When ACPE performs an evaluation of a California school, a representative from the Board of Pharmacy is invited to participate on the evaluation team.

ACPE invited the board to participate on the team that evaluated the Doctor of Pharmacy program of Thomas J. Long School of Pharmacy and Health Sciences at the University of Pacific on February 17-19, 2004. Board Member Stan Goldenberg participated and will report on the evaluation process and his experience at the April board meeting.

Adjournment

Licensing Committee Chair Clarence Hiura adjourned the meeting at 11:45 a.m.