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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE:	March 22, 2006
TIME:	9:30 a.m. – 12 noon
LOCATION:	Hilton Oakland Airport One Hegenberger Road Oakland, CA 94621
BOARD MEMBERS	Ruth Conroy, Pharm.D., Chair Clarence Hiura, Pharm.D. John Jones, RPh, JD Richard Benson, Public Member
STAFF PRESENT:	Patricia Harris, Executive Officer Virginia Herold, Assistant Executive Officer Robert Ratcliff, Supervising Inspector Dennis Ming, Supervising Inspector

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 9:30 a.m.

Request to Amend 16 CCR § 1728

Pharmacy students from USC and other pharmacy schools presented a proposal requesting that the Board of Pharmacy amend its regulations to allow up to 400 hours that an intern can earn for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. Under current law, an intern must earn a minimum of 900 hours of pharmacy experience under the supervision of a pharmacist in a pharmacy. The board has the discretion to grant a maximum of 600 hours for other experience substantially related to the practice of pharmacy. California pharmacy students earn the 600 hours for school required experiential training (clinical clerkship).

Therefore as proposed, an intern would only need to earn a minimum of 500 hours in a pharmacy and could earn a maximum of 1,000 hours of experience substantially related to the practice of pharmacy under the supervision of a pharmacist.

It was noted that opportunities for pharmacists has expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth year in both community and hospital pharmacy. In the fourth year, pharmacy experience is more clinical. It was anticipated that a large percentage of pharmacy students would still earn the majority of the intern hours in a pharmacy. This option would be for those students that show proficiencies in the pharmacy settings and would like to expand their experience in other areas.

The National Oncology Alliance, Inc. (NOA) spoke in support of the proposal and gave a presentation on opportunities that it has for interns outside a licensed pharmacy and under the supervision of a pharmacist. The intern would assist the NOA clinical team to prepare clinical summaries of articles in the medical literature, collect data about the status of drug approvals as it applies to NOA treatment guidelines and assist with the development and yearly revision of NOA treatment guidelines. NOA advocated that patient care activities meet the Accreditation Council for Pharmacy Education (ACPE) criteria and content outline of the California Pharmacy Jurisprudence Examination (CPJE).

The responsibility of the board is to protect the public. It is important that an intern pharmacist is capable of performing the core competencies of pharmacy practice. An intern has the authority to perform all the duties of a pharmacist under the supervision of a pharmacist. There was concern that a minimum of 500 hours of intern experience in a pharmacy is not sufficient to assure adequate public safety and the experience necessary to perform the duties of a pharmacist. It was not clear how experience with a pharmaceutical manufacturer, in regulatory affairs or association management would provide an intern with the skills critical to the practice of pharmacy. The core functions of pharmacy include patient consultation and quality assurance, key skill areas and knowledge that an intern can only gain in real life experience and daily practice in a pharmacy.

The proposal will be placed on the agenda for the April board meeting without a recommendation from the Licensing Committee.

Request from the Accreditation Commission for Health Care, Inc. (ACHC) and the Community Health Accreditation Program (CHAP) to Continue as Board Approved Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

B & P § 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of

Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The board approved Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for 3 years. At that time, ACHC accredited both home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. Recently ACHC has been reviewed by the Center for Medicare and Medicaid Services (CMS) and granted Deeming Authority for Home Health Medicare.

In July 2003, the board approved Community Health Care Accreditation Program (CHAP) as an accreditation agency. CHAPS is a national non-profit accreditation organization established in 1965 to accredit community-based health care organizations. Currently, one California is CHAP accredited and two pharmacies have applied. There are 63 CHAP accredited pharmacies in 23 states and 16 pharmacies that have applied for accreditation.

Supervising Inspector Dennis Ming reported that the board has not found any compliance issues with either ACHC or CHAP accredited pharmacies

In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors.

1. **Periodic inspection** – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. **Documented accreditation standards** – The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. **Evaluation of surveyor's qualifications** – The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payors** – Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

The Licensing Committee recommended that the Board of Pharmacy approve ACHC and CHAP for another 3 years as accreditation agencies pursuant to B & P § 4127.1(d) for pharmacies that compound sterile injectable drug products.

Proposal to Add a Regulation to Recognize Approved Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products

B & P § 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The board approved Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for 3 years. In July 2003, the board also approved Community Health Care Accreditation Program (CHAP) as an accreditation agency.

Since both agencies have requested that the Board of Pharmacy approve them again as accreditation agencies, and if the approval is granted, it is being recommended that the board pursue a regulation to recognize these agencies in regulation as the Joint Commission on the Accreditation of Healthcare Organizations is recognized in statute.

In addition, it was suggested to include the evaluation factors as part of the regulation, require that the accreditation agency use the board's self-assessment form for sterile injectable compounding pharmacies as part of the survey process, submit a copy of the survey report to the board and the process by which a board may no longer recognize an accreditation agency. If the board agrees with this recommendation, proposed language will be drafted.

The Licensing Committee recommended that the Board of Pharmacy pursue a regulation to recognize ACHC and CHAP as accreditation agencies for sterile injectable compounding pharmacies and specify the requirements and application process for accreditation agencies seeking approval.

Request to Extend the Waiver for the Study of UCSF School of Pharmacy and Cedars-Sinai Medical Center entitled "Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Association with Prescribing and Administration in the Hospital Setting"

Peter Ambrose, Professor of Clinical Pharmacy at UCSF and Rita Shane, Director of Pharmacy Services for Cedars-Sinai Medical Center requested an extension of the waiver for the study by UCSF School of Pharmacy and Cedars-Sinai Medical Center entitled, "Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration in the Hospital Setting." In April 2004, the Board of Pharmacy granted a two-

year waiver for this study. After board approval, the study was subsequently reviewed and approved by the Institutional Review Board at Cedars-Sinai Center and the Committee on Human Research at UCSF. In order to complete the data collection, analysis and review the results, an extension until December 31, 2006 was requested.

This study was a sequel to the successful experimental program that evaluated pharmacy technicians checking another pharmacy technician in a unit-dose drug distribution system in a hospital pharmacy.

The purpose of the sequel study is to 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.

Preliminary data from the study was provided to the board at its July meeting. At its last meeting, the board approved a regulation change to allow a specialized trained pharmacy technician to check another pharmacy technician in a unit-dose drug distribution system in a hospital pharmacy that has a clinical program. The proposed regulation change is scheduled for the April board meeting. If the board approves the proposed regulation, it will take approximately 6-9 months before the regulation would become effective.

The Licensing Committee recommended that the Board of Pharmacy extend the waiver until December 31, 2006.

NABP Announcement Regarding the Evaluation Process for Foreign Pharmacy Graduates

The National Association of Boards of Pharmacy (NABP) announced its partnership with the Educational Credential Evaluators, Inc. (ECE) for the educational credential evaluation of applicants to the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification Program. This partnership will change the method by which foreign pharmacy graduates will be evaluated.

ECE will be responsible for verifying the educational background of the applicant and NABP will verify the applicant's professional licensing and registration information. The foreign graduate will submit all documents directly to ECE for evaluation.

This new partnership is intended to address the increase of workload that this program has experienced over the last few years and improve the processing time for these applicants.

California requires all foreign graduates to be FPGEC certified before they can apply to be licensed as an intern or pharmacist.

Changes to the Pharmacy School Accreditation Procedures by the Accreditation Council for Pharmacy Education (ACPE)

ACPE recently announced changes to its accreditation procedures. After June 30, 2006, ACPE will require that any new doctor of pharmacy program seeking preaccreditation status must progress through both stages of preaccreditation, which is precandidate and candidate phases, before consideration of full accreditation. Prior to this policy change, it was not essential that a program be granted precandidate status before students were admitted.

After June 23, 2006, a new program must achieve precandidate status before admitting students. Should a new program admit students without achieving precandidate status, this will preclude ACPE from considering the program's application for candidate preaccreditation status, and full accreditation cannot be considered until graduation of the first class. Students graduating from a program without candidate status will thus have graduated from a program with no accreditation status and will likely not be eligible for licensure.

This change in policy is consistent with the board's recent regulation change that states that the board will recognize a school of pharmacy that is accredited or granted candidate status by ACPE or schools recognized by the board. The board has recently "recognized" new schools of pharmacy that have been granted precandidate status so that the students can be registered as interns.

Report on ACPE Site Visits

It was reported that board members have been actively participating on the ACPE evaluation teams for the California schools of pharmacy. President Goldenberg participated in the recent evaluation of Western University of Health Sciences College of Pharmacy. Former board member Darlene Fujimoto was on the team that evaluated UC San Diego Skaggs School of Pharmacy. The evaluation conflicted with the board's February meeting so Dr. Fujimoto graciously agreed to be the board's representative. Board member Ruth Conroy will be on the site team for Loma Linda University School of Pharmacy scheduled for April 18th – 20th. ACPE is scheduled to evaluate the Touro University California College of Pharmacy for candidate status on April 25-27, 2006, which conflicts with the board's April meeting. If the ACPE visit cannot be rescheduled then a former board member will serve as a representative on the site team.

Competency Committee Report

Virginia Herold reported that at the October 2005 board meeting, the board approved the use of the new content outline for the California Pharmacist Jurisprudence Examination (CPJE) given on or after April 1, 2006. The board posted the new content outline on the board's Web site and was included in the board's January 2006 newsletter.

The California Pharmacy Jurisprudence Examination (CPJE) handbook is in the process of being updated and will include the new content outline. There is also a sample CPJE exam that is posted on the board's Web site.

The Office of Examination Resources (OER) within the Department of Consumer Affairs is renewing its contract with a vendor to provide computer based testing. OER conducted the bidders' sessions on March 3 & 6, 2006. Final bids are due to OER on April 4, 2006. The cost opening is scheduled for April 13, 2006, with a Notice of Intent to Award the Contract on April 21, 2006. The anticipated contract award date is May 8, 2006. The duration of the contract is 3 years with 2 one-year optional extensions.

The next CPJE statistical report will cover performance data for 10/1/05-3/31/06. This report should be available at the April board meeting.

Adjournment

Chair Ruth Conroy adjourned the meeting at 12 noon.