



California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

LICENSING COMMITTEE Meeting Summary

DATE: June 24, 2003

TIME: 9:00 a.m. – 11:30 a.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA

BOARD MEMBERS Clarence Hiura, Pharm.D., Chair
Don Gubbins, Jr., Pharm.D.
John Tilley, R.Ph. (absent)

**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, Legislative Analyst

Call to Order

Committee Chair Clarence Hiura called the meeting to order at 9:00 a.m. He commended and thanked Dr. Fong for the excellent job he did as chair of the Licensing Committee last year.

Update on the Security Breach and Halt of the Administration of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE)

Ms. Harris reported that Business and Professions Code section 4200(a)(2)(B) requires an applicant who graduated from a foreign pharmacy school to receive a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that of domestic graduates.

To meet this requirement, the board relies on the FPGEE developed and administered by the National Association of Boards of Pharmacy (NABP).

As a result of the security breach last November, administration of the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) was suspended until a new test was developed and the investigation was completed. The new FGPEE test has been developed and was administered for the first time June 21, 2003, to approximately 2,100 candidates. The new test is not computer based but was given in 4 cities nationwide, including one location in California. NABP anticipates results will be released by the end of August. Over 500 applicants took the examination in California.

There is no set date for any subsequent administrations, but NAPB anticipates the next administration to be in late 2003 or early 2004.

As reported at the last licensing committee meeting, NABP identified 15 individuals implicated to Internet postings which may have caused or contributed to the compromise. As such the scores of those candidates were invalidated. None of the individuals listed were licensees or had pending applications with the board.

Update on the Joint Legislative Sunset Review Process Regarding the California Pharmacist Licensure Examination (SB 361)

Executive Officer Harris reported that the provisions regarding the use of the national examination in California are in SB 361. This bill passed the Senate and is scheduled for a policy hearing in the Assembly Business and Professions Committee on July 1, 2002.

Competency Committee Report on the June 2003 California Pharmacist Licensure Examination

Ms. Herold reported that the board administered the pharmacist licensure examination on June 17 and 18, 2003, at the San Jose Convention and Cultural Facilities. While 1,336 applicants were scheduled to take the examination, 1,284 actually took the exam.

Grading for this exam will be conducted in Sacramento on July 16 and 17, 2003. Board member graders are needed for this administration. Examination results will be released approximately September 1, 2003. The pass rate information will be available at the October 2003 board meeting.

Implementation on the Injectable Sterile Compounding Program for Pharmacies

Ms. Harris reported that on July 1, 2003, any California pharmacy that compounds sterile injectable drug products must be licensed by the board as a compounding pharmacy unless the pharmacy is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Accreditation Commission on Healthcare (ACHC).

Additionally any nonresident pharmacy that ships injectable sterile compounded products into California that is not licensed as a hospital, home health agency or skilled nursing facility and

has a current accreditation from JCAHO or ACHC must obtain a nonresident sterile compounding license from the board.

When licensure is required, part of the application process requires that the board must inspect the pharmacy. For nonresident pharmacies, the board is required to obtain a copy of the inspection report from the state pharmacy licensing agency or accreditation agency.

For the prior four months, board staff have been implementing this program. Application forms have been developed, programming for licensing records performed, training of staff provided in processing applications and condition inspections and information sessions with the profession conducted. It has been a team effort, but Supervising Inspector Dennis Ming has been instrumental in establishing the program and Suelynn Yee is processing the applications.

Applications are on the board's Web site for downloading. A self-assessment form has been developed so that pharmacies can review what elements inspectors will check during inspections. There have been a number of questions asked of diverse board staff regarding compliance and the process.

The board has also sent a letter to all state boards of pharmacy, advising them of California's requirements. It was suggested to send this information to the already licensed nonresident pharmacies.

To assure that the board inspects all sites possible before July 1, all inspectors have been assigned these inspections as a priority assignment. It was reported that as of June 23, 2003, the board had received 103 applications.

Of the 103 applications, inspectors completed 76 inspections (75%) with the remainder to be completed before June 27, 2003. Of the 76 inspections completed, 59 pharmacy sites (78%) have been approved for licensure and are in compliance with CCR section 1751 (including 4 non-resident applications). Nineteen out of 76 applications (25%) were placed on hold pending corrections to come into compliance with CCR 1751. Four (4) applications were found to be accredited by JCAHO and their applications were withdrawn.

Summary of inspector activities and highlights:

- All inspectors completed a one-day training session on conducting sterile compounding inspections.
- The supervising inspector for the program completed inspection assignments with each inspector to monitor uniformity and consistency in conducting the sterile compounding inspections.
- All inspectors have been assigned sterile compounding inspections throughout the state and these inspections were made a priority.
- Inspectors have been provided a standard format for preparing sterile compounding inspection reports.

- A compliance/non-compliance checklist was developed based upon CCR 1751 and used by inspectors to evaluate the pharmacies compliance with the regulation and is available on the board's web site for the licensee's own self assessment.
- A FAQ section on sterile compounding was developed and is on the board's web site.
- Applications for the sterile compounding license have been statewide as far north as Eureka and south to San Diego.
- Northern California applications have centered in the Bay area and Sacramento.
- Southern California applications have centered primarily in Los Angeles and Orange counties with a few in Riverside and San Diego.
- Approximately 10 pharmacies have purchased a commercially available policy and procedure for sterile compounding. These versions have been found unacceptable due to the generic characteristic of the manual. Pharmacies who have submitted "canned" policies and procedures have been contacted with suggestions for revision to make the document specific for their operation. The author of the manual was contacted and advised of the issues.
- The following areas of partial or non-compliance discovered during the sterile compounding inspections have resulted in withholding the issuance of sterile compounding licenses until corrections have been documented: incomplete policies and procedure manuals, lack or incomplete cleaning logs, lack or incomplete equipment calibration logs (pumps, balances, sterilizers, incubators, refrigerators etc), lack or incomplete personnel training/competency documentation, lack or incomplete patient records (some items are difficult for community pharmacies to obtain), presence of porous ceiling tiles over the preparation area (regulation requires non-porous ceiling tiles), lack or incomplete process validation documentation, and lack or incomplete end-product testing for sterility and quantitative analysis. One pharmacy was found to use expired drugs to compound injectable medications (a violation was issued).
- Follow-up telephone calls were made to the PIC one week after the inspection to remind them to submit the requested information. The licensees have been receptive to the corrections and guidance provided during and after the inspections. The pharmacies have complied in a timely manner with providing the requested documents and/or revisions, which has resulted in a relative high number of approved applications for sterile compounding licenses.

It is anticipated that the board will receive a large number of applications during the last week of June. It will not be possible to inspect all of the late applications prior to July 1st and will require a sustained effort by the inspectors after this time period to complete the inspection portion of the licensing process.

Ms. Harris reported that the board staff specifically Supervising Inspector Dennis Ming and the inspectors have taken extraordinary efforts to ensure that pharmacies are licensed by July 1, and patient care is not interrupted.

As determined by the board at its October 2002 meeting, the existing regulations for compounding parenterals is the standard the board is enforcing with respect to licensure. Meanwhile, the board is promulgating additional regulations to deal with requirements for

compounding injectables from nonsterile ingredients. At the April 2003 meeting, changes to this regulation were adopted and released for 15 days of comment. The responses were due June 19th. These new requirements will take effect in January 2005, if the regulation is approved.

Request for Comments Regarding Program Requirements for Interns

Ms. Harris stated that one of the Licensing Committee's strategic objectives has been to review the requirements for the Intern Program. Because of other priorities, this committee has not had the opportunity to perform such a review.

The purpose of this agenda item is to initiate the review by soliciting comments on how the intern program should be updated and streamlined operationally. About 10 years ago, to assist the intern and preceptor in complying with the program requirements, the board developed its Intern/Preceptor Manual, which is available to on the board's website. The regulations governing interns are found in CCR 1728(c).

No comments were received in advance of the meeting; however, it was recommended that the internship should include experience obtained under protocol with physicians as allowed by Business and Professions Code section 4052. It was recommended that the committee contact the 6 schools of pharmacy and invite them to the next meeting to discuss this issue and the concern raised at the previous meeting regarding the gap between pharmacy school curriculum and the California pharmacist licensure examination

Invitation from ACPE to Comment on Pharmacy Technician Training and Education

ACPE has initiated a profession-wide dialog concerning the possible development of national standards and an accreditation process for pharmacy technician education and training. ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmaceutical education.

The decision on whether or not to proceed with the development of national standards will be decided at ACPE's meeting in January 2004. If the decision is to establish a national standard, then ACPE anticipates that the process, from initiation to implementation will take about three years.

ACPE has invited organizations and individuals to submit written comments by October 31, 2003, that should be taken into consideration during this discussion. It was suggested that the board submit written comment to advise ACPE of California's education and training requirements for registration and the "pharmacy technician trainee" designee that allows practical training for the technician.

Request from the UC Davis Veterinary Medical Teaching Hospital (VMTH) for a Specialized Pharmacy Permit

Pharmacist Gale Moniz and Hospital Administrator Paul Brentson for VMTH appeared before the Licensing Committee to discuss the complexity and need for a specialized permit from the board. Prior to the opening of the VMTH as an academic fourth year clinical training facility for veterinary medical students in the School of Veterinary Medicine at UC Davis, veterinary medicine was modest, and veterinary practices were small in nature (typically a single veterinarian practice). Veterinarians ordered, managed, and dispensed their own drugs.

The VMTH, opened in 1970, was the first to consider the importance of drug management, and to incorporate this unique educational emphasis into the program by hiring a pharmacist, and centralizing the pharmacy function. Even though the functions performed at the VMTH pharmacy parallel many of those found in human healthcare settings, the emphasis is quite different. The veterinary drugs are used in the clinic (a combination of a veterinary clinic and a full service animal hospital) or are dispensed for home or farm administration to the animal patient.

The VMTH is an academic veterinary clinical training facility as well as a very large, complex veterinary practice. The standard of practice in Veterinary Medicine, as described in the Veterinary Practice Act, is the provision of drugs to a client by the veterinarian, through their practice, subsequent to a veterinarian-client-patient relationship being established.

By 1988, it was recognized that the VMTH had evolved into a very diverse and complex practice. It was also apparent that the centralized pharmacy function was recognized to be extremely important relative to (1) consistency of pharmaceutical practice, (2) having the most current pharmaceutical information available to its clients (by way of the veterinarians), (3) improving the students' education relative to the most current pharmacy practice and regulations, and (4) having the ability to order the appropriate drugs for such a complex practice quickly and efficiently. These factors led VMTH management to the conclusion that the pharmacy activity could best be managed under licensure through the Board of Pharmacy, rather than under the auspices of the individual veterinarians and Veterinary Practice Act.

At that time, the board determined that the closest fit for licensure was a drug room permit. This is a permit that is issued to hospitals that have less than 100 beds.

Subsequent to an inspection last year, it was determined by the board that this permit was not the appropriate licensure, and the only option was for licensure as a community pharmacy, which does not fit the needs of the VMTH. The other issue is that VMTH uses many human drugs that are not available through veterinary drug wholesalers and human drug wholesalers are making business decisions not to sell the drugs to VMTH even though pharmacy law does not preclude them from doing so. Veterinarians are defined as "prescribers" in pharmacy law.

Various options were discussed. An option was suggested that a "specialized" clinic permit be designed that would require a consultant pharmacist oversight over the drugs and distribution at the VMTH. It would allow for a common stock and provide a means for the VMTH to obtain a DEA permit. This option would require legislation.

The committee directed staff to work with VMTH to draft language for a specialized clinic permit and agreed to recommend to the board support of this specialized clinic permit.

Request from the Community Health Accreditation Program (CHAP) for Approval that Pharmacies Accredited by its Organization be Exempt from Licensure pursuant to Business and Professions Code section 4127.1(d)

Business and Professions Code section 4127.1(d) requires pharmacies that compound sterile injectable drug products to obtain a special pharmacy 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 bill exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accreditation agencies approved by the board from the license requirements. Exempted pharmacies still must comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license. At the last meeting, the board approved Accreditation Commission on Healthcare (ACHC) as an accreditation agency.

The Community Health Care Accreditation Program (CHAP) is also requesting approval as an accreditation agency as authorized under current law. CHAPS is a national non-profit accreditation organization established in 1965 to accreditate community-based health care organizations. CHAP currently accredits 35 pharmacies located in 14 states; currently there are 3 California pharmacies that are CHAP accredited and two have applied for licensure.

At its last meeting, the board recognized the importance of the 8 factors as key considerations as it works establishing a standard for analyzing accreditation applications. They are:

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 discussed the accreditation process with representatives from CHAP. Supervising Inspector Dennis Ming reported that he has inspected a CHAP accredited pharmacy and found it to be in compliance. The committee recommended that the board approve CHAP as an accreditation agency contingent on the outcome of the next inspection and submission of additional paperwork, which is a comparison of standards between CHAP and JCAHO.

Review of Strategic Objectives for 2003/04

The Licensing Committee reviewed the objectives and made some technical corrections. The committee discussed exploring special educational requirements for the pharmacists in charge (PIC). Concern was expressed that many newly licensed pharmacists are not taught the skills and knowledge required to be a PIC. Even experience pharmacists are not always aware of the expectations and responsibilities expected of the PIC.

Adjournment

Committee Chair Clarence Hiura adjourned the meeting at 11:30 a.m.