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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE:	June 9, 2004
TIME:	9:30 a.m. – 12 noon
LOCATION:	Hilton Burbank Airport & Convention Center 2500 Hollywood Way Burbank, CA 91505-1019
BOARD MEMBERS	Clarence Hiura, Pharm.D., Chair Ruth Conroy, Pharm.D.
STAFF PRESENT:	Patricia Harris, Executive Officer Virginia Herold, Assistant Executive Officer Robert Ratcliff, Supervising Inspector Dennis Ming, Supervising Inspector

Call to Order

Committee Chair Clarence Hiura called the meeting to order at 9:30 a.m. He explained that committee members John Tilley and Richard Benson were excused from the meeting.

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 statute and 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

The Licensing Committee recommended that the Board of Pharmacy amend the continuing education statute and regulations as requested by the Pharmacy Foundation of California.

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

Assistant Executive Officer Virginia Herold reported that as of May 28, 2004, the board has qualified 1,134 applicants to take the pharmacist licensure examination (the NAPLEX and CPJE). However, as of May 24, 2004, only 284 applicants had taken the CPJE. She stated that the board had processed 1,545 applications out of the 1,673 applications received. There were 128 applications to process with 411 deficient applications pending.

Ms. Herold added that the board will be releasing the CPJE scores in approximately two weeks with the goal of issuing pharmacist licenses by mid-June. She stated that the board has been releasing NAPLEX scores and does so on a weekly basis. She reported on the pass rate for the NAPLEX.

Ms. Herold advised the Licensing Committee that staff has experienced a substantial increase in telephone, faxed and in-person inquiries regarding the examination process. Even with the board's limited resources, staff has been performing extraordinarily to ensure timely processing and licensure of pharmacist applicants. Every effort is being made to assist applicants to the extent that the board can without impacting the application process.

Request from the Schools of Pharmacy to discuss the Intern Requirements

Committee Chair Clarence Hiura reported that on April 20, 2004, President John Jones received a letter from the Dean of UCSF, School of Pharmacy, Dr. Mary Anne Koda-Kimble. She wrote the letter on behalf of her fellow California School of Pharmacy Deans. The purpose of the letter was to express concern about the proposed changes to the licensure requirements contained in SB 1913, and to request that the board initiate an open dialogue with them on how the 1,500 hours of pharmacy internship would be defined.

It was explained to Dean Koda-Kimble that SB 1913 is not changing the 1,500 experience requirement that is currently specified in regulation, California Code of Regulations (CCR), title 16, sec. 1728. Specifically SB 1913 is moving the intern requirements from regulation to statute

(B&P Code sec. 4030), the length of time and circumstances that an intern pharmacist license may be issued (B&P Code sec. 4208), that the intern pharmacist must complete the 1,500 hours prior to applying for the pharmacist licensure examination and that the experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy education (B&P Code sec. 4209).

In her letter, Dean Koda-Kimble discussed the 1,500-intern requirement that is required by section 1728. Pharmacist interns must complete a minimum of 900 hours in a pharmacy under the supervision of a preceptor. Then the board can grant at its discretion a maximum of 600 hours for other experiences that substantially relates to the practice of pharmacy. California pharmacy students are granted the 600 hours for completing the School's Advanced Pharmacy Practice Experiences (APPEs or clerkships).

There was concern by the schools that SB 1913 changes the 1,500 intern requirement so that California pharmacy students would not be required to complete any intern hours of pharmacy practice experience beyond those associated with their formal curriculum in the school of pharmacy. The bill does not make this change.

The Licensing Committee initiated review of the intern program last June as part of its strategic objective. The program was discussed at subsequent meetings until December, when the committee recommended to the board that the intern requirements be placed in statute. The board acted on this recommendation at its January 2004 meeting. It was noted that once SB 1913 passes, the board will need to amend CCR 1728, to make it consistent with the new statutory changes.

The Licensing Committee discussed the intern requirements. The committee advised that it would review CCR 1728 at its next meeting in September and encouraged the schools to submit any recommendations at that time.

Report on the Implementation of the Licensure Program for Pharmacies that Compound Sterile Injectable Drug Products – One-year Evaluation

Supervising Inspector Dennis Ming reported that since the inception of the sterile compounding licensing program in July, 2003, the Board of Pharmacy has received and processed 238 applications and has approved 184 Sterile Compounding licenses, of which 16 are out of state. This is 77%. He stated that the three main reasons for the delays in approving applications are: the lack of adequate/detailed policies and procedures required for compliance with the regulations, incomplete applications relative to pharmacy ownership and pending licensure of the pharmacy.

Dr. Ming stated that inspections for new applications are completed within 3 weeks of assignment to an inspector. In April, the board began the re-inspection of these pharmacies prior to renewal and to date, 31 pharmacies were re-inspected. All the pharmacies were in compliance and sterile compounding pharmacy permits were renewed.

To maintain continuity in the licensing and inspection process, the re-inspections were assigned to inspectors who conducted the initial licensing inspection. A separate checklist was created to assist the inspector in comparing results of the initial licensing inspection to the observations made during the re-inspection. The results of the re-inspection were discussed with each licensee. This process enabled the inspector to identify areas of on-going compliance as well as trends/patterns in non-compliance with the regulations.

He stated that the initial results of the re-inspection process were as follows:

CCR 1751: Compounding Area for Parenteral Solutions: All of the pharmacies maintained on an on-going basis, the environment for the compounding sterile injectable drugs in compliance with this section.

CCR 1751.1 Laminar Flow Biological Safety Cabinet: One or two of the pharmacies converted from standard class 100 laminar air flow cabinets to class 100 barrier isolators in anticipation of the implementation of revised California Code of Regulations Section 1751 which requires specific environments in which to compound sterile injectable drugs from a non-sterile source. Pharmacies maintained annual certification of the laminar airflow hoods.

CCR 1751.2: Labeling Requirements: Pharmacies maintained compliance with this regulation. Pharmacies who contract with another pharmacy to compound sterile injectable drugs (Business and Professions Code Section 4123) were required to have the label of the compounding and dispensing pharmacy on the container.

CCR 1751.3: Record Keeping: Record keeping as required under current regulation will be changed when the revision to 1751 are finally approved and implemented. An area where record keeping was not strictly adhered to was radio pharmacies whose products are primarily intended for one time use and often for diagnostic purposes. In these cases, strict adherence to the record keeping requirements was not always possible or practical. Revisions to CCR 1751 will address and resolve these issues regarding record keeping requirements.

CCR 1751.4: Protective Clothing: This section was intended for pharmacies preparing cytotoxic (chemotherapeutic) medications for injection and for those pharmacies, compliance was on going.

CCR 1751.5: Training of Staff, Patient and Caregiver: Since the inception of the sterile compounding regulations, pharmacies were made more aware of the requirement to train and document competencies of the staff relative to utilizing aseptic technique etc. in the preparation of sterile injectable drugs. Records are being maintained; however, this area should be carefully monitored during the re-inspection process to ensure complete compliance.

CCR 1751.6: Disposal of Waste Material: Pharmacies were observed disposing of waste material from the preparation of sterile injectable drugs in an appropriate manner. Pharmacies compounding chemotherapeutic drugs disposed of residue in the appropriate chemo containers.

CCR 1751.7: Quality Assurance: This section has been the most problematic for pharmacies to maintain compliance. Results of the re-inspection demonstrate that a few pharmacies neglected to maintain records of cleaning, calibration of equipment, process validation, and end product testing. Some were confused as to how many tests should be done and how often. It would be beneficial to provide feed-back to licensees in either the board's newsletter or on its Web site on how to maintain compliance with quality assurance in pharmacies compounding sterile injectable drugs. None of the pharmacies that were observed to be weak in compliance with this section were issued written warnings of non-compliance; rather they were instructed by the inspector in how to improve their compliance.

CCR 1751.8: Policies and Procedures: Pharmacies maintained their written policies and procedures and a few have submitted revisions for review upon receiving the renewal notice from the board.

CCR 1751.9: Reference Materials: Pharmacies have maintained compliance with this section in having the necessary resource information for compounding sterile injectable drugs.

Supervising Inspector Ming concluded his report by providing a future action plan for the program, which is to:

- continue to conduct new and re-inspections for pharmacies applying for a sterile compounding license.
- provide additional information to the executive officer regarding the impact on inspector workload in conducting annual re-inspections of pharmacies compounding sterile injectable drugs relative to areas of compliance and non-compliance.
- continue to provide consultative/educational services to licensees to achieve and/or maintain compliance with sterile compounding regulations.
- modify the current sterile compounding checklist on the board web site to reflect the revisions in CCR 1751 (when approved for implementation).

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

SB 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

The protocol is available on the board's Web site and has been provided to the pharmacists associations for distribution. However, in order for the board to enforce the protocol, it must be adopted as a regulation. The proposed regulation has been noticed for adoption at the July board meeting.

It was noted during the discussion that the board was provided some changes to Appendix 1 of the protocol, which is the list of brands and doses of oral contraceptive tablets used for

emergency contraception. Staff will be exploring the process it must follow to update this appendix.

California Pharmacy Manpower Statistics

Ms. Harris explained that the pharmacy manpower statistics for California was provided for information purposes. She noted that as of December 2003, 5,624 pharmacies were licensed with the board. This is a 6.3% increase from January 2001.

As of December 2003, the board 37,756 pharmacy technicians were registered. This is a 41% increase from December 2001, where there were 26,706 registered pharmacy technicians. Also provided was the number of pharmacy technicians per pharmacists and per pharmacy.

In 2003, there were 24,256 licensed pharmacists with California addresses. This is a 16% increase from 2001, where 20,905 pharmacists were licensed. Also provided is the number of pharmacists per 100,000 Californians.

Adjournment

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