California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

LICENSING COMMITTEE MEETING MINUTES
January 6, 2000

PRESENT: Holly Strom, Chair
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Gilbert Castillo, Supervising Inspector
Ruta Arellano, Exam Coordinator
Paul Riches, Legislation/Regulation Analyst
LaVonne Powell, Legal Counsel
William Marcus, Deputy Attorney General

OLD BUSINESS

Report on Application/Licensing Statistics

Staff reported on the December statistics from the pharmacy licensing unit. The goal is to have the unit staff working on last week's applications as the performance standard. This may require an assessment to determine what steps must be taken to meet this goal. Applicant deficiencies need to be factored in when the processing time is calculated.

Proposed Legislation on Ambulance Restocking

The committee discussed the need for legislative action to address the lack of authority for hospitals to restock ambulances and the need for documentation by the parties involved.

The committee reviewed draft statutory language that would amend Business and Professions Code (B&P Code) section 4119 to authorize the restocking of ambulances by hospital pharmacies. The committee recommended not to pursue the authorization of other providers (such as fire districts and ambulance companies) to possess drugs and restock ambulances. Current law does not provide for this activity and the committee opined that it was the Office of Emergency Services' issue to resolve.

ACTION: Recommend to the Legislation and Regulation Committee that any proposed legislation should be focused on the board's statutes, B&P Code section 4119.

Waiver of Licensing Requirements – B&P Code Section 4118

The committee discussed possible approaches to expanding its waiver-granting authority regarding licensing requirements authorized by B&P Code section 4118. Expanded authority would include pilot projects, not necessarily involving pharmacy school participation, for the use of automated dispensing devices as remote controlled pharmacies.

ACTION: Further review of this proposal and possible regulation language will be drafted and brought to the committee for review and discussion at its April meeting.

NEW BUSNESS

Request from UCSF Regarding Technician Study Quarterly Audits

The committee considered a request from UCSF to extent the time between audits performed as part of the experimental program to evaluate pharmacy technicians checking other technicians. This pilot project is sponsored jointly by the UCSF School of Pharmacy, Long Beach Memorial Medical Center and Cedars Sinai Medical Center.

The UCFS's request was to perform audits on a monthly basis for the first quarter of phase II of the study and, contingent upon an accuracy rate of 99.8%, the audits would be conducted quarterly thereafter. Should the accuracy rate fall below the minimum target of 99.8%, future audits would revert to a monthly basis for the technician(s) failing to meet the target.

ACTION: The committee recommends that the board grant the UCSF's request.

Pharmaceuticals and Indigent Care

The committee discussed correspondence received from the Public Health Institute. The letter announced the settlement of a class action suit involving 19 pharmaceutical manufacturers that will provide $148 million worth of drugs over a three-year period to approximately 400 California clinics and hospitals.

Board licensing staff Sandi Moeckly and Brenda Cartwright worked with the institute and provided training to these clinics on how to file the proper applications with the board.

Request to Adopt Regulations to Require Manufacturers to Accept Expired Returns for Full Credit

The committee discussed a request from a reverse distributor that the board adopt similar regulations to those in effect in North Carolina. These regulations require manufactures receiving returned goods to issue full credit. The committee members were advised by Deputy Attorney General William Marcus that the issue is not within the board's purview.

FDA Regulations for Implementation of the Prescription Drug Marketing Act (PDMA) of 1987

The FDA has issued final regulations related to the PDMA that include the licensing requirements for drug wholesalers. The regulations require that a pharmacy whose drug sales to physicians exceed 5% of their gross sales must obtain a wholesale permit.

The committee members were advised by Deputy Attorney General William Marcus that the board does not need to take regulatory action.

ACTION: This new federal regulation will be the topic of a future newsletter article.

Clarification of Industrial Use of Hypodermic Needles and Syringes – B&P Code Section 4144

B&P Code section 4144 exempts a person from the permit requirements if the use and sale of hypodermic needles and syringes is for industrial purposes.

The committee discussed the need for regulations that would define "industrial use."

The committee members determined that no action is needed at this time. It is clear that the term "industrial use" means to be used as a part of a manufacturing process and not for commercial sale to an ultimate consumer. Should the issue become more prevalent and a demonstrated need be identified, steps will be taken to pursue regulations.

Request for Clarification Regarding the Ban of Advertisement of Compounding Services as Unconstitutional

The committee discussed correspondence relating to a recent court ruling in Nevada that a ban on advertising of compounding services is unconstitutional.

The board was asked if this ruling would affect California law regarding advertising of compounding services.

The committee was advised by legal counsel that California law is not affected.

ACTION: This issue will be researched and we will wait to hear from the FDA.

Protocol Practice in New Mexico

Board member Darlene Fujimoto requested a comparison of California's scope of practice for pharmacists with that of pharmacists in New Mexico. A comparison of the New Mexico scope of practice to California's was discussed. It appears that in New Mexico all prescribers, including pharmacists, are issued a controlled substances number. This is not done in California. However, efforts need to be made to change the statute so at least California pharmacists would be recognized by the DEA as mid-level practitioners.

NABP Internet Assistance for State Boards of Pharmacy

The NABP is developing an Internet-based licensure and renewal system that will be available to boards of pharmacy in the next year.

The committee will track this developing technology and the progress of this project.

The meeting adjourned at 11:20 a.m.