



California State Board of Pharmacy

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

LICENSING MEETING

March 28, 2000

PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Bob Ratcliff, Supervising Inspector
Gilbert Castillo, Supervising Inspector
Paul Riches, Legislative Analyst
Ruta Arellano, Exam/Regulation Coordinator
Sandi Moeckly, Pharmacy Licensing Analyst
LaVonne Powell, Legal Counsel

Patricia Harris called the meeting to order at 9:30 a.m.

OLD BUSINESS

Reporting of Application/Licensing Statistics

Staff reported on the February statistics from the site-licensing unit. There was discussion regarding the amount of time involved to retrieve and calculate the statistics. It was determined that an Access computer program would be written to reduce the time used in retrieving the statistics, provide a clearer picture of how many are actually pending, and where they are in the approval process.

Use of Automated Devices/Waiver of Licensing Requirements

This issue was put over to the next licensing committee.

Recommendation to Board Regarding Pharmacist Manpower Concerns

The Licensing Committee held two informational hearings on the issue of pharmacy manpower – the pharmacist shortage (reciprocity), use of ancillary pharmacy personnel and automation. In discussing this issue with the Licensing Committee Chair Holly Strom, it is the committee's recommendation that the board not to take any action regarding reciprocity (the use of the NABPLEX) until such time that the board has completed its review of the examination. The board is in the process of completing the job analysis for the California examination. Once this is done, then the board will contract with the Department of Consumer Affairs – Office of Examination Resources to conduct the review. It is anticipated that this will commence around January 2001. However, this timeline is contingent upon the status of the job analysis for NABPLEX.

It is staff recommendation that the board continue with the number one strategic objective for the Licensing Committee, which is to respond to emerging professional practice issues (e.g. technology, pharmacy manpower, changed practice settings and pharmacists' role). The Licensing Committee should continue developing statutory language regarding the use of automated dispensing devices. However, the profession should initiate legislation to address the expanded use of pharmacy personnel especially technicians although the board may want to develop a policy statement on this issue.

Meanwhile, the U.S. Department of Health & Human Services – Health Resources and Services Administration (HRSA) is conducting a study required under the Healthcare Research and Quality Act of 1999, to determine how many pharmacists it will take to fill America's prescription needs. HRSA is inviting all interested parties to submit resource information, data and documented studies that verify pharmacist shortages. Comments are due by May 1, 2000.

Licensing staff recommends that the board submit comments regarding California laws governing the use of technicians to fill prescriptions, the use of technology to assist pharmacists, and the current pharmacist education process including any policy positions that the board may take in these areas. In addition, the board may want to point out any outdated and restrictive federal law that places a burden on the pharmacist and which impacts their workload and ability to fill prescriptions.

The announcement regarding the study will be in the board's April newsletter with a request to send comments to the Health Resources and Services Administration 's Bureau of Health Professions regarding the shortage.

Status of Job Analysis

The data collected from the 900 responses to the board's job analysis survey has been tallied. At their March 29 & 30, 2000 meeting the members of the Competency Committee completed modification of the test specifications for the multiple-choice exam. These specifications are the basis of the board's new examination content outline. The content outline is used to determine the number and type of items used on the examination.

The next step in this process is the reclassification of the pool of multiple-choice items to conform to the new content outline. This activity will take place at the Competency Committee meeting scheduled for May 10 & 11, 2000.

The new content outline will be used for the first time to determine the mix of items to be pulled for the June 2001 exam.

NEW BUSINESS

Referral of Proposed Regulation section 1714.5

Effective January 1999, Business and Professions Code section 4057 was amended through board-sponsored legislation to remove the list of dangerous drugs and devices that can be

stored in non-pharmacy areas of a hospital, clinic or institution, or by licensed practitioners. This list will be maintained in proposed section 1714.5 of the California Code of Regulations.

The board published a notice for a comment period that ran from 10/29/99 to 12/13/99. No hearing was scheduled in the matter. Comments were submitted during the 45-day comment period by the California Society of Health-System Pharmacists and Kaiser Permanente. Both parties suggested changes to the board's proposal.

At its January 2000 meeting the Legislative and Regulation Committee referred the proposal to the Licensing Committee for further review. It was determined that staff member Ruta Arellano will schedule a meeting in Sacramento for the purpose of getting input from the interested parties. Those who will be invited are: Gilbert Castillo, Robert Grimm, Steven Gray, Teresa Miller and Ms. Arellano. The group will review previously submitted suggestions for amending the board's proposal and report back to the committee.

Compliance Policy Regarding the Electronic Transmission of Prescriptions

The board has received many inquiries regarding companies providing online Internet prescription services for physicians to electronically transmit prescriptions. The law states that as part of the prescription dispensing process, the prescriber can electronically transmit the prescription to a licensed pharmacy and California Code of Regulations section 1717.4 provides for an interim storage device where the prescription data can reside until it is transmitted to the pharmacy. After discussion, it was recommended that section 1717.4(h) be updated to include the word "authenticity" since board staff has determined it is the prescriber's responsibility to assure confidentiality when a prescription is written.

It was also recommended that a statement be added to the newsletter stating the board's position on the issue of confidentiality related to electronically transmitted prescriptions.

Repackaging of Dispensed Prescriptions by Another Pharmacy – Manufacturing

Board staff received a request to address the practice of repackaging prescriptions previously dispensed from a pharmacy into ATC bubble packaging for patients in assisted care. Current law does not authorize a pharmacy to repackage prescription drugs already dispensed by another pharmacy into ATC/bubble packaging. There are many concerns that are raised when this type of practice occurs. Current law requires that in order for a pharmacy to provide this service it must be licensed as a manufacturer.

While recordkeeping concerns were discussed, there was also discussion on how this practice can prevent prescription errors when there is a uniform distribution system in assisted and skilled care facilities.

After discussion, it is recommended that the board include language in the omnibus bill to amend Business & Professions Code section 4033 to exempt from the definition of manufacturer the repackaging of a dispensed prescription into an ATC/bubble pack by a pharmacy at a patient's request.

Application Requirements for Sites

Pursuant to Business and Professions Code section 4207, the Board currently asks applicants for pharmacy permits to provide the board with financial information. The board uses this authority to assure the true ownership interest and control of the assets of applicants for pharmacy permits. While the board has authority to require financial information, it does not have the authority to exempt it from public disclosure.

It was requested that Staff Counsel LaVonne Powell draft language to exempt financial information from public disclosure.

Call In Centers for Pharmacists

Assembly Bill 285 (Chapter 535, Statutes of 1999) requires telephone medical advice services to be registered with the Department of Consumer Affairs (DCA). To qualify for registration, the business entities providing telephone medical advice services must, among other requirements:

- Ensure that all staff who provide medical advice services are appropriately licensed, certified, or registered health care providers and operating consistent with the laws governing their respective scopes of practice in the state within which they provide telephone medical advice services.
- Ensure that all registered nurses providing telephone medical advice services are licensed in California.
- Ensure that the telephone medical advice provided is consistent with good professional practice.
- Maintain records of telephone medical advice services, including records of complaints, provided to patients in California for a period of at least five years.

AB 285 also defines medical advice as any activity that requires licensure as a health professional. The bill also exempts licensed individuals who provide telephone medical advice that is incidental to the primary focus of their professional practices.

The legislation also provides for provisional registration until DCA can implement the registration program. Any entity that submits proof of accreditation by the American Accreditation healthcare Commission, URAC, the National Committee for Quality Assurance, the National Quality health Council or the Joint Commission on Accreditation of Healthcare Organizations is deemed provisionally registered.

Specifies that DCA may suspend, revoke, or deny registration for the following:

- Incompetence, gross negligence, or repeated similar negligent acts performed by the registrant or any employee of the registrant.
- An act of dishonesty or fraud by the registrant or any employee of the registrant.
- The commission of any act, or being convicted of a crime, that constitutes grounds for denial or revocation of licensure for any California licensed health professional.

Requires DCA to conduct studies on telephone medical advice services and medical advice services as specified and report to the Legislature.

Requires every health plan that provides, operates, or contracts for telephone medical advice services to ensure that a physician is available on an on-call basis at all times that the service is available.

Pharmacists are included in the requirements of this legislation because they are health professionals as defined by Division 2, of the Business and Professions Code. Therefore, an out-of-state pharmacist that is providing telephone medical advice must be licensed as a pharmacist in California, unless they are providing this service as part of the dispensing process through a California registered nonresident pharmacy. DCA is pursuing various amendments to this bill including the clarification that licensure in California is required. However, even if the amendments are not pursued, current interpretation of pharmacy law does require California licensure of pharmacists.

60-day Cancellation of Licenses

Currently, there are over 500 sites and 350 exemptees that are 60 days or more delinquent in submitting their renewal. Section 4402(e) states the board may cancel the license if it is not renewed within 60 days after its expiration. Board staff is currently working on procedures to cancel these permits. There will also be a notification placed on renewals that states the permit will be cancelled if it is not renewed within 60 days after expiration.

PIC Changes not Being Reported

There are a number of pharmacies without a PIC or are not reporting PIC changes in a timely manner. In order to bring these pharmacies into compliance the committee recommends expanding their authority to cite and fine the pharmacies for non-compliance.

Implementation of MDR Home Ownership Prohibition

Since there is now a requirement in place that does not allow MDR's to be located at the home address of the owners, board staff will send letters to existing MDR's located at home addresses informing them they are required to relocate.

Strategic Planning

There were no recommendations for revisions to the Board's Strategic Plan.

Meeting adjourned at 12:45 p.m.