



California State Board of Pharmacy

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

**LEGISLATION & REGULATION COMMITTEE MEETING MINUTES
JANUARY 18, 2000**

Present: Tom Nelson, Chair
Andrea Zinder, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Ruta Arellano, Regulations Coordinator
Paul Riches, Legislative Analyst

I. Update on Bill Proposals for 2000 Legislative Session.

A. Senate Bill 1339 (Figueroa) relating to pharmacy quality assurance programs.

This bill originated with the Board of Pharmacy based on the regulation proposed in July of 1999 and the strategic goal of the Enforcement Committee to reduce and prevent prescription errors. The Legislation requires that each pharmacy implement a quality assurance program no later than January 1, 2002. The Board of Pharmacy is required to adopt regulations specifying the requirements of the program before September 1, 2001. The bill further specifies that any data or records gathered as part of the quality assurance program are confidential and exempt from discovery. The bill also defines a prescription error.

ACTION: The Committee recommends that the Board of Pharmacy sponsor SB 1339.

B. CURES Legislation. The Committee reviewed the proposal to sponsor legislation that will repeal the triplicate prescription program and make CURES permanent.

ACTION: The Committee recommends that the Board of Pharmacy sponsor this legislative proposal.

C. Omnibus Provisions. The ambulance restocking language was presented to the committee with changes reflecting the comment of counsel.

ACTION: The Committee recommends that the ambulance restocking proposal and the two prior proposed changes be submitted for inclusion in the Senate Business and Professions Committee omnibus bill as Board of Pharmacy sponsored provisions.

II. Regulations Proposed for 2000

Each of the proposed regulations for 2000 was discussed with regard to the timing for the notice and possible hearing in the matter.

A. Self-Assessment Update. The Committee discussed updating the self-assessment forms to include new statutes and regulations that pertain to the operations of a pharmacy. The amendment will need to be approved by the Office of Administrative Law before the end of 2000. The revised forms will be sent to pharmacies in early 2001, consistent with the odd numbered year completion requirement.

B. Foreign Graduates. The committee determined that an amendment to allow evaluation of semester units for foreign graduate transcripts would be noticed late in 2000.

C. Disciplinary Guidelines. The guidelines will be amended to correct drafting errors and update some minor edits. The amendment will be coordinated with the Enforcement Committee with a board vote to come at the October meeting.

D. Citation and Fine. An informal hearing on these regulations to authorize the board to cite and fine for all violations of pharmacy law will be held at the April board meeting and the regulation hearing will be scheduled for July.

II. Pending Regulations

The committee discussed each of the regulations that is currently in the process of adoption or amendment.

With regard to section 1707, Waiver Requirements for Off-Site Storage of Records, the committee, in response to comments received, drafted modified language.

This modification would extend the time allowed for retrieval of records stored off-site from 48 hours to 48 business hours. In addition, the on-site retention time for non controlled drug records would be shortened to one year. The two-year retention time for controlled drug records would remain consistent with federal law.

ACTION: The committee recommends that the board adopt the modified language as drafted.

With regard to the adoption of section 1714.5, Dangerous Drugs Exempt from Storage in a Pharmacy, the committee discussed the proposed modifications received during the 45-day comment period.

This adoption would move the listing of dangerous drugs and dangerous devices previously contained in section 4057 of the Business and Professions Code to the California Code of Regulations.

ACTION: The committee, in response to comments received, referred the proposal to adopt section 1714.5, to the Licensing Committee for refinement.

IV. Pending Legislation

The committee considered three pending bills (AB 163, AB 751, and AB 1772) and does not recommend any position from the Board of Pharmacy on those measures. None of these measures fall directly under the Board of Pharmacy's jurisdiction and therefore do not require a position.

V. Implementation of 1999 Legislation.

Implementation of SB 393. Ms. Harris informs the committee that the Department of Health Services intends to have computer systems changed to permit pharmacies to submit dummy claims to EDS for pricing of drugs sold at retail to Medicare beneficiaries. Ms. Harris also indicated that the Board of Pharmacy has agreed to take consumer inquiries and questions regarding this new law.

VI. Update on the CURES Conference.

The Committee was provided with a draft agenda of the CURES conference for its consideration.

VII. Internet Pharmacy Update.

The Committee was provided with the Whitehouse press release detailing the President's proposal to have the Food and Drug Administration license internet pharmacies. Committee was also advised that Senator Jackie Speier will be introducing legislation creating new penalties for unlicensed practice via the internet. Fines would be increased to a maximum of \$25,000.

VIII. Other Business.

The Committee chose to defer advancing a proposal regarding the authority of pharmacists to make dosage form changes to prescriptions without the prescriber's authorization.

The meeting adjourned at 1:30 p.m.