



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

ENFORCEMENT COMMITTEE MEETING

MINUTES

March 12, 2001

**Department of Consumer Affairs
400 R Street, Suite 1030
Sacramento, CA 95814**

Present: Darlene Fujimoto, Chair, and Board Member
John Jones, Board Member
Elena Almanzo, Liaison Deputy Attorney General
LaVonne Powell, DCA-Staff Counsel
Patricia Harris, Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector

Call to Order

Enforcement Committee Chair Darlene Fujimoto called the meeting to order at 1:30 p.m.

Expiration Date on Prescription Labels – Enforcement Options

The Enforcement Committee presented the “draft” Compliance Policy on Expiration Dates. The policy had been revised to include the recommendations from the United States Pharmacopeia (USP). The USP guidelines recommend that the beyond-use (expiration) date not be later than the expiration date on the manufacturer’s container, or (b) one year from the date the prescription drug is dispensed. There was some concern expressed that the inspectors have cited pharmacies for using a one-year arbitrary expiration date, which is contrary to the USP recommendation. Therefore, it was suggested that as part of the guidelines the board address this inconsistency.

Prescriber Dispensing – Legal Interpretation of Pharmacy Law

The California Pharmacists Association (CPhA) provided its position paper on the board’s Compliance Guideline on Prescriber Dispensing. Specifically, their concern is that the analysis fails to define the term “retailing.” CPhA provided a definition, the legislative intent of AB 1732, which in 1987, was the vehicle for the last major revisions to the prescriber dispensing law. Further, CPhA provided the findings of the Texas Attorney General, who interpreted

similar language in the Texas Pharmacy Act that prohibits physicians from profiting from medication sales.

CPhA requested that the compliance guideline be revised to reflect the limits contained in pharmacy law and that the Board of Pharmacy be more active in enforcing those limits. They disagree with the conclusion in the draft guidelines that "...alleged violations of law involving whether a prescriber is improperly charging (or charging an improper amount) for dispensing drugs to his or her patients are the purview of the prescriber's licensing board." It is their position, that a prescriber cannot profit from the dispensing of medications he or she prescribes and this is the core issue of consumer protection incorporated in Business and Professions Code section 4170, 4111, 650.1 650 and the companion state and federal laws and regulations.

Responsibility of the Pharmacist-in-Charge (PIC)

The committee discussed that Business and Professions Code section 4113(b) Business and Professions Code states the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

It was explained that the PIC could be held responsible for misconduct at a pharmacy, which may have occurred, when the PIC was not present and the conduct violates clear policies established by the PIC. It is the circumstances, taken as a whole, which determines whether the PIC should be held responsible in such a situation.

Some factors that are considered include the nature of the misconduct, how obvious it should have been, how long it went on, and whether the PIC learned of it and then promptly moved to correct the problem. There are circumstances under which the PIC who may have good policies and procedures in place and can articulate them, but may still be subject to discipline (or cited for the violation) for conduct occurring in the his or her absence.

Primary concern was raised about a PIC being responsible for a prescription error. The supervising inspectors explained that when prescription errors are mediated, it is determined if policies and procedures are in place. If so, did the pharmacist follow them? Did the pharmacist deviate from them on his/her own. What caused the error? Was it a staffing issue? It was also explained that if the PIC is held responsible, he or she would be issued a violation notice.

It was suggested that an article on this issue be written for the board's newsletter.

Written Proposals to Suggest Improvements to the Enforcement Program to Enhance the Board's Ability to Protect the Public

The California Pharmacists Association, Longs Drug Stores, United Food and Commercial Workers Union Local #770 and the Guild for Professional Pharmacists submitted proposals to change the board's enforcement program regarding its routine inspection program, review of

disciplinary actions, cost recovery and standard terms and conditions of probation. These proposals were also submitted during the board's regulation hearing on its revised disciplinary guidelines. Since the comments were not specific to the disciplinary guidelines, they requested that the Enforcement Committee consider the proposals. The Committee referred them to the Enforcement Team for consideration.

Request to Amend Regulation CCR 1709.1 to Allow a Pharmacist-In-Charge (PIC) to be Responsible for More than One Pharmacy

The California Retailers Association (CRA) submitted a request that the board amend its regulations to permit a pharmacist-in-charge to be responsible for more than one pharmacy. The CRA argued that the PIC's duties do not require the pharmacist to be continually present in the pharmacy. Moreover, pharmacy law does allow the PIC to designate day-to-day functions to the pharmacist on duty such as signing for receipt of drug deliveries and producing hardcopies of records.

It was further argued that the pharmacist shortage in California mandates the most efficient use of pharmacist time and skills. Pharmacists who do not desire to be a PIC will have more time to perform pharmaceutical care. Also, a pharmacist who develops these skills better performs many of the PIC responsibilities. Because most chain stores have a number of stores in geographically close regions, this allows the PIC to oversee more than one pharmacy.

There was considerable discussion regarding the advantages and disadvantages of allowing a PIC to be responsible for more than one pharmacy. It was recommended that the Pharmacy Manpower Task Force consider this proposal.

Request to Amend Regulation CCR 1793.3, to Eliminate the Clerk-Typist Ratio and Expand the Duties of the Clerk-Typist

The California Retailers Association (CRA) requested that the board eliminate the clerk-typist ratio and expand the duties. Currently, the law only allows one clerk-typist per pharmacist. The CRA argued that significant time at the pharmacy is devoted to handling third party claims, working with a different number of formulary restrictions, and contacting insurers and HMOs. The insurance industry has shifted the burdens of adjudicating drug benefit claims to the pharmacy. The pharmacy has become the "claims" administrator. These claims-related and other clerical tasks are non-judgmental, non-discretionary and can be performed by non-licensed personnel.

It was further explained that other personnel that are not part of the clerk-typist ratio could perform these claims-related tasks because these tasks do not include calling for prescription refills or entering prescription information into the computer to create the prescription label. However, because most claims are adjudicated on-line, real time, when the prescription information is being entered, the adjudicating problems are usually resolved by the clerk-typist at

the time of entering the prescription data. Because of the restricted number of clerk-typists that the pharmacist can supervise, the pharmacist ends up performing many of the non-judgmental tasks.