

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Citations and Fines

Sections Affected: 1775, 1775.1, 1775.15, and 1775.2

Problem Addressed

The Board of Pharmacy is a consumer protection agency charged with ensuring public safety through licensure and education of practitioners and enforcement of the laws governing the distribution of prescription drugs. Over 70,000 licensees are regulated by the board in twelve major license categories. Increasing numbers of complaints (10% increase per year since 1995) against licensees and ongoing difficulties in achieving licensee compliance with routine licensure requirements demonstrate the need for added enforcement options. Currently, the board must choose between admonition (i.e. field admonitions by inspectors, office conferences and compliance committee actions) and formal disciplinary action against a license when imposing sanctions for violations. Current regulations do not provide the board with appropriate options for violations that warrant more severe sanction than admonition but are not appropriate for formal disciplinary action. Referring many of these cases to the Attorney General for administrative hearing is not effective because the licensee can correct the violation prior to hearing, rendering the process moot. Such an approach needlessly adds to the workload of the deputy attorneys general handling board cases and causes the board to incur increased billings from the Attorney General. Admonition relies on professional pride or the fear of formal discipline to effect a change in behavior. Those who ignore repeated admonitions for lesser violations of the Pharmacy Law have little incentive to correct those violations if their violations are not severe enough to warrant formal discipline. Citation and fine provides the board with an intermediate sanction to increase compliance and expend limited board resources more efficiently.

Specific Purpose of the Regulation

The proposed regulation would permit the board to issue citations and fines for any violation of the Pharmacy Law. Business and Professions Code sections 125.9 and 148 permit, by regulation, professional licensing boards to establish citation and fine programs for violations of the licensing act they administer or any regulations adopted pursuant to the act. This expanded authority is not a substitute for formal disciplinary action against a license for egregious violations of the Pharmacy Law and will not reduce the number of cases referred to the Attorney General for administrative hearing.

Section 1775 would be amended.

(a) The changes to this subdivision would expand the board's existing citation and fine program to include all provisions of the Pharmacy Law. This expansion is needed by the board to increase compliance with the Pharmacy Law. Under current regulations, the board may only

issue citations and fines for violations related to patient consultation, unlicensed activity, and continuing education. Absent this added authority, board sanctions are limited to either admonition (i.e. field admonitions by inspectors, office conferences and compliance committee actions) or taking action against a license by filing the case with the Attorney General.

(d) This subdivision would be added to define the procedure for a committee of the board considering alleged violations and issuing citations and fines. The procedures permit the board to issue a citation and fine in the absence of a respondent after two failures to appear before the committee. This authority is required to prevent alleged violators from delaying action by refusing to appear.

Section 1775.1 would be repealed.

This section would be repealed because of the change in 1775 (a) that broadens citation and fine authority to all provisions of the Pharmacy Law. Section 1775.1 lists those sections whose violation is subject to citation and fine. Existing provisions are unnecessary with the changes to 1775.

Section 1775.15 would be added.

(a) This section would be added to permit the executive officer to issue citations and fines for specified violations of the Pharmacy Law. These violations relate to licensees other than pharmacies and pharmacists, but do include violations relating to continuing education and the failure to file a notice of discontinuance of business. These violations generally relate to the administrative requirements of site permits rather than the provision of patient care.

(b) This subdivision would permit the executive officer to issue citations and fines for violations relating to unlicensed practice. These violations are easily established.

(c) This subdivision would be added for clarity by defining the appeals process for citations and fines issued by the executive officer.

Section 1775.2 would be amended.

This section would be amended to conform to those made in 1775 and 1775.15. The changes would also permit the number of violations in any investigation to be considered in setting the amount of the fine. Section 125.9 of the Business and Professions Code caps the fine per investigation or inspection at \$2,500.

Factual Basis

Complaints and investigation volume have been increasing steadily in recent years. In the 1999-00 fiscal year, the board is on pace to open 1250 complaints or investigations. That figure is up from 842 in the 1995 - 96 fiscal year, a 48% increase (approximately 10% per year). In the last fiscal year the board has substantiated 416 violations of the pharmacy law that were not submitted to the Attorney General for formal disciplinary action.

A brief survey of the citation and fine regulations adopted by other healing arts licensing boards indicates that the proposed regulation is consistent with those other regulations both in the scope of violations subject to citation and fine and the authority of executive officers to issue the citations.

Underlying Data

Complaint statistics were gathered from the year end enforcement workload statistics included in board meeting materials which are attached and available from the board.

The following healing arts licensing boards have regulations that permit citations for any violation of their practice acts and permit the executive officer to issue citations.

Dental Board of California. (Title 16 CCR, Division 10)

Medical Board of California. (Title 16 CCR, Division 13)

State Board of Optometry. (Title 16 CCR, Division 15)

Veterinary Medical Board. (Title 16 CCR, Division 20)

Board of Registered Nursing. (Title 16 CCR, Division 14)

Board of Behavioral Sciences. (Title 16 CCR, Division 18)

Board of Vocational Nursing and Psychiatric Technicians. (Title 16 CCR, Division 25)

Board of Psychology. (Title 16 CCR, Division 13.1)

California Board of Podiatric Medicine. (Title 16 CCR, Division 13.9)

Physical Therapy Board. (Title 16 CCR, Division 13.2)

Speech-Language Pathology and Audiology Board. (Title 16 CCR, Division 13.4)

Senate Bill 2335 (Chapter 1379, Statutes of 1986) established citation and fine authority for boards and bureaus within the Department of Consumer Affairs. The Board of Pharmacy first adopted the existing citation and fine regulations in 1995 (effective date, June 30, 1995).

Business Impact

Businesses will be affected by this regulation to the extent they fail to comply with existing provisions of the Pharmacy Law and are fined for those violations. This regulation imposes no new requirements.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

The board has identified no alternatives that would lessen any adverse impact on small business.