

Title 16. California Board of Pharmacy

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101 at 1:30 p.m. on July 25, 2000.

Written comments must be received by the Board of Pharmacy at its office not later than 5 p.m. on June 26, 2000.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposal substantially as described below or may modify the proposal if the modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this notice as the contact person. The notice also will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: The Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations pursuant to the authority vested by sections 125.9, 148, and 4005 of the Business and Professions Code and to interpret or make specific sections 125.9 and 148 of the Business and Professions Code. These changes are discussed below.

INFORMATIVE DIGEST/PLAIN ENGLISH POLICY STATEMENT OVERVIEW

Amend sections 1775 and 1775.2.

Repeal section 1775.1.

Adopt section 1775.15.

Violations Subject to Citation and Fine.

Business and Professions Code section 125.9 authorizes the board to establish by regulation a system of citations and fines for violations of the Pharmacy Law (Business and Professions Code, Commencing Section 4000). Section 148 authorizes the board to issue citations using a system consistent with the provisions of section 125.9, to persons who act in the capacity of a licensed person under the jurisdiction of the board without benefit of a license (i.e., unlicensed practice). Section 4005 authorizes the board to adopt and amend rules and regulations to interpret and make specific any provision of the Pharmacy Law.

Section 1775 permits a board inspector and a committee of the board to issue citations and fines for violations of statute and regulation specified in section 1775.1.

Section 1775.1 specifies that citations and fines may be issued for violations relating to patient consultation, unlicensed activity, and continuing education.

1775.2 specifies the criteria that may be considered when setting the amount of a fine.

1775.3 establishes the rules for complying with orders of abatement.

1775.4 establishes the appeal process for citations.

The objective of this proposal is to increase the types of violations subject to citation and fine to include any violation of the Pharmacy Law or regulations adopted pursuant to the Pharmacy Law. The proposal would make an additional substantive change to existing law by granting the executive officer the authority to issue citations and fines for specific categories of violations. The proposed amendments would remove authority from board inspectors to issue citations. This is consistent with current board procedures that require citations and fines be subjected to internal staff review prior to issuance by a committee of the board.

Section 1775 would be amended to remove reference to section 1775.1 and the series of laws whose violation are subject to citation and fine. Instead, language would be added to broaden the scope of violations to include any violation of the Pharmacy Law. This section would be further amended to detail the procedure for a committee of the board to meet and consider alleged violations and the issuance of citations and fines.

Section 1775.1 would be repealed.

Section 1775.15 would be added to grant authority to the executive officer to issue citations for specific violations of the Pharmacy Law.

Section 1775.2 would be amended to conform to changes made in section 1775 and 1775.15 granting authority to the executive officer to issue citations and fines and removing reference to the list of violations subject to citation and fine in 1775.1. The section would be amended to permit the number of violations in an investigation to be considered in setting the amount of a fine.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: \$375,000 in added revenue per year, \$170,000 per year in added costs.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Significant Adverse Economic Impact on Business: The board has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: None

The Board of Pharmacy has determined that this regulatory proposal will not affect the creation of new businesses and jobs. The board has determined that the proposal

will not have a significant impact on the elimination of jobs or existing businesses or the expansion of businesses in California.

The benefits of this proposal include improved enforcement of laws designed to protect public safety and preserve the health and welfare of California citizens.

Statement of Potential Cost Impact on Private Persons or Businesses Directly Affected: To the extent that they are cited and fined for violation of the Pharmacy Law, both individuals and businesses will incur costs. Fines are capped at \$2,500 per investigation or inspection. The proposed regulation imposes no new requirements.

Housing Costs: None

PLAIN ENGLISH REQUIREMENT

The Board of Pharmacy has determined that this regulation would affect small businesses. The express terms of the proposed action written in plain English are available from the agency contact person named in this notice.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no alternative which it considered would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at a public hearing.

STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared a statement of the reasons for the proposed actions and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulation and of the statement of reasons and other information, if any, may be obtained at the hearing or upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814.

CONTACT PERSON

Inquiries concerning the proposed administrative action may be addressed to Patricia Harris at the above address or at (916) 445-5014.