

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on February 5, 2007.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on January 22, 2007.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such 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 contact person and 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: Pursuant to the authority vested by Sections 125.9, 148, 685 and 4005 of the Business and Professions Code and Section 56.63 of the Civil Code, and to implement, interpret or make specific Sections 125.9, 148 and 685 of the Business and Professions Code and Section 56.63 of the Civil Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 125.9 authorizes the board to establish by regulation, a system for issuing citations and fines up to \$5,000 for violations of the Pharmacy Law (Business and Professions Code section 4000 et seq.) and the regulations adopted pursuant thereto.

Business and Professions Code Section 148 authorizes the board to establish by regulation, a system for issuing citations and fines for up to \$5,000 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).

Business and Professions Code Section 685 permits the board to issue a citation and fine to any currently licensed health care practitioner that defaults on specified student loans.

Business and Professions Code Section 4005 authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Business and Professions Code Section 4067 authorizes the board to issue a citation with a fine of up to \$25,000 per violation for dispensing a dangerous drug or dangerous

device over the internet when the person knew or reasonably should have known the prescription was not based on a good faith medical examination.

Business and Professions Code Section 4127.4 authorizes the board to issue a citation with a fine of up to \$2,500 per occurrence for violations relating to the compounding of sterile injectable drug products.

Civil Code Section 56.36 authorizes the board to issue citations and fines ranging from \$5,000 up to \$250,000 to its licensees for violation of the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

Section 1775.4 details the procedures for contesting a citation. This proposal would allow for a person or entity to request that the informal office conference to contest a citation issued be rescheduled. Such a request could only be made once.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

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.

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:
The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not affect small businesses. The proposed regulations affect internal board operations and would have no effect on small businesses.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy determined that no reasonable alternative which it considered either would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

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

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	anne_sodergren@dca.ca.gov

The backup contact person is:

Name: Virginia Herold
Address: 1625 N. Market Blvd. N219
Sacramento, CA 95834
Telephone No.: (916) 574-7911
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E-Mail Address: virginia_herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.