

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 October 20, 2008.

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 October 6, 2008.

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 4005 of the Business and Professions, and to implement, interpret, or make specific sections 4300 of the Business and Professions 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 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

Amend Section 1773 to include completion of an ethics course that meets requirements specified in 16 CCR section 1773.5.

Adopt Section 1773.5 to define the ethic course required as a condition of probation as provided for in the "Disciplinary Guidelines."

Existing regulation 16 CCR 1760 specifies that the board. In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 1/2001), which are incorporated by reference in this section. These "Disciplinary Guidelines" provide for an ethics course, but does not address minimum requirements for the provider or course content.

The proposed regulation would specify all the criteria for an ethics course to include: duration; faculty; educational objective; method of instruction; content (background assessment, baseline assessment, participant's expectations, didactic presentation, experiential exercises, and a longitudinal follow-up); class size, evaluation; records; program completion; and change in course content or instructor.

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 determined that the proposed regulatory action would have no significant, statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states. This proposal would apply to all pharmacies. Nonresident pharmacies providing compounded medications to California residents would also need to comply with this regulation, providing parity for business and consumer protection to Californians.

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 is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. This regulation will not have a significant adverse economic impact on businesses since the regulation would only be applicable to pharmacists who are disciplined by the board, placed on probation, and ordered to take an ethics course as a condition of probation.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The board has determined that this proposed regulation would not affect small businesses because the regulation is applicable only to pharmacists who are disciplined by the board, placed on probation, and ordered to take an ethics course as a condition of probation.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine 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 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:	Karen Cates
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7914
Fax No.:	(916) 574-8618
E-Mail Address:	karen_cates@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
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Address: 1625 N. Market Blvd. N219
Sacramento, CA 95834
Telephone No.: (916) 574-7910
Fax No.: (916) 574-8618
E-Mail Address: anne_sodergren@dca.ca.gov

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