

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 December 14, 2009.

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 15 days before the close of the written comment period.

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 Section 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 123, 496, and 4200 of said 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 necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 123 sets forth the criminal penalty for a person who engages in conduct which subverts or attempts to subvert any licensing examination or the administration of an examination.

Business and Professions Code section 496 authorizes the board to deny, suspend, revoke, or otherwise restrict applicants or licensees who violate the provisions of Business and Professions Code section 123.

Business and Professions Code section 4200 generally provides for the license requirements of an applicant for a pharmacist license. One of the qualifying criteria is that an applicant must pass the written and practical examination given by the board prior to December 21, 2003, or pass the North American Pharmacist Licensure Examination (NAPLEX).

Existing regulation at Title 16 California Code of Regulations (CCR) section 1721 specifies that an applicant who engages in dishonest conduct during the examination shall not be approved to take the examination for twelve months from the date of the incident, that the applicant shall surrender his or her intern card until eligible to take the examination, and that an applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

This proposed regulation would amend Section 1721 to increase the period of time that an applicant for examination as a pharmacist is not approved to take the examination from twelve months to three years, if the applicant engages in dishonest conduct during the examination. Further, this proposed regulation would provide that an intern 'license' (not card) shall be surrendered until such time that the applicant is eligible to take the examination. This latter amendment ensures that the terminology in Section 1721 is consistent with the language in Section 4208 of the Business and Professions Code related to an intern pharmacist license.

Existing regulation in 16 CCR 1723.1 declares that examination questions are confidential and provides that an applicant who subverts the licensing examination may be disqualified as a candidate for a license.

This proposed regulation would strengthen the existing penalty provided in Section 1723.1 by adding the following requirements: (1) that the applicant shall not be approved to take the examination for three years from the date of the incident; and, (2) that the applicant shall surrender his or her intern license until he or she is again eligible to take the examination. The proposed regulation would further provide that the applicant would not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

The board has determined that the amendments to 16 CCR sections 1721 and 1723.1 to increase the penalties as proposed are necessary to further protect from subversion the CPJE examination.

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 Sections 17500 – 17630 Require 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 businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts or evidence/documents/testimony:

From calendar year 2005 through 2009, the board has denied licensure or eligibility to take the California Practice Standards and Jurisprudence Examination (CPJE) due to dishonest conduct or exposure of a qualifying examination to three persons. Applicants for licensure who apply for and take the CPJE pay a fee (as specified in 16 CCR §1749(d)).

If a person is denied licensure or eligibility to take the examination because they are found to have engaged in dishonest conduct or they expose any part of the qualifying examination to another person they are precluded from again taking that examination for a period of time specified in the regulations. As such, there is no cost to a person or to a business to comply with the regulation. However, the cost to generate a new test item for the CPJE examination is approximately \$2,000 per item and compromised test items not only pose a financial loss to the board, but also inhibit the board's ability to test for minimum competency. Further, if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation or elimination of jobs within the State, the creation of new businesses or the elimination of 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. This regulatory proposal will not have a significant adverse economic impact on businesses since the regulation would only be applicable to applicants for examination as a pharmacist who engage in dishonest conduct during an examination as a pharmacist or who subvert any part of a qualifying examination.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that this proposed regulation would not affect small businesses because the regulation is applicable only to applicants for examination as a pharmacist who engage in dishonest conduct during an examination for licensure as a pharmacist or who subvert any part of a qualifying examination.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either 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 in this Notice.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

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, and all of the information upon which the proposal is based, 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's 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 regulations are 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 Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

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

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

The backup contact person is:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7910
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Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.