

## 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 November 22, 2010.

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 4200.2., 4202, 4231 and 4232 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 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 4200.2. sets forth the requirements that the board shall utilize for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists.

Business and Professions Code section 4202 sets for the requirements for the issuance of a pharmacy technician applicant.

Business and Professions Code section 4231 specifies the number of hours of continuing education a pharmacist must complete during a two-year period preceding an application for renewal. This section also specifies that a pharmacist does not require completion of continuing education for the first renewal of a pharmacist license.

Business and Professions Code section 4232 specifies the content of courses that may be approved for continuing education for the renewal of a pharmacist's license.

This proposed regulation would amend Section 1732.2. to provide for consistency in terminology used, and to specify a variety of ways approved by the board that an individual may accrue continuing education satisfactory to the board. While none would be a requirement for renewal of a pharmacist's or pharmacy technician's license, the following are ways in which this proposal would permit an individual to acquire board approved continuing education:

- A pharmacist serving on a designated subcommittee of the board for purposes of developing the California Practice Standards and Jurisprudence Examination for pharmacists may be awarded up to six hours of continuing education annually for conducting a review of exam test questions, as proposed;
- A pharmacist or a pharmacist technician may receive a specified number of hours of continuing education for attending board and/or committee meetings, as proposed;
- A pharmacist who completes the Pharmacist Self-Assessment Mechanism (PSAM) that is administered through the National Association of Boards of Pharmacy may be awarded up to six hours of continuing education; and
- An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

This proposed regulation would also amend subdivision (a) of section 1732.2 of Title 16 of the California Code of Regulations to change the word "credit" to "hours", so as to be consistent with the definition of "hour" that is specified in existing regulations in section 1732(b) of Title 16 of the California Code of Regulations.

Existing regulations contained in Article 4 of Division 17 of Title 16 California Code of Regulations (beginning at section 1732) specify accreditation agencies for continuing education, requirements for accredited providers, requirements for continuing education courses, provider audit requirements, renewal requirements for a pharmacist, exemptions from CE requirements, and a complaint mechanism for a provider. However, existing law does not specify additional methods of accruing CE that would be deemed "satisfactory" to the board.

This proposed regulation will provide additional board-approved continuing education options available to applicants for renewal of a pharmacist license. The board does not currently require continuing education for an applicant for renewal of a pharmacy technician license. However, one of the qualifying methods of an applicant for a pharmacy technician license is certification through the Pharmacy Technician Certification Board (PTCB) pursuant to section 4202 of the Business and Professions Code. For purposes of maintaining certification with the PTCB, pharmacy technicians must meet that board's requirements for continued education. This proposed regulation specifies board approved continuing education options for pharmacy technicians licensed by the Board of Pharmacy.

## 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.

**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 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 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:

There is no requirement for a pharmacist or pharmacy technician to utilize the board-approved continuing education as specified in the proposed regulation. For board-approved continuing education awarded for attending a board or committee meeting, as specified in the proposed regulation, the board does not charge any fee for the award of the continuing education.

For a pharmacist who wishes to take the Pharmacist Self-Assessment Mechanism (PSAM) administered through the National Association of Boards of Pharmacy (NABP), that pharmacist may be required to pay a fee to the NABP for such purposes. However, the California State Board of Pharmacy does not require a pharmacist to complete the PSAM as a requirement for renewal of a license by the board.

An individual who wishes to be certified by the Commission for Certification in Geriatric Pharmacy may be required to meet certification requirements by the CCGP, including the payment of any fee required to take the CCGP examination. However, the California State Board of Pharmacy does not require an individual to be certified by the CCGP as a requirement for renewal of a license by the board.

#### 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](http://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](http://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  
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The backup contact person is:

Name: Anne Sodergren  
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Website Access. Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).