

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (Board) 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 at its office not later than 5:00 p.m. on December 28, 2015.

The Board does not intend to conduct a Regulation Hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the written comment period.

The Board, 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 to implement, interpret, and make specific sections 4200.2, 4202, 4231, and 4232 of the Business and Professions Code, the Board is proposing to amend Sections 1732.05, 1732.2, and 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations as follows:

Informative Digest/Policy Statement Overview

The Board of Pharmacy (Board) proposes to amend Sections 1732.05, 1732.2, and 1732.5 of Article 4 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of updating the name of a Board-approved continuing education (CE) provider, to grant CE credit for serving on a committee developing the California Practice Standards and Jurisprudence Examination (CPJE), to grant CE credit for attending Board meetings or committee meetings, and to define specialized subject areas necessary to meet the CE hour requirement.

Business and Professions Code (B&P) section 4001.1 specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Business and Professions Code section 4200.2 defines 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 defines the requirements for the issuance of a pharmacy technician applicant.

B&P section 4005 generally authorizes the Board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

B&P section 4231 generally states that the Board shall not renew a pharmacist license unless the licensee has completed 30 hours of continuing pharmacy education.

B&P section 4232 generally states the form and content of acceptable continuing education courses.

This proposed regulation would amend 16 CCR Section 1732.05 to correct the name of a Board-approved CE provider that was changed as a result of restructuring at the Pharmacy Foundation of California.

This proposed regulation would amend 16 CCR Section 1732.2 to provide additional ways licensees may accrue continuing education satisfactory to the board. While the additional options would not be a requirement for the renewal of a pharmacist's or pharmacy technician's license, the following are ways in which this proposal would permit a licensee to acquire Board approved continuing education:

- A pharmacist serving on a designated subcommittee of the Board for purposes of developing the CPJE 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;
- An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

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.

Anticipated Benefits of Proposal

This proposal will update the name of a Board-approved accreditation agency and will reduce confusion for pharmacists selecting CE courses. Additionally, awarding CE for attending Board

and Committee meetings will encourage more pharmacists and pharmacy technicians to attend the meetings and be more involved within their profession. This will result in additional education to licensees on issues impacting the practice of pharmacy and may contribute to improving public health and safety. Furthermore, by awarding CE to pharmacists for participating in development of the CPJE, a more diverse group of pharmacists may provide their expertise, resulting in an efficient and stronger exam. Finally, assuring that pharmacists take CE hours in critical subject matter areas will contribute to public health and safety by increasing the number of pharmacists trained in those content areas.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs/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 fact that the proposed regulation does not affect a business. The proposed regulation affects Board individual licensees and not businesses. Pharmacists are currently required to complete continuing education pursuant to B&P section 4231. The proposed regulation further defines the content area for six of the required thirty hours. Additionally, the proposed regulation permits that Pharmacists and Pharmacy Technician's be awarded continuing education for attending Board and/or Committee meetings, which are free of charge.

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.

Effect on Housing Costs: None

Effect on Small Business:

While the Board does not have nor does it maintain data to define if any of its licensees (pharmacies) are a “small business” as defined in Government Code section 11342.610, the Board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses.

There is no requirement for a pharmacist or pharmacy technician to utilize the Board-accredited continuing education as specified in the proposed regulation. For Board-approved continuing education awarded for attending a Board and/or Committee meeting, as specified in the proposed regulation, the board does not charge any fee. An individual who wishes to be certified by the Commission for Certification in Geriatric Pharmacy (CCGP) may be required to meet certification requirements by the CCGP, including the payment of any fee required to take the CCGP examination. However, the Board does not require an individual to be certified by the CCGP as a requirement for renewal of the license. Finally, while the proposed regulation is requiring CE in specific subject areas, this is not in addition to the CE a pharmacist must currently complete. These required subject areas will be part of the 30 hours of CE currently required.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The Board 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. This initial determination is based on the fact that under B&P section 4231, a pharmacist is currently responsible completing 30 hours of CE biennially. This proposed regulation is not requiring additional CE hours. There is no requirement for a pharmacist or pharmacy technician to utilize the Board-accredited continuing education as specified in the proposed regulation.

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and state’s environment because the proposed regulation will require continuing education in specific subject areas that are critical to patient care in California. This will increase the number of pharmacists with additional education in those subject areas. Additionally, the proposed regulation will provide additional methods for an individual to obtain Board-approved continuing education relevant to the practice of pharmacy. This will increase the number of licensees with education on the issues impacting the practice of pharmacy as they occur and will increase involvement in these issues.

Consideration of Alternatives

The Board 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, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

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 any document incorporated by reference, 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 website at <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 website listed below.

Contact Person

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

Name:	Lori Martinez
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Phone No.:	(916) 574-7917
Fax No.:	(916) 574-8618
E-Mail Address:	Lori.Martinez@dca.ca.gov

The backup contact person is:

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

Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website:
www.pharmacy.ca.gov.