

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 in writing relevant to the action proposed. Written comments, including those sent by mail, facsimile, or email 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 8, 2016.

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 45-day written comment period.

The Board, upon its own motion or at the request 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 in the Board by sections 4005 and 4210 of the Business and Professions Code to implement, interpret and make specific sections 4052.6, 4210, and 4233 of the Business and Professions Code, the Board is proposing to add and adopt Section 1730.2 of Article 3 of Division 17 of Title 16 of the California Code of Regulations, as follows:

Informative Digest/ Policy Statement Overview

The Board proposes to add and adopt Section 1730.2 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of adding to the Board's regulations specific requirements for certification programs related to Advanced Practice Pharmacist licensure as part of the Board's efforts to implement Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013). SB 493 established the new license category of Advanced Practice Pharmacist at Business and Professions Code (B&P) section 4210.

B&P section 4210(a)(2)(A) permits certification as a criteria to obtain an Advanced Practice Pharmacist license. This section states that qualifying certification must be earned from an organization recognized by the Accreditation Council for Pharmacy Education (ACPE) or another entity recognized by the Board. This proposed regulation will standardize the requirements for certification programs that will satisfy the criteria.

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.

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

B&P section 4052.6 generally defines the duties a pharmacist holding an Advanced Practice Pharmacist license may perform.

B&P section 4210 generally defines the requirements to obtain an Advanced Practice Pharmacist license.

Anticipated Benefits of Proposal

This proposal will define and standardize the certification program requirements necessary to earn a certificate to obtain an Advanced Practice Pharmacist license. By having clear and standardized requirements, pharmacists who wish to obtain an Advanced Practice Pharmacist license will be able to find and take Advanced Practice Pharmacist appropriate certification program. Additionally, new programs can be developed by qualified agencies to meet the specifications needed for certification. This is will benefit businesses, licensees, and residents of California by encouraging development of programs, more knowledgeable and specialized pharmacists, and increased access to health care providers.

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 defines the certification program requirements for a voluntary program. Additionally, businesses who wish to provide a certification program would do so voluntarily and would receive

compensation from pharmacists that wish to complete the certification program. Any cost associated with the creation of the certification program would be offset by the charges to those attending the program.

Cost Impact on Representative Private Person or Business:

As obtaining an Advanced Practice Pharmacist license is voluntary, the Board believes that pharmacists who seek to obtain an Advanced Practice Pharmacist license will do so with the expectation that the cost involved in obtaining and maintaining an Advanced Practice Pharmacist license will be fully compensated by the increased income generated as a result of the expanded scope of practice possible with the Advanced Practice Pharmacist licensure. Aside from this issue, 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 Businesses:

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 regulation would not have a significant adverse economic impact directly affecting small businesses. This determination was made based on the fact that the proposed regulation does not require that businesses participate. Additionally, if businesses elect to develop certification programs, they can be reimbursed by a licensee (pharmacist) by charging a fee for the program.

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 the program is voluntary. Additionally, it is based on the absence of testimony to that effect during the development of the proposed regulations.

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and the state’s environment because this proposal standardizes the requirements for a certification program to qualify a pharmacist to obtain an Advanced Practice Pharmacist license. This new license type adds pharmacists to the list of health care providers from which Californians can obtain advice, treatment and referrals. This will lower the overall

cost of health care for Californians, help ease the shortage of primary care physicians in the state, and broaden public access to health care.

Consideration of Alternatives

The Board must determine that no reasonable alternative it considered 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 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 regulation, 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., N-219, 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 of the information upon which the proposed regulation is based is contained in the rulemaking file which is available for public inspection by contacting the contact 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 website at <http://www.pharmacy.ca.gov>.

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
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E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Anne Sodergren
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Sacramento, CA 95834
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Website Access

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