

## **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 September 14, 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 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: Under the authority conferred by Business and Professions Code (“B&P”) section 4005 in order to implement, interpret and make specific B&P sections 4016.5, 4052.6, 4210, and 4233, the Board is proposing to amend Article 5 of Division 17 of Title 16 of the California Code of Regulations (“CCR”), as follows:

### **INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW**

The Board proposes to add and adopt Sections 1730, and 1730.1 and amend Section 1749 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to set out specific requirements for the type of training, documentation, and fees needed to be paid to obtain an Advanced Practice Pharmacist (“APP”) license. This adoption of two new regulation sections and an amendment to an existing regulation section is necessary to carry out the purposes of B&P sections 4016.5, 4052.6, 4210, and 4233, and will allow pharmacists to seek training for, apply for, and start practicing as APPs. The proposed rulemaking will broaden public access to health care and may result in a proportionate easing of physician workloads, as APPs work in conjunction with physicians to care for patients, and may free up physicians to concentrate on patients with other medical issues. There are no existing federal regulations or statutes which touch on or concern pharmacists providing these types of health care services.

Specific Benefits Anticipated: Having pharmacists with the APP license perform physical assessments, order and interpret drug therapy-related tests, refer patients to other health care providers, and initiate, adjust, and discontinue drug therapies and evaluate and manage diseases and health conditions in collaboration with other health care providers or as a participant in a system of care will improve and broaden the public’s access to health care. Adding pharmacists to the pool of health care providers from which Californians can obtain

advice, treatment and referrals will reduce costs for patients and help ease the effects from the shortage of primary care physicians in the state.

**Consistency with and Compatibility with Existing State Regulations:** During the process of drafting the two new regulations and one amendment to an existing regulation, the Board has determined that the two (2) regulations to be adopted and one (1) to be amended are the only regulations that deal with the Board's APP program. Therefore, as to 16 CCR sections 1730, 1730.1 and 1749, the Board finds that these proposed regulations are consistent and compatible with existing state regulations.

**Mandate of Local Agencies or School Districts:** This regulatory action does not impose a mandate on local agencies or school districts.

**FISCAL IMPACT:**

- A. Cost or Savings to any state agency: NONE
- B. Cost to any local agency required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- C. Cost to any school district required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4: NONE
- D. Other nondiscretionary cost or savings imposed on local agencies: NONE
- E. Cost or savings in federal funds to the state: NONE

**Effect on Housing Costs:** NONE

**Business Impact:** The Board has made an initial determination that the two, new proposed regulations and one amendment will have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

**Statewide Economic Impact:** Pharmacists wishing to become licensed as APPs must complete the requirements set out in B&P section 4210(a)(2)(A). The first regulation section proposed to be adopted in this regulation package establishes that pharmacy patient care certification programs certified by the National Commission for Certification Agencies ("NCCA") are recognized by the Board as satisfying the requirements of B&P section 4210(a)(2)(A). The second regulation section proposed to be adopted sets out the documentation pharmacists will have to submit to become licensed as APPs. The third regulation section proposed to be amended sets out the fees for becoming licensed as an APP, renewing that license, and the penalty for failure to renew an APP license. The Board believes that individuals who seek to obtain the APP license do so with the expectation that the cost involved in obtaining and maintaining the APP license will be compensated with the increased income generated by the APP licensure. Thus, while this package of regulatory proposals will affect pharmacies, it will not have a significant statewide adverse economic impact directly affecting businesses or businesses' ability to compete.

**ECONOMIC IMPACT ASSESSMENT:** The Board has determined that this regulatory proposal will not have any impact on the creation of jobs or elimination of jobs, or on the creation of new businesses or the elimination of existing businesses nor on the expansion of businesses in the State of California.

**Benefits of the Regulations:** This regulatory proposal benefits the health of California residents by adding 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.

**Cost Impacts:** Obtaining an APP license is voluntary. The Board believes that pharmacists who seek to obtain an APP license will do so with the expectation that the cost involved in obtaining and maintaining an APP license will be fully compensated by the increased income generated as a result of the expanded scope of practice possible with the APP 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.

**Business Report:** The proposed regulations do not require a new report to be made. Pharmacists submit documentation to the Board to obtain their initial pharmacy license and to renew their pharmacy license. The documentation which must be submitted to obtain an APP license does not constitute a report.

**Effect on Small Businesses:** The Board has determined that the proposed regulation would have no economic impact on small businesses. All pharmacists have the option of getting the additional training and experience required to obtain an APP license, whether they work at a small community pharmacy or a large chain pharmacy.

**CONSIDERATION OF ALTERNATIVES:** The Board must determine that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's 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 proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policies or other provision of law.

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

**INITIAL STATEMENT OF REASONS AND INFORMATION:** The Board has prepared an initial statement of the reasons for the proposed actions and has available all of the information upon which the proposals are based.

**TEXT OF PROPOSAL:** Copies of the exact language of the proposed regulation, the Initial Statement of Reasons, and all of the information upon which the proposal is based may be obtained upon request from the person designated below as Contact Person, or by accessing 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:** Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov). Inquiries or comments concerning the proposed rulemaking actions may be addressed to:

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(Backup contact person)  
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