

**BOARD OF PHARMACY**  
**INITIAL STATEMENT OF REASONS**

Hearing Date: No hearing is presently planned unless one is requested no later than 15 days before the close of the 45-day comment period.

Subject Matter of Proposed Regulations: Advanced Practice Pharmacist.

Sections Affected: 16 CCR Sections 1730, 1730.1 and 1749.

Specific Purpose of Adoption: Business & Professions (“B&P”) Code sections 4016.5, 4052.6, 4210 and 4233 all concern the license category of Advanced Practice Pharmacist (“APP”). The Board of Pharmacy (“Board”) has developed new regulations to clarify what education and experience is required to obtain an APP license, what documentation must be provided to the Board with an APP license application, and the fees involved.

The Board seeks to add and adopt 16 CCR Sections 1730, 1730.1 and to amend 16 CCR Section 1749.

The problem to be addressed: These regulations address that the Legislature has created a new pharmacist licensure category, and the Board must establish the education and experience required to obtain this new APP license, the documentation required to establish a candidate has the required education and experience, and the fees which must cover the Board’s cost of creating and maintaining this new licensure category.

The anticipated benefits from this regulatory action: Pharmacists with the APP license will be able to 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. This will improve and broaden the public’s access to health care. Adding pharmacists to the pool of health care providers from which California residents can obtain advice, treatment, and referrals will also reduce costs for patients and help ease the effects of the shortage of primary care physicians in the state.

**Factual Basis/Rationale**

This proposal seeks to add and adopt 16 CCR Sections 1730, 1730.1 and amend Section 1749, all of which concern various aspects of the APP license. These adoptions and amendment are necessary to carry out the purpose of B&P sections 4210, 4216.5, 4210, and 4233, which create and concern a new license category called Advanced Practice Pharmacist.

In 2013, the Legislature enacted, and the Governor signed Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) which enables pharmacists to serve as health care providers to the public in enumerated areas. SB 493 established a new license category of Advanced Practice Pharmacist. Pharmacists with this APP license may 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. Since the 1980s, health-system pharmacists have been managing drug therapies, often overseeing specialized clinics which care for patients with asthma, diabetes, hypertension, hypercholesterolemia, and other conditions. This model of expanded practice for pharmacists in the health-system arena has resulted in reduced costs and increased access to health care for health-system patients, and improved patient outcomes for health-system patients. By adopting and amending the proposed regulations, community-based APPs will be able to similarly work in concert with physicians to participate more directly in patient care, thus reducing costs, increasing access, and improving outcomes for the general public.

Adopting 16 CCR Section 1730 will set out the Board's recognition of the pharmacy patient care certification programs certified by the National Commission for Certification Agencies (NCCA), which satisfy the requirements of B&P section 210(a)(2)(A). Adopting 16 CCR Section 1730.1 will list the documentation required to be submitted to the Board when applying for an APP license. 16 CCR Section 1749 is the existing regulation section regarding Board fees, and the proposed amendment establishes the fees for obtaining and renewing an APP license, and the fee for failing to renew an APP license.

To determine the fee established for application or renewal of an APP license, the board considered the cost of providing the service to issue, renew, and enforce the provisions of the applicable requirements. In the board's licensing and enforcement programs, the board utilizes Office Technicians, Staff Services Analysts and Associate Governmental Program Analysts under the direction of one or more Staff Services Manager Is. Should the board receive complaints related to an APP licensee or find it necessary to deny an application or revoke a license, the board utilizes Board of Pharmacy Inspectors (all pharmacists) to investigate and report on these cases. The board had an initial estimate of approximately 2,100 pharmacist licensees that may seek licensure as an Advanced Practice Pharmacist. Based on the estimate, and given estimated staff processing times, the board concluded that the cost of processing, issuing, renewing and enforcing these licensees would be \$300. Thus, the application fee was set as such. The delinquency fee is fifty percent of the application or renewal fee, as specified in section 163.5 of the B&P Code.

As of 2008, there were approximately 32,000 practicing pharmacists and approximately 23,000 primary care physicians in California. With the adoption of the Affordable Care Act, many California residents who were not previously insured now have insurance and are seeking care. With baby boomer California residents continuing to age, an increasing number of Californians with chronic conditions are taking multiple medications to manage their health conditions. By adopting the APP regulations, the most highly educated and experienced pharmacists who opt to obtain this license will be able to make more health care services available to the public and ease the strain on the California health care system.

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 impact of the shortage of primary care physicians in the state.

**Underlying Data:**

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held June 3-4, 2015.
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held April 21-22, 2015.
3. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee Meeting held April 13, 2015.
4. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee Meeting held February 25, 2015.
5. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 27-28, 2015.
6. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee Meeting held December 16, 2014.
7. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee Meeting held November 5, 2014
8. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 29-30, 2014,
9. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee Meeting held August 6, 2014
10. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 30-31, 2014.
11. Relevant Meeting Materials and Minutes from SB 493 Implementation Committee Meeting held June 4, 2014.

**Business Impact:** The Board does not believe this regulation will have a significant 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:

- Adopting 16 CCR Section 1730 establishes that the Board-recognizes the pharmacy patient care certification programs certified by the National Commission for Certification Agencies ("NCCA"), and that NCCA programs can be used to satisfy the requirements of B&P section 4210(a)(2)(A).
- Adopting 16 CCR Section 1732.2 establishes which documents are required to be submitted to the Board in order to obtain an APP license.
- Adopting 16 CCR Section 1732.5 simply establishes the fees for obtaining and retaining an APP license, and for failing to renew an APP license.

### **Economic Impact Assessment Results:**

This regulatory proposal creates a new license category, the APP, which is an optional Advanced certification which can only be obtained by pharmacists who meet the education and experience requirements and are already licensed to practice pharmacy in California. An APP will have an expanded scope of pharmacy practice, and will be able to take the actions described herein, which were previously performed only by doctors. Because this is a new license, the exact economic outcome resulting from the creation of this new license category is unknown. The Board believes this regulatory proposal will have the following effects:

- For pharmacists who do not choose to get an APP license, there should be no impact on the creation or elimination of jobs in California. For pharmacists who do choose to get an APP license, they will do so with the belief that having this license may bring in additional patients, and perhaps allow the APPs to charge more. Such growth should increase the economic activity for pharmacies, and thus may have a positive impact on the creation of jobs in California. Allowing pharmacists to practice under an APP license may reduce some demand for physician services, but this should not eliminate jobs in California because of the shortage of primary care physicians in California.
- For pharmacists who do not choose to get an APP license, it should not create new businesses or eliminate existing businesses within California. For pharmacists who do choose to get an APP license, they will do so with the belief that having this license may bring in additional patients, and perhaps allow the APPs to charge more. If these things happen, this should increase the economic activity for pharmacies, and may generate enough economic activity to create new businesses. Allowing pharmacists to practice pharmacy under an APP license may reduce some demand for physician services, but this should not eliminate jobs in California because of the shortage of primary care physicians in California.
- For pharmacists who do not choose to get an APP license, it should not affect the expansion of businesses currently operating in California. For pharmacists who do choose to get an APP license, they will do so with the belief that having this license may bring in additional patients, and perhaps allow the APPs to charge more. Such growth should encourage the expansion of pharmacies, the pharmacy business, and the businesses that educate APPs in California. Allowing pharmacists to practice pharmacy under an APP license could create a minor reduction in demand for physician services, and thus could contract the business of physicians, but for the existing and predicted increasing shortage of primary care physicians in California.
- This regulatory proposal benefits the health and welfare of California residents because it will broaden public access to health care. Adding pharmacists to the pool of health care providers from which Californians can obtain advice, treatment, and referrals will improve access and reduce costs for patients and help ease the impact of the shortage of primary care physicians in the state.
- This regulatory proposal has no impact on worker safety.

- This regulatory proposal will have no impact on the state's environment because the APP license is simply an optional Advanced certification for pharmacists already licensed to practice pharmacy in California.

**Specific Technologies or Equipment:** This regulation would not mandate the use of specific technologies or equipment.

**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 actions are proposed, or would be as effective and less burdensome to affected private persons than the proposals described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law. The Board believes that taking no action is an unacceptable alternative in light of B&P sections 4016.5, 4052.6, 4210 and 4233 which concern the Legislature's intent to create the new APP license in order to broaden public access to health care.