

# Board of Pharmacy

## Initial Statement of Reasons

Subject Matter of Proposed Regulation:      Advanced Practice Pharmacist – Certification Programs

Sections Affected:      Add Section 1730.2 to Article 3 of Division 17 of Title 16 Cal.Code Reg.

### **Specific Purpose of the Proposed Changes/Problems Addressed**

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), as defined below.

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) establishes certification as one criteria to allow an individual to obtain an Advanced Practice Pharmacist license. This regulatory proposal will specify the types of certifications which may be accepted by the Board.

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 the 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, specialized pharmacists, and increased access to health care providers.

The purpose of the Board's proposal makes the following additions:

#### Adopt 16 CCR Section 1730.2 Certification Programs

Subdivision (a) adds "For purposes of Business and Professions Code Section 4210, subdivision (a)(2)(A), general clinical pharmacy practice is among the relevant areas of practice for which certification may be earned." This section is being added to recognize general clinical pharmacy as it is not identified as a subject area in B&P section 4210(a)(2)(A) with the other areas that are specified.

Subdivision (b) adds "For a pharmacist seeking to demonstrate certification in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, the certification may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education or accredited by the National Commission for Certifying Agencies as a certification provider, so long as:" This section is necessary to add the National Commission for Certifying Agencies as a recognized agency for certification programs. The Accreditation Council for Pharmacy Education is also included as outlined in B&P section 4210(a)(2)(A).

Subdivision (b)(1) adds "The certification program includes specified learning objectives in at least five sequentially-ordered education modules, covering the following topics: performing

patient assessments; ordering and interpreting drug therapy-related tests; referring patients to other health care providers; participating in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiating, adjusting, modifying or discontinuing drug therapy;” These sections were selected based on the five key modules an Advanced Practice Pharmacist is authorized to perform as defined in B&P section 4052.6(a). This section requires that the program have specified learning objectives and that the five modules be presented to participants in the certification program in the same order that they are in the regulation. This is because the participant should have a mastery of one module in order to better understand the next module. Better understanding should lead to better prepared participants, who can ultimately practice with safety to the public.

Subdivision (b)(2) adds “The certification program requires assessment after completion of each of the education modules in an examination format or by other assessment methodology that confirms the participant’s understanding, knowledge, and application of the specified learning objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module;” This section is necessary to ensure that the certification programs provide progressive training with assessments upon completion of each module. This ensures that participants are developing the necessary knowledge to perform the specialized duties. Additionally, the general requirement of an “assessment” allows the program to determine and develop the type of testing for that program. This will provide public protection because a participant who has passed such each assessment should have a solid understanding of each module before progressing to the next module.

Subdivision (b)(3) adds “The certification program requires that instruction and assessments in each of the modules are developed and provided by either:” This section specifies the qualification of staff involved in development and presentation of a program. This will provide public protection because someone with the required qualifications should have a better ability to develop and provide instruction and assessments so that participants are adequately trained.

Subdivision (b)(3)(A) adds “An advanced practice pharmacist licensed by the board or...” This section is necessary to authorize licensed Advanced Practice Pharmacists to develop and/or provide training and certification to pharmacists seeking certification. This is because those who currently hold the license would have the proper training and education needed to train others.

Subdivision (b)(3)(B) adds “An expert with experience in the respective area(s) of focus specified in subparagraph (1), where “expert” means a person who qualifies to teach at a school of pharmacy recognized by the board.” This section is necessary to provide another option for those who may develop and provide the instruction and assessments. Staff providing the training and certification must be qualified to do so. The Board recognizes all pharmacy schools within the United States that are accredited by the Accreditation Council for Pharmacy Education.

Subdivision (b)(4) adds “The certification program requires that, upon successful completion of all modules and their respective assessments, each participant shall earn a passing score on a final overall assessment before being awarded certification. The assessment shall be either a final written examination or an objective structured clinical examination developed and administered in collaboration with an accredited school of pharmacy recognized by the board; and...” This section is necessary to include successfully passing a comprehensive assessment to ensure that the participant has mastered all five modules. A key to certification is successfully passing the final assessment to confirm the knowledge and training that the pharmacist will need to perform the specialized duties. This will provide public protection because a participant who has passed such a final assessment should have a solid understanding of the modules and be able to practice them safely on the public.

Subdivision (b)(5) adds “The certification program require(s) a minimum of ten hours of continuing education on the topics identified in (b)(1) every two years to maintain certification.” This section is necessary to ensure that licensees complete continuing education in the specialized duties authorized by an Advanced Practice Pharmacist license. The ten hour requirement aligns the regulation with B&P section 4233, which requires ten hours of continuing education. Continuing education makes it more likely that individuals with a certification have the current knowledge, skills, and abilities to safely assist consumers.

Additionally, “Note: Authority cited: Section 4005 and 4210, Business and Professions Code. Reference: Sections 4052.6, 4210, and 4233, Business and Professions Code.” is added to comply with the Administrative Procedures Act.

### **Factual Basis/Rationale**

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 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.

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 as an Advanced Practice Pharmacist. Pharmacists with an Advanced Practice Pharmacist 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. This regulatory proposal will provide certification standards required to satisfy B&P section 4210(a)(2)(A). The regulation will address things like the relevant area of practice, from whom certification must be earned, and requirements of the programs.

### **Underlying Data**

1. Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013).
2. Relevant Meeting Minutes from Board of Pharmacy Meeting held November 11, 2015.
3. Relevant Meeting Minutes from Board of Pharmacy Committee Meeting held October 30, 2015.

### **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 to businesses associated with the creation of the certification program would be offset by the income received from those attending the program.

### **Economic Impact Assessment**

This regulatory proposal will have the following effects:

It may create jobs, but will not eliminate jobs within the State of California because the proposed regulation only specifies the certification program requirements in order for pharmacists to obtain a specialized Advanced Practice Pharmacist license.

It may create new business, but will not eliminate businesses within the State of California because the proposed regulation specifies the certification program requirements in order for pharmacists to obtain a specialized Advanced Practice Pharmacist license. Offering a certification program that meets the requirements is optional and businesses can be reimbursed by charging a fee for the program if they wish to participate.

It may affect the expansion of businesses currently doing business within the State of California because the proposed regulation specifies the certification program requirements in order for pharmacists to obtain a specialized Advanced Practice Pharmacist license. Offering a certification program that meets the requirements is optional and businesses can be reimbursed by charging a fee for the program if they wish to participate.

This regulatory proposal benefits the health and welfare of California residents because the proposed regulation specifies the certification program requirements in order for pharmacists to obtain a specialized Advanced Practice Pharmacist license. This specialized license will allow pharmacists to provide additional health care services to patients within a pharmacy setting.

This regulatory proposal does not affect worker safety because the proposed regulation only specifies the certification program requirements in order for pharmacists to obtain a specialized Advanced Practice Pharmacist license.

The regulatory proposal does not affect the state's environment because the proposed regulation only specifies the certification program requirements in order for pharmacists to obtain a specialized Advanced Practice Pharmacist license.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Alternatives**

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law begin implemented or made specific. The only alternative would be not to specify the certification program requirements and this would result in a licensee's inability to meet the requirements for licensure as they would not know which certification programs were acceptable to the Board.