

TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Advanced Practice Pharmacist – Certification Programs.

Section Affected: Adopt title 16 California Code of Regulations (CCR) section 1730.2.

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the adoption of the above section. The initial Statement of Reasons is updated as follows:

The 45-day public comment period began on December 25, 2015 and ended on February 8, 2016. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

During the 45-day comment period several comments were received. On February 25, 2016, after having considered all comments in the record, the Board adopted the regulation text as noticed on December 25, 2015.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of substantive comments and the lack of any requests for a hearing regarding this rulemaking proposal. Additionally, this regulation defines the certification program requirements for a voluntary program. 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.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulation or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the 45-day public comment period from December 25, 2015 to February 8, 2016, the Board received several comments. The comments were provided to the Board in the Meeting Materials for the February 25, 2016 Board meeting, and were reviewed and considered by the Board.

Written Comments from Dr. C. Edwin Webb, American College of Clinical Pharmacy (ACCP)

Comment #1: Dr. Webb expressed concern about the reference to the National Commission for Certifying Agencies (NCCA). Dr. Webb expressed a belief that reference to NCCA will cause confusion between NCCA accredited programs and other activities that Board wishes to recognize. Dr. Webb recommended that the language be modified to only allow the Accreditation Council for Pharmacy Education (ACPE) approved practice-based continuing professional education (CPE) activities.

Response to Comment #1: This comment is rejected because the Board does not agree with the exclusion of NCCA accredited providers from the ability to develop certification programs that meet the requirements as defined in the regulation.

Comment #2: Dr. Webb recommended that definitions of “Certificate Program” and “Certification” be added to the regulation text; however, necessity for the inclusion was not provided.

Response to Comment #2: This comment is rejected because the Board does not agree the definitions are necessary. The term “certificate program” is not utilized within the regulation. The term “certification program” is utilized and is defined in 1730.2(b)(1) with the program requirements in (b)(2) – (b)(5).

Written Comments from Thomas E. Menighan, American Pharmacists Association (APhA)

Comment #3: Mr. Menighan and APhA recommended that the Board consider recognizing the ADAPT US program as an acceptable pathway for licensure. APhA recommended that section (a) be modified to change “which certification may be earned” to “which the certification requirement may be met.” Additionally, APhA recommended that section (b) be modified to change “demonstrate certification in” to “meet the requirement for” and change “certification” to “credential.” They also recommended that “certification is received from an organization” be added following ACPE. APhA indicated that the proposed changes align the regulation with industry-accepted language. Additionally, APhA is accredited by the ACPE and offers the ADAPT US continuing education program.

Response to Comment #3: This comment is rejected because the changes recommended did not add clarity to the proposed text. The ADAPT US program is not being excluded and will be accepted if the program meets the requirements defined in b(1) – (b)(5). Additionally, “certification” is utilized in the regulation for consistency with statute. The Board is recognizing NCCA accredited organizations as a certification provider if they meet the program requirements. Certification is not being limited to only ACPE accredited organizations.

Comment #4: APhA recommended that the language to section (b)(2) be modified to eliminate the need to pass each module prior to advancing to the next module. APhA recommended the language be changed to “where any failure to successfully complete the assessment in any module prevents participants from passing the program;”

Response to Comment #4: This comment is rejected as the Board determined that the training to be an advanced practice pharmacist needs to be progressive and show that ongoing learning is taking place. The key to a certification program is the assessments to confirm the training. If a pharmacist cannot successfully understand and apply the knowledge for each module, they should not advance in the program until that knowledge is gained.

Written Comments from William M. Ellis, Board of Pharmacy Specialties (BPS)

Comment #5: BPS recommended the section (b) be modified to change “to demonstrate certification” to “certification credential” and that “certification” be changed to “credential.” Additionally, BPS recommended adding “for practice-based continuing pharmacy education (CPE) activities” after ACPE and changing “as a certification provider” to “for certification program. Finally, in subsections (1)-(5), BPS recommended changing “certification program” to “practice-based CPE activity.” BPS stated a belief that utilization of the term “certification” is inconsistent with the term as used in the pharmacy profession. Additionally, the regulation does not differentiate programs and activities recognized by ACPE from those accredited by the NCCA.

Response to Comment #5: This comment is rejected because the Board is accepting certification provided by both ACPE and/or NCCA. Specifying “practice-based CPE activity” may eliminate the NCCA accredited provider and may cause confusion with the other parts of the regulation because the certification that must be earned is something more than what is required to complete traditional continuing education requirements. Additionally, the term “certification” is utilized to maintain consistency with the statute in B&P code section 4210(a)(2)(A). The specification shows a clear path for any provider recognized by ACPE or NCCA to develop a program that meets the requirements within the regulation. If the developed program meets the requirements, it will be accepted by the Board for licensure as an Advanced Practice Pharmacist.

Written Comments from Barry Solomon, Pharmacist

Comment #6: Mr. Solomon does not support an advanced practice pharmacist license as he is against anything that separates one pharmacist from another. Mr. Solomon expressed his belief that an advanced practice pharmacist license will affect how pharmacists are viewed and will affect job offers and the workplace.

Response to Comment #6: This comment is rejected as the advanced practice pharmacist license is authorized in B&P Code section 4052.6.

Written Comments from Dr. Henry Delu Jr., Pharmacist

Comment #7: Dr. Delu Jr. expressed concern that the proposed text would only benefit 5 to 10 percent of pharmacists because some certification programs require completion of a pharmacy residency. Dr. Delu Jr. recommended that the language be modified to allow a pharmacist to challenge an exam and become certified.

Response to Comment #7: This comment is rejected as certification is only one of the three areas that a pharmacist can meet to qualify for an advanced practice pharmacist license. Additionally, the statute at B&P section 4210, does not permit a pharmacist to take an exam and become certified.

At its February 25, 2016, meeting, the Board considered all of the comments and voted to adopt the regulation text as it was noticed on December 25, 2015.