



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**XVIII. Proposed Regulations to Add Title 16 California Code of Regulations (CCR) section 1730.2, Related to Advanced Practice Pharmacist – Certification Programs**

At the November 2015 Board Meeting, the board approved proposed text to add Section 1730.2 of Title 16 CCR, related to Advanced Practice Pharmacist – Certification Programs. The 45 day comment period began on December 25, 2015 and ended February 8, 2016.

The Board received several comments during the comment period.

**At this Meeting**

The board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the November 2015 Board meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

**The Attachment** immediately following this memo contains the proposed regulation text as noticed on December 25, 2015 and a compilation document of the comments received during the 45 day comment period.

**Advanced Practice  
Pharmacist –  
Certification Programs  
1730.2**

**Advanced Practice  
Pharmacist –  
Certification Programs**

**45- Day Comments**

**Comment Period**

**Closed**

**February 8, 2016**

Code Section	Commenter	Comment
1730.2(b)	<b>Board of Pharmacy Specialties</b>	<p>The Board of Pharmacy Specialties (BPS) wishes to express support for the California State Board of Pharmacy's approval of Acceptable Certification Programs, Section 1730 of Article 2 of Division 17 of Title 16 of the California Code of Regulations. Based on this approval, National Commission for Certifying Agencies (NCCA) accredited programs administered by BPS would qualify as meeting requirements under Article 16. Application. 4210(a)(2)(A) Advanced Practice Pharmacist Licensure.</p> <p>BPS is also writing to express concerns with the language contained in the proposal to add Section 1730.2 of Article 2 of Division 17 of Title 16 of the California Code of Regulations. While BPS fully recognizes that the law allows for alternate pathways to achieve Advanced Practice Pharmacist (APP) status, this proposal utilizes the term "certification" in a manner that inconsistent with terms adopted by the pharmacy profession and confusing to other healthcare providers and the public. BPS believes that the appropriate terms that need to be added and defined should be "credential" as well as "certificate program" or "practice-based continuing pharmacy education (CPE) activity." The current language, "certification program" used in this proposal co-mingles "certificate programs" and "board certification programs." BPS highlighted these differences in a letter to the Board under a separate cover dated November 11, 2015.</p> <p>(b) For a pharmacist seeking to demonstrate certification <u>credential</u> in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, the <u>certification credential</u> may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education for <u>practice-based continuing pharmacy education (CPE) activities</u> or accredited by the National Commission for Certifying Agencies <u>for certification program</u> as a <u>certification provider</u>, so long as:</p>
1730.2(b)(1) - (5)	<b>Board of Pharmacy Specialties</b>	<p>Furthermore, the language proposed in Section 1730.2(b) subparagraphs 1 through 5 outlines requirements for an alternate educational pathway specific to certificate programs or practice-based CPE activities categorized by the Accreditation Council for Pharmacy Education (ACPE). The purpose of practice-based CPE activities is to instill knowledge, skills, and attitudes, and to conduct formative and summative learning assessments. Conversely, board certification programs assess knowledge, skills, and/or competencies previously acquired, and validate the participant's competency through a conformity assessment system in compliance with standards established by the National Commission for Certifying Agencies (NCCA).</p> <p>BPS believes that the intent of Section 1730.2 is to provide specific requirements for programs seeking to develop activities for alternate pathways and encourages the Board to clarify the purpose of 1730.2. BPS respectfully submits edits to the proposed language for the Board's consideration. BPS recognizes the Board's authority to develop requirements for all programs to qualify as meeting 4210(a)(2)(A), and requests that the terminology and requirements clearly and accurately differentiate programs and activities recognized by ACPE and those programs accredited by the NCCA. Thank you in advance for your consideration of this correspondence.</p> <p>Recommendation: Change "certification program" in (b)(1) - (b)(5) to read "practice-based CPE activity."</p>

Code Section	Commenter	Comment
1730.2(a), (b), (b)(1)	<b>American Pharmacist Assoc.</b>	<p>Proposal to add Section 1730.2 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:  § 1730.2 Certification Programs  (a) For purposes of Business and Professions Code section 4210, subdivision (a)(2)(A), general clinical pharmacy practice is among the relevant areas of practice <u>for which the certification requirement may be met</u>.<del>which certification may be earned.</del></p> <p>(b) For a pharmacist seeking to <u>meet the requirement for demonstrate certification</u> in general clinical pharmacy as a criterion for advanced practice pharmacist licensure by the board, <u>a credential</u> <del>the certification</del> may be earned from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education or <u>certification is received from an organization</u> accredited by the National Commission for Certifying Agencies as a certification provider, so long as:</p> <p>(1) The <del>certification</del> 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;</p> <p>APhA proposes the recommended edits above in order to bring the California regulations in-line with industry-accepted standard language.</p> <p>The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. ADAPT US is approved for 100 hours (10.0 CEUs) of continuing pharmacy education credit. ADAPT US covers each of these topic areas interwoven throughout the course. The ADAPT program teaches participants a systematic process to more effectively apply their clinical knowledge and undertake the evaluation and management of disease states and health conditions in their practices including 20 hours of coursework on performing patient assessments; 6 hours on ordering and interpreting drug therapy-related tests; 6 hours on the topic of referring patients to other healthcare providers; and 20 hours on initiating, adjusting, modifying or discontinuing drug therapy. In addition, the ADAPT US program includes 21 hours of coursework on incorporating Evidence-Based Medicine into practice, and 14.5 hours on documentation practices.</p>
1730.2(b)(2)	<b>American Pharmacist Assoc.</b>	<p>(2) 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;</p> <p>ADAPT US requires participants to complete an action plan at the end of each module. APhA will develop a scoring rubric to make this a graded activity for California. However, APhA requests the California Board of Pharmacy alter the language requiring participants to successfully pass a module before advancing to the next. The ADAPT US course adheres to a very rigorous schedule. Because of the significant time commitment involved, occasionally a participant will experience an absence. ADAPT addresses this by making all modules accessible to participants so that if a participant falls behind, they are able to complete the scheduled activities with the rest of the class while simultaneously making up the assignment(s) missed. We propose the alternate language in the regulation to read "...where any failure to successfully complete the assessment in any module prevents participants from passing the program;"</p>

Code Section	Commenter	Comment
1730.2(b)(3)	<b>American Pharmacist Assoc.</b>	<p>(3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either:</p> <p>(A) An advanced practice pharmacist licensed by the board or</p> <p>(B) 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.</p> <p>APhA agrees with these requirements to ensure the highest quality instructors are utilized for content creation and teaching California pharmacists. ADAPT US has requirements for faculty and content developers in place that meets these requirements.</p>
1730.2(b)(4)	<b>American Pharmacist Assoc.</b>	<p>(4) 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</p> <p>ADAPT US utilizes a comprehensive two-part written, cumulative examination at the end of the course which assesses comprehension of the content taught throughout all modules of the course. This “certificate challenge” is only available to those participants who have successfully completed all course requirements. The final comprehensive exam uses an established rubric for scoring. The grading is completed by independent assessors who meet the qualifications stated in (b)(3).</p>
1730.2(b)(5)	<b>American Pharmacist Assoc.</b>	<p>(5) 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.</p> <p>APhA will include the following language on each issued certificate to pharmacists licensed in California: “The training associated with this APhA issued certificate is current for 2 years from this date of issue. It is the responsibility of the practitioner to engage in continuing professional development and education to meet the existing standards of practice set by the practitioner’s state board of pharmacy and/or the policies and procedures of the organization that employs the practitioner.” APhA will develop an ADAPT reevaluation product, at least 10 hours in length, which would be required for California pharmacists who wish to keep their ADAPT certificate current to meet the board requirement.</p>

Code Section	Commenter	Comment
Overall	ACCP	<p>We are pleased to understand that decisions made by the Board toward the end of 2015 have recognized practitioner certification programs at the national level, such as those of the Board of Pharmacy Specialties (BPS), that are accredited by the National Commission for Certifying Agencies (NCCA), consistent with the following language:  “§1730 Acceptable Certification Programs. The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).”</p> <p>We are concerned, however, that the most recent version of draft language now under review and comment continues to retain language and reference to NCCA accredited certification programs within Section 1730.2. We believe this is unnecessary given the decision previously made by the Board as referenced above. More importantly, if that language is not removed, it could easily contribute to confusion regarding the structural differences between NCCA accredited programs and other types of activities the Board wishes to recognize.</p> <p>We therefore recommend that section 1730.2 address only the particular proposed alternative pathway the board is establishing relative to Accreditation Council for Pharmacy Education (ACPE) approved practice-based continuing professional education (CPE) activities for pharmacists. We are aware that various other commenters have provided similar recommendations, and proposed language changes, to achieve that objective. ACCP is supportive of those efforts.</p>
Overall	ACCP	<p>Finally, ACCP recommends the inclusion in the regulation or its references/appendices of the following definitions established by the Council on Credentialing in Pharmacy (CCP), a national coalition of twelve organizations across pharmacy’s practice and education spectrum. CCP’s purpose is to provide “...leadership, guidance, public information, and coordination for the profession of pharmacy’s credentialing programs. The vision of CCP is that all credentialing programs in pharmacy will meet established standards of quality and contribute to improvement in patient care and the overall public health.”</p> <p><b>*Certificate Program:</b> A structured, systematic, postgraduate education and continuing education experience for pharmacists that is generally smaller in magnitude and shorter in duration than a degree program or residency training program. Certificate programs are designed to instill, expand, or enhance practice competencies through the systematic acquisition of specific knowledge, skills, attitudes, and performance behaviors. (Note: the Accreditation Council for Pharmacy Education (ACPE) has recently replaced this term with the term “Practice Based CPE Activity.”</p> <p><b>* Certification:</b> The voluntary process by which a nongovernmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization. This formal recognition is granted to designate to the public that this individual has attained the requisite level of knowledge, skill, and/or experience in a well-defined, often specialized, area of the total discipline. Certification usually requires initial assessment and periodic reassessments of the individual’s knowledge, skills, and/or experience.</p>
Overall	Barry Solomon Licensed since 1958	<p>I am against anything that separates one pharmacist from another. I am not in favor of an advanced practice pharmacist. It will affect the way a pharmacist is viewed and will affect job offers and the workplace.</p>

Code Section	Commenter	Comment
Overall	Henry Delu Jr.	<p>I read the proposal and thought that this would only benefit 5-10 percent of pharmacist. Some of the certification programs require 1 or 2 year of pharmacy residency, yet a person practicing for 2 to 3 years would have seen the same thing in a community pharmacy. Second, I read the training requirements and they put a strain on pharmacist who have recently graduated. I think language should be added that at any time any pharmacist should be able to challenge the exam. For example, I have worked in community pharmacy for more than 6 years as a tech, intern, and pharmacist(2.5 years as a pharmacist) yet I would not qualify to take the exam.To me that is asinine since I am licensed in 3 states, have served as a clinical manager for asthma, diabetes, and hypertension and other clinical conditions, but cannot take the certification since I do not have a residency or have not been a pharmacist for 6 years.Below are the requirements for specialty pharmacist and other certification programs for pharmacist. Also, even in psychiatry, a community pharmacist is not eligible for the exam at all without a residency, which I think is ridiculous since a community pharmacist dispenses over 700 psychotropic medications in a given week at a chain pharmacy and deals with such patients more so that psychiatric pharmacist. Basically, I think there should be a section in CA Pharmacy law that allows any pharmacist (practicing 1 year or just a recent graduate) to challenge the exam and become certified. Thus not doing a residency program (which is difficult to get anyway) should not disbar nor disenfranchise recent pharmacist.</p>
Overall	Henry Delu Jr.	<p>Specialty Pharmacy practice is defined as pharmacy practice that includes medications and pharmaceuticals that are high in cost, require special handling, are subject to limited or restricted distribution, require ongoing assessment, treat rare diseases, or require active monitoring of side effects; with an increased emphasis on patient management, medication adherence, collaboration with other members of the health care team, an ability to use metrics to drive optimization of patient care, and an ability to assist the patient to access additional supportive resources.</p> <p>Specialty Pharmacy practice includes both operational and clinical pharmacists who dispense specialty pharmacy drugs as well as pharmacists who are responsible for the management or direction of specialty pharmacists / specialty pharmacies. As an example job titles may include, Staff Pharmacist, Clinical Pharmacist, Specialty Pharmacist, Pharmacy Manager, Clinical Services Manager, Manger of Pharmacy Benefits, Director of Pharmacy, Director of Specialty Pharmacy Practice, Director of Clinical Services, Director of Pharmacy Operations, VP Pharmacy Operations, VP of Clinical Services, and VP of Specialty Pharmacy Development, Chief Pharmacy Officer, etc. The 3,000 hour experience requirement includes time spent working in Specialty Pharmacy practice in a variety of capacities. For example, a pharmacist in a retail or hospital environment with 6,000 hours of work experience who spends approximately 50% of his/her time working with specialty pharmaceuticals would meet the requirement and should report only the relevant specialty practice hours.</p> <p>-----</p> <p>The purpose of the Certified Geriatric Pharmacist (CGP) credential is to identify and recognize those pharmacists who have expertise and knowledge of drug therapy principles for older adults. For this reason, the CGP credential is ideal for pharmacists who provide MTM services to older adults.</p> <p>To be eligible for the certification examination in Geriatric Pharmacy Practice, an applicant must currently be a licensed pharmacist and must have a minimum of two years of experience as a licensed pharmacist. Applications must be accompanied by a photocopy of current pharmacist registration certificate/license and a check, money order, or credit card payment.</p>



Code Section	Commenter	Comment
Overall	Henry Delu Jr.	<p>Eligibility Requirements (all practice eligibility requirements must be met prior to the candidate sitting for the examination)</p> <p>The minimum requirements for this specialty certification are:</p> <ul style="list-style-type: none"> <li>• Graduation from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) or a program outside the U.S. that qualifies the individual to practice in the jurisdiction.</li> <li>• Current, active license to practice pharmacy in the U.S. or another jurisdiction.</li> <li>• Completion of four (4) years of practice with at least 50% of time spent in psychiatric pharmacy activities (as defined by the BPS Psychiatric Pharmacy Content Outline)</li> <li>• Completion of a PGY1 residency* plus two (2) additional years of practice post-pharmacist licensure with at least 50% of time spent in psychiatric pharmacy activities (as defined by the BPS Psychiatric Pharmacy Content Outline) OR</li> <li>• Completion of a specialty (PGY2) residency* in psychiatric pharmacy, and</li> <li>• Achieving a passing score on the Psychiatric Pharmacy Specialty Certification Examination</li> </ul>

**Advanced Practice  
Pharmacist –  
Certification Programs  
Initial Proposed Text**

**Title 16. Board of Pharmacy  
Proposed Text**

Proposal to add Section 1730.2 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§ 1730.2 Certification Programs

- (a) 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.
- (b) 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:
  - (1) 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;
  - (2) 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;
  - (3) The certification program requires that instruction and assessments in each of the modules are developed and provided by either:
    - (A) An advanced practice pharmacist licensed by the board or
    - (B) 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.
  - (4) 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
  - (5) 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.

Note: Authority cited: Section 4005 and 4210, Business and Professions Code.

Reference: Sections 4052.6, 4210, and 4233, Business and Professions Code.