



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: November 9, 2015

To: Board Members

Subject: Agenda Item VI: Draft APP Regulation Language

The SB 493 Committee met on October 30, 2015 following the board meeting. As part of the meeting, the committee heard presentations to enable the committee to establish the parameters for a certification program for general clinical pharmacy practice. Presentations were also heard from the American Pharmacists Association, Ralphs as well as the California Pharmacists Association and National Association of Chain Drug Stores. Following the presentations the committee discussed the proposed language and made modifications based on the information provided by presenters and public comments received.

Attachment 1 is the language as provided at the committee meeting.

Attachment 2 contains the language as edited based on the committee discussion.

The proposal is being provided to the board for its review and possible action to initiate a rulemaking.

Attachment 1

Proposed Language

***As Provided at the October 30, 2015, SB 493 Implementation Committee**

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 (a) In addition to the relevant areas of practice certification programs specified in Business and Professions Code Section 4210 (a)(2)(A), for purposes of a community pharmacist seeking to demonstrate certification as one of the criterion for advanced practice pharmacist recognition by the board, the board recognizes pharmacy patient care certification programs in relevant areas of practice that are provider by an organization recognized as a continuing education provided by the Accreditation Council for Pharmacy Education or accredited by the National Commission for Certifying Agencies as a certification provider, so long as the certification program meets the following minimum requirements:

- (1) The certification program includes specified learning objectives in at least five sequentially-arranged 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 and discontinuing drug therapy;
 - (2) The certification program includes 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 specific learn objectives for the module, where any failure to successfully complete the assessment in any module prevents advancement to the next module;
 - (3) The instruction and assessments in each of the modules are performed by an advance practice pharmacist recognized by the board or by an expert with demonstrated expertise in the respective area of focus;
 - (4) Upon successful completion of all modules and their respective assessments, each participant must successfully complete a final overall assessment with a passing score before being awarded certification, using 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;
 - (5) The certification program must be completed within one year of entrance in order to receive certification; and
 - (6) Upon successful completion within one year, the certification program provides participants with written documentation of certification that includes the name of the individual and the date of completion.
 - (7) The certification program must require a minimum of 10 hours of continuing education in the authorities established in B&PC 4052.6 (a)(1)- (a)(5) every two years as a condition to maintain certification.
- (b) To satisfy the certification requirement as one criterion for recognition as an advanced practice pharmacist, an applicant must have completed the certification program within one year of the entry date.

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

Attachment 2

Proposed Language

***Revised Based on the Discussion at the October 30, 2015, SB 493 Committee Meeting**

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 (a) For purposes of Business and Professions Code Section 4210, subdivision (a)(2)(A), general clinical pharmacy practice, whether in a community or institutional pharmacy setting, 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 by 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 an advance practice pharmacist licensed by the board, or by a licensed healing arts practitioner or an expert with experience in the respective area(s) of focus specified in subparagraph (1), where an "expert" means a person who qualifies to teach a class at a college, university or an accredited school of pharmacy;
- (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, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.