



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SB 493 IMPLEMENTATION COMMITTEE MEETING
MINUTES**

DATE: October 30, 2015

LOCATION: Department of Consumer Affairs
1st Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Stanley C. Weisser, President, Committee Chair
Deborah Veale, RPh
Amy Gutierrez, PharmD.
Victor Law, RPh
Ricardo Sanchez, Public Member
Allen Schaad, RPh (temporary appointment)

COMMITTEE MEMBERS

NOT PRESENT:

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Legal
Joshua Room, Deputy Attorney General
Laura Hendricks, Staff Analyst

Call to Order

Chairperson Weisser called the meeting to order at 1:00 p.m.

Committee members present: Stanley Weisser, Amy Gutierrez, Victor Law, Allen Schaad and Deborah Veale.

At the request of Chairperson Weisser, Ms. Sodergren briefly reviewed the requirements applicants must meet to become licensed as an advanced practice pharmacist as outlined in

Business and Professions Code section 4210.

a. Development of Additional Qualifying Methods for Advanced Practice Pharmacists as Authorized by SB 493

Chairperson Weisser explained that over the past 18 months, the committee has focused on multiple elements to implement provisions in SB 493, including regulations to identify criteria of acceptable certification programs. The board currently has a regulation pending to clarify one pathway for certification programs. Chairperson Weisser stated that the board has planned to look at alternative pathways for qualification under the certification provision.

Chairperson Weisser reported that during the June 2015 Board Meeting, the board heard a presentation from CPhA and NACDS requesting consideration of an alternative pathway for certification programs that more closely aligns with community pharmacy practice.

Chairperson Weisser stated that during this meeting, the committee will hear presentations involving two proposed certification programs as well as a proposal developed by staff to add a second pathway for certification.

Chairperson Weisser asked Laura Freedman to briefly define certification. Ms. Freedman explained that certification is earned after successfully completing an education or training program that reflects a level of expertise in a particular area of the practice of pharmacy. She noted that a certification program must contain an assessment of the knowledge, skills and competency gained as the result of the program. Ms. Freedman stated that the board could define certification in its regulation, but she advised the board to ensure that any definition contains an assessment component.

Chairperson Weisser reported that staff drafted language to create an additional pathway to certification. Ms. Sodergren explained that the draft language provided by staff was intended to create a pathway to certification for pharmacists in the community pharmacy setting. She noted that staff is recommending that the board not amend the current regulation that has already been approved; rather, staff recommends adding a new regulation section (1730.2). Ms. Sodergren reviewed the proposed language as provided below.

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 pharmacy 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 provided 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.

Chairperson Weisser explained that later in the meeting the committee would be reviewing the language in detail.

1. Presentation by The American Pharmacists Association on Community-Based Care Models for Pharmacists

The Executive Vice President and CEO of The American Pharmacists Association, Thomas Menighan, BSPHarm, MBA, FAPhA, provided a presentation on the ADAPT Program.

Mr. Menighan explained that ADAPT is an educational program designed to increase access to care for Californians by creating options for qualified pharmacists to earn Advanced Practice recognition and to provide additional services.

Mr. Menighan reviewed the ADAPT program including the learning modules and testing components. The entire presentation has been provided immediately following these minutes.

The committee thanked Mr. Menighan for his presentation.

2. Ralphs Pharmacy-Training of Pharmacists in the American Pharmacists Association Model

Rebecca Cupp from Ralphs reported to the committee on their experience using the community pharmacist training program offered by the American Pharmacists Association.

Ms. Cupp explained that two Ralphs pharmacists have completed the ADAPT program and they were very satisfied with the program. She noted that Ralphs has enrolled two additional pharmacists in the program.

A Ralphs pharmacist who is currently enrolled in the program shared her experience participating in the program including the information covered, testing components and how it has improved her knowledge as a pharmacist.

The committee asked if Ralphs anticipated enrolling more pharmacists in the program. Ms. Cupp responded she would anticipate enrolling approximately five to ten percent of their pharmacists. She noted that this rate would depend on the opportunities for APP pharmacists to practice in the community setting.

The committee asked if the program focuses more on primary care rather than specialized areas of pharmacy practice. The Ralphs pharmacist responded that the program does focus mostly on primary care; however specialty areas are touched on.

b. Proposal by the California Pharmacists Association and the National Association of Chain Drug Stores on Elements of an Advanced Practice Pharmacist Certification Program for Community Pharmacists

Jon Roth from the California Pharmacists Association (CPhA) and Jennifer Snyder from the National Association of Chain Drug Stores (NACDS) presented their proposal to establish a program which would allow a pharmacist, upon completion of the proposed program, to qualify as fulfilling Business and Professions Code section 4210(a)(2)(A), as one of the three requirements to achieve APP licensure.

Mr. Roth stated that the CPhA/NACDS APP proposed program will deliver educational content and use a variety of assessment methods for determining candidate competency in the relevant areas of practice. The program will be delivered both online and in-person. Overall the program is expected to contain up to 38 hours of content and assessment.

Mr. Roth explained that upon successfully completing this proposed program, candidates will have learned and been assessed on their knowledge and skills to competently perform those duties specified in Advance Practice Pharmacists' scope of practice.

A copy of the proposal for the CPhA/NACDS Advanced Practice Pharmacist Program has been provided following these minutes.

The committee asked if there would be a third party that would verify that the program meets the requirements in the APP regulations. Ms. Snyder responded that they would be open to considering this. Mr. Roth added that as an ACPE provider they are held to a certain standard when offering educational programs.

The committee asked how many hours of continuing education the program would offer. Mr. Roth stated that similar to the ADAPT program, the minimum hours of continuing education offered would be 38 hours. He added that it may take a pharmacist longer to complete the education.

c. Discussion on Advanced Practice Pharmacist Qualifications

Ms. Sodergren again reviewed the proposed regulation language as provided below. Note: the language was also projected during the meeting so that the public could follow along the discussion.

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 pharmacy 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 provided 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.

Mr. Law asked if the proposed language creates a certification program that is comparable to the Board of Pharmacy Specialties (BPS) Certification. Mr. Room responded that the proposed language is intended to create a separate pathway to certification for pharmacists who work in community pharmacies.

Mr. Law expressed his concern that the proposed language creates a disparity between pharmacists who complete BPS certification and those who complete the community pharmacy certification. Ms. Sodergren noted that the elements of the community pharmacy program are intended to be equal to the elements of the BPS program.

Dr. Gutierrez stated that the intent of the proposed language is to create options for pharmacists when they are working towards obtaining APP licensure.

Ms. Freedman stated that she would recommend defining certification more generically in the draft language. She also stated that the language should clearly differentiate between BPS certification and the community pharmacy certification described in the proposed language.

The committee discussed the policy questions as provided below.

Section 1730.2(a)(1)

1. Does the committee agree with the five education modules detailed in proposed section 1730.2 (a)(1)?
 - The committee agreed with the five educational modules.
2. Does the committee wish to establish a minimum number of instructional hours for each module?
 - No, the committee decided to leave flexibility for the programs to decide how many instructional hours would be needed.

Section 1730.2(a)(2)

1. Does the committee have a preference about the assessment method used, or is the proposal's flexibility in that regard appropriate?
 - The committee agreed with the flexibility provided in the proposed language.
2. Does the committee wish to require additional education in a specific module if the individual does not pass an assessment?
 - The committee elected to allow programs to determine if remedial education should be required.

Section 1730.2(a)(3)

1. Is the committee comfortable with the criteria for who can perform the instruction and assessments of the modules?
 - The committee approved the criteria as outlined in the draft language.

Section 1730.2(a)(4)

1. Does the committee wish to specify a specific form of the final overall assessment (e.g. examination versus OSCE) or does it prefer the proposal's current flexibility?
 - The committee decided to give the programs the flexibility to determine what type of assessment would be most appropriate.

Section 1730.2(a)(5)

1. Does the committee believe that one year is sufficient time to complete a certification program?
 - After discussion the committee decided to remove the one year time requirement.

Section 1730.2(a)(7)

1. Does the committee agree that continuing education should be required to maintain certification?
 - The committee confirmed that continuing education should be required to maintain certification.
2. If so does the committee agree with the 10 hours as proposed?
 - The committee agreed with the 10 hours continuing education as required in the proposed language.

Ms. Sodergren stated that counsel had drafted language for 1730.2 (a) that would serve as a more effective introduction to the section. The language was projected so that the committee and public could review the language. The language is provided below.

1730.2 (a) For purposes of Business and Professions Code Section 4210, subdivision (a)(2)(A), community pharmacy is a relevant area of practice for which certification may be earned.

Public Comment

Mr. Roth stated that CPhA supports the direction of the proposed language as well as the committee's desire to provide flexibility to organizations as they develop programs.

Lisa Kroon, UCSF, spoke in favor of the ADAPT program. Dr. Kroon expressed her concern that some of the specificity in the language might not allow pharmacists to take the ADAPT course.

Dr. Kroon asked why the proposed language uses the term "community pharmacy" when a clinical pharmacist may want to utilize the program. The committee discussed the possibility of making the language more generic. Staff stated that they would review the draft language in 1730.2 (a) to be sure it does not exclude certain practice settings.

Mr. Room noted that the language would be modified based on the committee's discussion and would be brought to the November 11 board meeting for review and approval by the full board.

Ms. Sodergren asked if the committee wanted to have any requirements related how the courses are offered (online vs. in person). The committee did not want to specifically require how the courses should be offered.

Motion: Remove the one-year time limit to complete the program.

M/S: Law/Veale

Support: 6 Oppose: 0 Abstain: 0

Motion: Approve the draft language (section 1730.2) with the modifications discussed at the committee meeting. Provide the modified language to the full board at the November 11, 2016, meeting to review and approve.

M/S: Gutierrez/Sanchez

Support: 6 Oppose: 0 Abstain: 0

d. Public Comment on Items not on the Agenda, Matters for Future Meetings*

*Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).

There were no comments from the committee or from the public.

Chairperson Weisser adjourned the meeting at 3:55 p.m.