



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
PUBLIC BOARD MEETING
MINUTES**

DATE: November 11, 2015

LOCATION: University of Southern California
Orange County Center
2300 Michelson Drive
Irvine, CA 92612

BOARD MEMBERS

PRESENT: Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Stanley Weisser, RPh
Gregory Lippe, Public Member
Allen Schaad, RPh
Ramon Castellblanch, Public Member
Albert Wong, PharmD

BOARD MEMBERS

NOT PRESENT: Lavanza Butler, RPh
Rosalyn Hackworth, Public Member
Ryan Brooks, Public Member
Ricardo Sanchez, Public Member
Gregory Murphy, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Deborah Damoth, Staff Manager
Laura Hendricks, Staff Analyst

Note: This meeting was not webcast

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 9:31 a.m. Board members present: Stanley Weisser, Allen Schaad, Amy Gutierrez, Victor Law, Albert Wong, Deborah Veale, Ramon Castellblanch and Greg Lippe.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

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

III. DCA Fee Audit and Possible Statutory Changes to Board Fees

President Gutierrez stated that at previous meetings the board has discussed the need to pursue a fee increase. The board reviewed the current fund condition (provided below) that illustrates that without a fee increase the board will have negative months in reserve beginning in fiscal year 2017/18.

Fiscal Year	Fund Amount	Months in Reserve
2014/15	\$11,741,000	7.1 (actual)
2015/16	\$8,577,000	5.1 (projected)
2016/17	\$5,118,000	2.7 (projected)
2017/18	-\$1,391,000	-0.8 (projected)

President Gutierrez reported that as part of the fee increase process board staff have been working with the DCA budget office to conduct an audit of the board’s application and renewal fees. President Gutierrez asked Assistant Executive Officer, Anne Sodergren, to report the findings of the fee audit.

Ms. Sodergren explained that the purpose of this fee analysis is to determine the sustainability of the board's fund and to ensure that the board is collecting sufficient revenue to fully reimburse the board for the cost of regulating the pharmaceutical industry. Ms. Sodergren also noted that the fee audit is intended to provide the board with the information necessary to make an informed decision regarding the board’s fee structure.

Ms. Sodergren explained that the DCA budget office worked with board staff to time task their job duties in order to determine the cost to deliver each service. She also explained that indirect costs (i.e. administrative staff, pro rata, etc.) were factored into the cost.

Ms. Sodergren explained that the DCA budget office is currently working on finalizing the final fee numbers. She added that as soon as the numbers were finalized they would be provided to the board for review.

Board member Veale asked if the board would need to pursue an attorney general augmentation this year. Ms. Sodergren explained that the board would need to request an AG augment this year. Executive officer Herold explained that an AG augment is a one-time increase in the board's funding. In order to secure permanent funding the board will need to pursue a budget change proposal.

The board asked if peaks in license applications due to mergers were accounted for. Ms. Sodergren explained that the DCA budget office used a three year average when collecting their data. The board asked that the analysis be modified to use a five year average when calculating the data.

Board member Wong asked when the last time the board raised its fees. Ms. Herold responded that in 2009 the board raised its fees for the first times since 1987. At that time the board set a minimum and maximum fee range. Ms. Herold explained that in 2014 the board raised its fees to the statutory maximum fees.

Board member Castellblanch asked if the CURES fees provide additional revenue for the board. Ms. Sodergren explained the CURES fees are collected by the board, but the money is then provided to the Department of Justice who maintains and operates the CURES system.

President Gutierrez asked if staff expects the future use of BreEZe to streamline licensing processes; and if so would the fees go down in response to the faster processing times. Ms. Sodergren responded that one of the recommendations in the DCA fee analysis is for the board to complete a review of its fees at least every five years to ensure that the amount charged to applicants and licensees is still appropriate.

The board expressed their dissatisfaction that the draft report provide by the DCA budget office did not include actual fees for the board to review. Ms. Sodergren apologized and explained that the DCA budget office is working on finalizing the fees and added that as soon as they were completed the numbers would be provided to the board. Ms. Sodergren explained despite the actual fees not being finalized, staff wanted the board to review and approve the methodology being used to develop the fees.

The board asked the Greg Lippe, who is a Certified Public Accountant, to work with board staff to review the methodology by the DCA budget office. The board also asked that the President and Vice President review and approve the final fees, once completed by the DCA budget office, before they are included in the board's Sunset Report.

Motion: Delegate to the executive officer, with input from the president and vice president, authority to propose a recommended statutory fee change based on the final

fee audit report from the DCA budget office.

M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler				X
Castellblanch	X			
Gutierrez	X			
Hackworth				X
Law	X			
Lippe	X			
Murphy				X
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

The board recessed for a break at 10:25 a.m. and resumed at 10:35 a.m.

IV. Review of the Sunset Review Process

The board was informed that the Sunset Report is due to the Senate Committee on Business, Professions and Economic Development and the Assembly Committee on Business and Professions on December 1, 2015.

Ms. Herold noted that a hearing will be scheduled in early spring where the president and executive officer will testify before the committees.

V. Review of the Draft Sunset Report

The board reviewed each section of the draft Sunset Report and provided feedback to board staff. Below is a brief summary of the comments and requested modifications made by the board.

Section 1: Background and Description of the Board and Regulated Professions

- Add information on the board’s new Advanced Practice Pharmacists license category.
- Highlight the work the board has been doing to improve the safety of sterile compounded drugs.

- Update the information on the Organizational Development Committee to include their work in monitoring the board's fund.
- Reorganize the section so that the committee rosters come before the committee descriptions.
- Ensure that terms are used consistently throughout the report (i.e. "professional member" vs. pharmacist member").

Section 2: Performance Measures and Customer Satisfaction Surveys

- No comments.

Section 3: Fiscal Information and Staff

- Continue to work with the DCA budget office to finalize the fee analysis.

Section 4: Licensing Programs

- Clarify that the processing times provided in the report reflect the processing time that is within staffs' control, not when an applicant is unresponsive to deficiency notifications.
- Update the language to better explain that there was a spike in applications due to major pharmacy chain mergers.

Section 5: Enforcement Programs

- President Gutierrez noted that currently the board is not meeting the required timeframe to complete investigations. Staff explained that this is due to backlogs with other agencies such as the Attorney General's office. The board asked staff to better highlight that investigations are often prolonged due to outside agencies.

Section 6: Public Information Polices

- No comments.

Section 7: Online Practice Issues

- No comments.

Section 8: Workforce Development and Job Creation

- Review and re-word the statement regarding the shortage of pharmacists as recent data shows that if a shortage exists it is only a slight shortage.

Section 9: Current Issues

- Modify the report to better highlight the board's funding issues.

Section 10: Board Action and Response to Prior Sunset Issues

- Define "Section 800."
- Clarify the section explaining the dramatic reduction of pharmacies acting as wholesalers

- Include general statistics on board’s drug diversion enforcement efforts.
- Note the success the board had had in registering licensees for CURES.
- Add more information to the “Workforce Development” section.
- Highlight the board’s work in developing the Advanced Practice Pharmacist license category.
- Add information on the board’s work in securing translated directions for use.
- Make the “Implementation of a Prescription Label Standard” section easier to read by using bullet points.
- Highlight the important role that drug take-back programs play in public safety.
- Albert asked if we can expand the review process timeline. Giny stated that staff does not want to recommend it –but the board could if it wanted to.

Section 11: New Issues

- No comments.

Board member Wong asked if Ms. Herold could request that the next sunset review be conducted in six years rather than the current four-year schedule. Ms. Herold responded that a request to extend the board’s sunset date would have to come from the board not staff.

Motion: Delegate authority to the executive officer to make changes to the Sunset Report based on the input from the board. Delegate the authority to the president and vice president to approve the final Sunset Report for submittal on December 1, 2015.

M/S: Weisser/Law

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				X
Butler				X
Castellblanch	X			
Gutierrez	X			
Hackworth				X
Law	X			
Lippe	X			
Murphy				X
Sanchez				X
Schaad	X			
Veale	X			
Weisser	X			
Wong	X			

VI. Discussion and Possible Action on Advanced Practice Pharmacist Qualifications

President Gutierrez reported that the SB 493 Implementation Committee met on October 30, 2015.

President Gutierrez reported that she and Mr. Weisser met with Senator Hernandez, the author of SB 493, to discuss the vision of SB 493 and the implementation timeline.

At the request of President Gutierrez, Chairperson Weisser reviewed the changes that had been made to the proposed language based on the discussion at the October 30 committee meeting.

The language reviewed by Chairperson Weisser has been provided below.

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.

Board member Castellblanch asked how the term “assessment” would be defined as used in 1730.2 (b)(2). President Gutierrez explained that the term assessment was used so that programs could determine what type of testing would be most effective.

Chairperson Weisser reviewed section 1730.2 (b)(3) as provided below and asked for input from board members and members of the public regarding the definition of “expert.”

Dr. Castellblanch expressed concern that an expert is defined as anyone who qualifies to teach a class at a college, university or school of pharmacy. He stated that this requirement was far too broad and would not assure that someone is truly an expert qualified to teach advance practice pharmacists.

Chairperson Weisser explained that the staff had added the definition for expert in order to provide clarity to the Office of Administrative Law. However, he agreed with Dr. Castellblanch that the definition provided may be too broad.

Board member Veale noted that the requirement for participants to complete the certification program within one year had been removed. She explained that this would allow flexibility to participants who may be unable to complete a program in one year due to health or work obligations. It was also noted that participants must pass each assessment test before they can move forward in the program and there is a cumulative exam at the end of the course.

Dr. Castellblanch again stated his concern that the definition of expert as provided in section 1730.2 (b)(3) would not ensure that those teaching advance practice pharmacists were truly qualified to do so.

President Gutierrez stated she was concerned that section 1730.2 (b)(3) would allow any healthcare practitioner to teach advanced practice pharmacist courses, including pharmacy technicians.

Jon Roth, CEO of the California Pharmacist’s Association, and Dr. Jason Ausili, representing the National Association of Chain Drug Stores, expressed their support of the language

revised after the October 30 committee meeting.

Mr. Roth stated that CPHA supports section 1730.2 (b)(3) as written as it is consistent with the ACPE requirements for professors in accredited schools of pharmacy.

Board member Veale stated that the language would allow a professor from any university, not just an accredited school of pharmacy, to teach advanced practice pharmacists. Mr. Roth responded that CPHA believes this is acceptable because it would allow professors from nursing or medical schools to teach advanced practice pharmacists.

President Gutierrez asked Mr. Roth if the language should be modified to limit the expert teachers to only healthcare practitioners. Mr. Roth responded that this would be too limiting as some experts may have PhD's in relevant areas of knowledge, but may not be a licensed healthcare practitioners.

After discussion the board decided to define an expert as a person who qualifies to teach at a school of pharmacy recognized by the board.

Additionally the board discussed removing the requirement for the expert to be a healthcare practitioner.

Mr. Roth recommended changing the language of 1730.2 (a) as provided below.

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.

The board agreed with the change to 1730.2 (a) suggested by Mr. Roth.

Dr. Ausili thanked the board for working towards increasing patient access to quality healthcare.

Dr. Lee Meyer, from the California Coalition for the Advancement of Pharmacy, discussed his concern with the use of the term certification program as it may be confused with other certification programs such as those offered by the Board of Pharmacy Specialties.

Chairperson Weisser stated that the board and the SB 493 committee had discussed the use of the term certification at multiple meetings. Laura Freedman added that the certification program as defined in 1730.2 does not supersede the certification programs offered by the Board of Pharmacy Specialties. Ms. Veale also stated that the statute uses the term certification.

Board member Albert Wong asked if advanced practice pharmacists would be compensated for their work. President Gutierrez responded that the regulation language

does not address reimbursement, however as the work force is created and the demand for the services grows the insurance industry will recognize advanced practice pharmacists as providers and will reimburse them for their service.

Ms. Freedman provided the board with the following language based on the discussion.

- (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.

The board agreed that the language provided by Ms. Freedman captured the intent of their discussion.

Ms. Herold noted that the board also decided earlier in the meeting to change the language in 1730.2 (a) 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.

Chairperson Weisser noted that 1730.2 (b) should to be changed as follows.

(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~~ from an organization recognized as a continuing education provider by the Accreditation Council for Pharmacy Education...

The board agreed with Chairperson Weisser’s recommended change.

Doug Barcon, pharmacist, expressed his concern that the certification program as described in 1730.2 does not have a recertification requirement. He also added that he had some concern with the Canadian program that had been discussed at previous SB 493 Committee meetings.

Motion: Modify the language as provided below and move it forward in the regulation process.

Proposed Language

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~~ 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: an advanced 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;~~

(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, 4210 and 4400, Business and Professions Code.
Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

M/S: Lippe/Weisser

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch	x			
Gutierrez	x			
Hackworth				x
Law	x			
Lippe	x			
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

VII. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

A representative of Kaiser Permanente was late to the meeting so President Gutierrez re-opened the floor for public comments on items not on the agenda.

The representative from Kaiser Permanente asked the board to agendaize a discussion on AB 1073. Specifically, the representative asked that the board consider granting waivers for organizations who may not be able to meet the January 1, 2016 implementation date due to programing issues.

President Gutierrez adjourned the meeting at 1:05 p.m.