
California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE
MEETING MINUTES**

DATE: September 10, 2015

LOCATION: DCA Headquarters, First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Stan Weisser, Chair, Professional Member
Albert Wong, Professional Member
Allan Schaad, Professional Member
Ricardo Sanchez, Public Member
Victor Law, Professional Member

COMMITTEE MEMBERS NOT PRESENT: Greg Murphy, Vice-Chair, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Hendricks, Associate Analyst
Laura Freedman, DCA Staff Counsel

Call to Order

Mr. Weisser, chair of the committee, called the meeting to order at 10:04 a.m.

Mr. Weisser welcomed those in attendance. Roll call of the board members present was taken and a quorum of the committee was established.

1. Public Comment for Items Not on the Agenda

No public comments were offered.

2. Pharmacy Technician Requirements Assessment

a. Pharmacy Technician Accreditation Commission (PTAC) Information

Relevant Law

Business and Professions Code Section 4202 establishes the general requirements for an applicant seeking licensure as a pharmacy technician and further requires the board to adopt regulations for the specification of training courses.

Title 16 CCR Section 1793.5 specifies application requirements for a pharmacy technician license.

Title 16 CCR Section 1793.6 provides the requirements for acceptable training courses as one of the pathways to licensure as a pharmacy technician licensure.

Background

Current law creates several pathways to licensure as a pharmacy technician, including the completion of a training program that meets one of the following criteria:

- Training program is accredited by the American Society of Health-System Pharmacists (ASHP)
- Training program is provided by a branch of the federal armed services
- Course provides a training period of at least 240 hours of instruction covering specified areas of pharmacy practice.

Committee Meeting Discussion

The committee heard a presentation by Dr. Peter Vlasses, Executive Director, ACPE, on the Pharmacy Technician Accreditation Commission. As part of the presentation, Dr. Vlasses advised the committee that in 2013 the New Pharmacy Technician Accreditation Commission (PTAC) launched. The committee was advised that the commission is collaboration between (ASHP) and the Accreditation Council for Pharmacy Education (ACPE) and is tasked with assuring and advancing the quality of pharmacy technician education and training programs. A copy of the presentation is provided as an attachment to these minutes.

The committee asked about background checks for applicants and was advised that background checks are completed in advance of the experiential component of the training program. The committee expressed concern with the timing of the background check as it occurs after program costs have been incurred by the student.

In response to queries from the committee members, Dr. Vlasses explained that the ACPE has established continuing education courses for pharmacy technicians and that training programs encompass language proficiency.

The committee commented that pharmacy technicians obtain their license too easily and discussed the need to increase the requirements for licensure.

Dr. Vlasses emphasized that there is not a common vision among various states on how to regulate pharmacy technicians.

Public Comment:

Steve Gray, representing Kaiser, asked about the ACPE's involvement with other national organizations and was advised that ACPE has given presentations to various stakeholders. Dr. Vlasses commented that ACPE has heard some concerns from community pharmacy representatives expressing concerns about the proposed changes.

A representative of California Society of Hospital Pharmacists spoke in support of two separate classifications of pharmacy technicians.

The committee also heard members of the public expressing concerns about over education and that education requirements need to remain within the scope of the pharmacy technician.

The committee did not take action on this item.

b. National Changes to the Pharmacy Technician Certification Board (PTCB)

Relevant Law

Business and Professions Code Section 4202 establishes the general requirements for an applicant seeking licensure as a pharmacy technician.

Committee Meeting Discussion

The committee discussed the several pathways to licensure as a pharmacy technician including certification by the Pharmacy Technician Certification Board (PTCB).

The committee briefly discussed changes to the Pharmacy Technician Certification Board (PTCB) certification program that are and will occur between 2014 and 2020. It was noted that the changes are designed to advance pharmacy technician qualifications by elevating PTCB's standards for certification and recertification.

The committee did not take action on this item.

3. Discussion of Pharmacy Technician Licensure Requirements and Practice

Relevant Law

Business and Professions Code Section 4038 defines a pharmacy technician as an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified.

Business and Professions Code Section 4202 establishes the general requirements for an applicant seeking licensure as a pharmacy technician.

Title 16 CCR Section 1793 provides additional context to the definition of a pharmacy technician including the duties that a licensed pharmacy technician are authorized to perform (packaging, manipulative, repetitive or other nondiscretionary tasks related to the processing of a prescription in a pharmacy) under the direct supervision and control of a pharmacist.

Title 16 CCR Section 1793.2 further details nondiscretionary tasks including:

- Removing the drug or drugs from stock
- Counting, pouring, or mixing pharmaceuticals
- Placing the product into a container
- Affixing the label or labels to the container
- Packaging and repackaging

Title 16 CCR Section 1793.5 provides the application requirements for a pharmacy technician license including:

- Identifying information
- Description of qualifications and supporting documentation
- Criminal background check
- Self-Query from the National Practitioner Data Bank

Title 16 CCR Section 1793.6 provides the requirements for acceptable training courses as one of the pathways to licensure as a pharmacy technician licensure.

- Training program accredited by the American Society of Health-System Pharmacists (ASHP)
- Training program provided by a branch of the federal armed services
- Course that provides training period of at least 240 hours of instruction covering specified areas of pharmacy practice.

Title 16 CCR Section 1793.7 establishes the requirements for pharmacies employing pharmacy technicians. The section includes provisions that the supervising pharmacist is fully aware of all activities of a pharmacy technician under his or her direct supervision. Further, this section provides that a pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk to patients. This section also establishes the pharmacist-to-pharmacy technician ratio.

Title 16 CCR Section 1793.8 establishes the “technician check technician” program in acute care inpatient hospital pharmacy settings.

Committee Meeting Discussion

As is the case with prior Licensing Committee meetings, the committee discussed different facets of the pharmacy technician program. Most recently, during the April 2015 Board Meeting, the board expressed their desire to raise the bar to qualify for licensure as a pharmacy technician. The board also expressed concern with the training programs that are accepting students with criminal backgrounds, who will likely not become licensed. The board also requested that the committee consider the possibility of creating different types of pharmacy technician licensure (i.e., hospital, compounding, community, etc.).

Committee member Law commented that the profession is changing and the educational requirements for pharmacists have changed, yet the technician requirements have not changed.

An initial motion was offered by committee member Law to raise the education requirements to a two-year associate degree or a minimum of 60 hours of post-high school college credit and completion of a PTCB accredited training program. The motion was seconded by Albert Wong.

Committee member Schaad spoke in opposition to the motion noting that the cost of education versus the dollar reward would not exist. Member Schaad agreed that the board needs to increase the value of the license.

The committee briefly discussed if there should be two types of pharmacy technician classifications.

Mr. Law clarified his earlier motion to include, in addition to the current high school graduation, a requirement to also complete an associate (AA) degree or 60 units (post-high school) of college, as well as completion of a pharmacy technician program that is accredited by PTAC. In addition the applicant would be required to take and pass the PTCB exam. A phased-in approach would be used to facilitate the changes in the licensure requirements.

Public Comment

Steve Gray sought clarification from the committee on the problem it was trying to solve and how the proposal would solve the problem. Dr. Gray suggested that the board should consider a law and ethics course to address the concerns of the committee. Dr. Gray also spoke in support of a multilevel pharmacy technician program.

Jeannie Li agreed that pharmacy technicians need to have more knowledge, but indicated that not all pharmacy technician applicants cannot afford to go to college.

Mr. Pat Waylen of the National HealthCare Association (NHA) expressed concern about PTCB certification. He indicated that the wages of pharmacy technicians will not offset the licensing requirements.

The committee also heard a request that the committee consider allowing military training in lieu of the proposed licensure requirements.

Committee Action

MOTION: Recommend that the board approve changes to Pharmacy Technician as follows:

Recommend that the board approve changes to Business and Professions Code Section 4202 to require that for all new applicants seeking licensure as a pharmacy technician to meet one of the following educational requirements:

1. Be required to have two years (60 college credits) or an associate degree, and successful completion of a pharmacy technician training program accredited by the PCAB, and be PTCB certified at the time of application
2. Military training
3. Graduation from a school of pharmacy recognized by the board.

M/S: Law/Wong

Support: 3 Oppose: 1 Abstain: 0

Mr. Sanchez was not present during the vote.

4. North American Pharmacist Licensure Examination (NAPLEX) Changes

Relevant Law

Business and Professions Code Section 4200 establishes the requirements for pharmacist licensure, including a passing score on the NAPLEX examination.

Committee Meeting Discussion

The committee briefly discussed changes to the NAPLEX examination. Specifically, in November 2015 a new NAPLEX competency statement and a revised passing standard will be implemented. Further, the NAPLEX will make a progressive transition to a new administration model in 2016 after which the NAPLEX will increase in length from 185 items to 250 items. Additional changes to the NAPLEX scoring are being evaluated as well; however, there is no proposal yet for state boards of pharmacy to consider.

There was no public comment on this item and the committee did not take action on this item.

5. Accreditation Council for Pharmacy Education (ACPE) Updates of Curriculum Requirements

Background

The Accreditation Council for Pharmacy Education (ACPE) is the national agency for the accreditation of professional degree programs in pharmacy. During its January 2015 meeting the ACPE Board of Directions announced its approval of new *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor in Pharmacy Degree ("Standards 2016")*. In its press release the ACPE noted the following:

"Standards 2016 are employed for quality assurance so graduates of pharmacy education programs are practice-ready and team-ready and therefore, prepared to directly provide patient care in collaboration with other healthcare providers. Standards 2016 articulate the expectations of ACPE, the academy, the practice communication, and the U.S. Department of Education and are solidly based on evidence and experience."

The new standards and guidance will become effective July 1, 2016 and will be used in accreditation reviews beginning September 2016.

Committee Meeting Discussion

The committee heard a presentation from Dr. Peter Vlasser, Executive Director, ACPE, on the new standards. Mr. Weisser encouraged committee members to participate in an ACPE accreditation survey. A copy of Dr. Vlasses' presentation is attached to these minutes.

The committee did not take action on this item, but was advised that members will receive information on the accreditation status of schools.

6. Implementation of Pharmacy Curriculum Outcomes Assessment (PCOA) to be used by Schools of Pharmacy

Background

On June 23, 2015, the NABP released updated information about the status of implementation of the Pharmacy Curriculum Outcomes Assessment (PCOA) to all schools and colleges of pharmacy. As part of its release, the NABP provided information about the administration of the PCOA and noted that the assessment tool provide a valid and reliable assessment of student competency in four areas.

Committee Meeting Discussion

The committee briefly discussed the assessment tool and was advised that PCOA assessments for all students will start in the spring of 2016. Schools will be provided scores for their students as well as the national average for scores.

The committee did not take action on this item.

7. Competency Committee Report

Committee Meeting Discussion

Members were advised that the competency committee held its annual meeting in August to discuss examination development as well as to begin the transition to the new content outline of the examination. The committee was reminded that it is anticipated that the new content outline will go into effect in early 2016.

There was no additional committee or public comment. The committee did not take action on this item.

8. Advanced Practice Pharmacist (APP) Licensure (As Established in SB 493) - - Discussion on Qualifying Methods

Committee Meeting Discussion

The committee heard a presentation from John Roth and Brian Warren representing the California Pharmacists Association regarding a possible alternative qualification route for advance practice certification, including the framework that would establish requirements for certification programs, that would then not require the board to independently approve all programs. The presentation included draft regulation language that included suggested revisions to Title 16 California Code of Regulations Section 1730. As part of the proposal, it was suggested that a definition of "certification" could be included in the regulation to clear up any confusion about what would satisfy the statutory requirements. The presenters indicated that definitions are necessary because there is no legal definition of "certificate program" versus "certification program." The presenters included that as the sponsors of SB 493, the intent of the legislation was to create multiple pathways to licensure as an APP for meeting two of the three qualification methods.

Ms. Herold requested that the presenters from CPhA request a presentation on the Canadian practice environment demonstration as it may be helpful for members. This would allow the board to see the component being offered and was advised that the Canadian model may be helpful, but that the intent of CPhA was to offer an alternative model.

Member Law asked for guidance on what “recognized by the board” means and was advised that the entire statute must be considered to ensure the context is not missed. As part of this, the board would need to consider what ACPE provides. Counsel advised the members that the statute requires one of the pathways to licensure to include a certification program.

Dr. Vlasses indicated that the ACPE standards do not reference certification programs or certificate programs, rather practice based continuing education activity. Dr. Vlasses reminded the committee that ACPE accredits a provider, they do not attest to the individual completing a program, rather the provider is responsible for doing that. Dr. Vlasses noted that a provider that wants to design a higher model program is free to do so, but not every provider would be required to do so. Dr. Vlasses expressed some of the current challenges with integrating in the CPhA recommendation as it relates to ACPE programs. Dr. Vlasses indicated that ACPE does not currently have the capacity to assess programs being described by CPhA.

Counsel noted that is a concern because of the requirements in the statute. Counsel noted that there is a sharp distinction between a certification standard versus a certificate program. Counsel noted that the components of the different programs vary.

Public Comment

The committee heard public comment expressing concern about the need to maintain the integrity of certification programs and concerns with the content of some of the proposed changes offered during the presentation.

The committee did not take action on this item, but indicated that a workgroup may be appropriate to further discuss the issue. A copy of the presentation is provided as an addendum to these minutes.

9. Pending Regulations Related to Implementation of SB 493

Committee Meeting Discussion

The committee was provided with an update on a number of regulations that are in various stages of promulgation to implement the provisions of Senate Bill 493.

Waiting to be noticed for the initial 45-day comment period:

- Travel medications

Undergoing the initial 45-day comment period:

- APP licensure requirements (comment period concludes September 14)
- Vaccinations (comment period concludes September 7)

Undergoing 15-day comment period:

- Permanent adoption of Naloxone protocol

Board adopted and undergoing Administration review:

- Nicotine replacement products

Needing return to Medical Board for approval:

- Hormonal contraception protocol

Currently in effect:

- Emergency adoption of naloxone protocol

The committee did not take action on this item.

10. Pharmacy Application Requirements

Committee Meeting Discussion

Senior Manager Carolyn Klein provided a presentation on the requirements for licensure as a pharmacy. Ms. Klein discussed the application process as well as common deficiencies. A copy of the presentation is provided as an addendum to these minutes.

11. Status of Implementation of Legislation (AB 2605) Regarding Third-Party Logistics Providers

Background

Effective January 1, 2015, the board implemented licensing Third-Party Logistics Providers in state and out of state as well as Designated Representatives-3PL based on the recent change in federal legislation that expressly states 3PLs cannot be licensed as wholesalers but as a unique licensure class.

Current Status

In December 2014, the board received its first nonresident Third-Party Logistics Provider application. Staff initially processed the applications received for Third-Party Logistics Providers and Designated Representative – 3PL manually during the programming of the licensing category in the Applicant Tracking System (ATS) and the Consumer Affairs System (CAS). The board issued its first nonresident Third-Party Logistics Provider and Designated Representative – 3PL licenses in February 2015. The board issued temporary license numbers to these licensees until the department completed its programming of establishing these license types in ATS and CAS, which was fully migrated in May 2015.

As of July 31, 2015, the board issued the following licenses:

45	Designated Representative-3PL
3	Third-Party Logistics Providers
10	Nonresident Third-Party Logistics Providers

The licensing statistics provided in the meeting materials contain additional statistical information.

The board is continuing to educate applicants and other states about the requirements for these three new license categories. On April 17, 2015, the board issued a subscriber alert on “Guidance for Third-Party Logistics Providers Currently Licensed as Drug Wholesalers” in order inform consumers and licensees of the new law and to provide guidance on the licensure requirements.

12. Licensing Statistics

Licensing Statistics for July 1, 2015 – July 31, 2015

The committee reviewed and discussed various licensing statistics and also discussed the current processing times for applicants. Chairman Weisser provided an overview of the board's license population.

At the board's direction staff has started tracking and reporting on the numbers of calls and emails responded to from the licensing programs. It was noted that staff has experienced challenges retrieving information from its existing computer system, but has been working with the department to develop a more robust reporting tool. Staff has been advised that the development of new reports may be available in December.

The committee was provided with general processing times by license type, which reflect the time an application is received by the board through the time either a deficiency letter is issued or a license is issued. If an incomplete application is received, there will be additional processing time involved.

Individual Application Type	Number of Days
Pharmacist Exam	40
Pharmacist Initial License	7
Pharmacy Technician	35
Intern Pharmacist	20
Designated Representative	22
Designated Representative – 3PL	12

Site Application Type	Number of Days
Pharmacy	29
Nonresident Pharmacy	40
Sterile Compounding	17
Nonresident Sterile Compounding	15
Hospital	15
Clinic	40
Wholesaler	22
Nonresident Wholesaler	29
Third-Party Logistics Provider	15
Nonresident Third-Party Logistics Provider	15

Staff also advised the committee that the processing time for evaluating deficiency mail is averaging between 35 days to 13 days, depending on the license type.

13. Request for a Waiver Under California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Sections 4128 et seq. Requests Are from Three Hospitals

The committee did not discuss this item.

14. Discussion on Waivers Previously Granted by the Board Pursuant to Business and Professions Code Section 4118 Relating to Centralized Hospital Packaging Licensing

Committee Discussion

The committee discussed the initial legislation for Centralized Hospital Packaging Licensing including requirements that could not be satisfied because of technology implementation. In recognition of the benefits to patient care such a license would offer to patients admitted to hospitals, the board has considered and granted several waiver requests to exempt certain elements of the technology requirements if the elements could otherwise be achieved. These waivers have been granted for a five-year period.

The committee was advised that because of enactment of Assembly Bill 486 (Bonilla) waivers are no longer required. The committee was advised that AB 486 amended the language in section 4028.4 to require that any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be "machine readable" at the inpatient's bedside with software that shall permit the health care practitioner to ensure that, before a medication is administered to the inpatient, it is the right medication, for the right inpatient, in the right dose, and being administered via the right route.

Committee Recommendation

Recommend to the board to direct staff to prepare correspondence advising appropriate parties that because of changes in the law, the waiver is no longer necessary. The committee and board may choose to also include as part of this correspondence that we encourage development in technology to address the current limitations and to ultimately achieve all of the bar coding requirements originally envisioned in AB 377 (Solorio, Chapter 687, Statutes of 2012).

M/S: Law/Wong

Support: 4

Oppose: 0

Abstain: 0

15. Future Committee Meeting Dates for 2016

The following dates have been established for future meetings:

January 6, 2016

March 30, 2016

May 26, 2016

September 21, 2016

The meeting adjourned the meeting at 3:28 p.m.