



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
LICENSING COMMITTEE MEETING
MINUTES**

DATE: April 7, 2015

LOCATION: Department of Consumer Affairs
1st Floor Hearing Room
1625 North Market Blvd. Ste. N-219
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Deborah Veale, RPh, Committee Chair
Stanley Weisser, RPh
Albert Wong, PharmD.
Victor Law, RPh
Lavanza Butler, RPh
Ricardo Sanchez, Public Member

COMMITTEE MEMBERS

NOT PRESENT:

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Hendricks, Staff Analyst
Debi Mitchel, Staff Manager
Laura Freedman, DCA Legal Counsel

Call to Order

Chairperson Veale called the meeting to order at 9:06 a.m.

Chairperson Veale conducted a roll call. Committee members present: Stanley Weisser, Albert Wong, Victor Law, Ricardo Sanchez and Lavanza Butler.

1. Status of Implementation of Recently Enacted Legislation Impacting Licensing Programs for the Board

Chairperson Veale explained that AB 2605 was board sponsored to ensure the appropriate and continued regulation over third party logistics providers. Specifically, the measure creates three new licensing categories for the board as well as establishes the requirements for application, licensure and renewal. The specific new licensing classifications include:

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

Chairperson Veale reported that during the January Board Meeting, members were advised that the freeze exemption was approved and board staff is working with the department to identify the necessary programming requirements. At that time the department estimated that programming changes would be completed by April 1, 2015, but committed to completing prior to that date if possible. Chairperson Veale noted that draft applications and instructions were submitted for legal review in December.

Chairperson Veale stated that unfortunately because of delays in finalizing the business requirements, the programming necessary to fully implement this program has been delayed. Chairperson Veale noted that there is no new estimated date from the department, but work continues. She added that most recently staff started testing in one of the legacy environments and is working with the department to identify changes.

Chairperson Veale reported that board staff posted the approved applications in early February on the board's website and sent out a subscriber alert advising that the applications were available. In addition, the most recent issue of the *Script* includes an article. Chairperson Veale stated that staff has developed a guidance document designed to highlight the steps licensees and applicants must take to secure compliance with the new law.

Chairperson Veale explained that board staff has developed temporary workaround solutions to issue licenses. The first licenses were issued in February, but the board has not received the volume of applications we would have expected based upon the inquiries we are receiving.

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

a) SB 1159 (Lara) Professions and Vocations: License Applicants: Individual Tax Identification Number

Chairperson Veale explained that this legislation requires the board on or before January 1, 2016, to accept either a social security number or an individual tax identification number as a condition of licensure. She noted that prior to this legislation, the board could only collect a social security number.

Chairperson Veale reported that board staff has undertaken revisions of several of the application forms and instructions. Further, as the pharmacy technician application is incorporated by reference in regulation, implementation of this update needs to occur via regulation. Chairperson Veale explained that the formal rulemaking process was initiated on February 20, 2015 and runs through April 6, 2015. Absent any negative comments, the rulemaking will be brought back to the board at the April Board Meeting for final adoption. She noted that board staff does not anticipate any challenges with meeting the January 1, 2016, legislative mandate.

Chairperson Veale explained that in addition board staff is evaluating additional changes that may need to be made to facilitate full implementation for the pharmacist examination administration. This review should be completed no later than June 30, 2015, and an update provided during the July Board Meeting.

b) SB 1226 Veterans: Professional Licensing

Chairperson Veale reported that this measure requires the board, on or after July 1, 2016, to expedite the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the Armed Forces and was honorably discharged. She added that implementation of this provision will require updating application and instruction forms.

Chairperson Veale stated that this legislation takes effect on July 1, 2016, so implementation efforts are not yet underway. The DCA has advised all boards and bureaus within the department that no modifications will be made to legacy computer systems. Chairperson Veale explained that as such any implementation efforts necessary will require manual workarounds by the board to implement.

The committee briefly discussed the process by which the board currently expedites applications for military spouses.

c) SB 1466 (Omnibus) Business and Professions

Chairperson Veale reported that SB 1466 contained two provisions that impact board licensing programs. The first amends the definition of a correctional facility. Implementation of this provision will require updating application and instruction forms as well as securing changes to the existing licensing and application system. Chairperson Veale

explained that the board will need to secure a freeze exemption. She noted that board staff will work with the department to secure the necessary changes.

Chairperson Veale stated that SB 1466 also changed the requirements for an applicant designated representative to require that the individual be at least 18 years of age. She added that this provision only requires a procedural update.

Chairperson Veale reported that board staff has initiated implementation efforts including creations of new application forms for the licensed correctional facility license category as well as revision of the designated representative application forms. Chairperson Veale stated that board staff is preparing the freeze exemption request as the first step to implementing the necessary changes in our legacy systems.

Chairperson Veale reported that the changes to the designated representative application are currently under review and should be finalized in the next few weeks.

The committee discussed the scope of the changes that will be necessary to implement that provisions for the Licensed Correctional Facility and converting them from government owned to private ownership. In addition, Ms. Herold indicated that there are larger issues related to Licensed Correctional Facility regulations, including their unique operational needs and the use of automated delivery devices.

2. Department of Education's Acceptance of Additional Tests for Fulfillment of General Educational Development Certificate Equivalency

Chairperson Veale explained that Business and Professions Code Section 4202 establishes the requirements for licensure as a pharmacy technician including the provision that an application be either a high school graduate or possess a general education development certificate equivalent.

Chairperson Veale reported that board staff was recently advised that the Department of Education has recently approved two additional exams that will satisfy our requirements. Below is a list of the three exams:

- GED – General Education Development Test
- HiSET – High School Equivalency Test
- TASC – Test Assessing Secondary Completion

Chairperson Veale concluded that board staff is in the process of updating the instruction sheets to incorporate reference to these additional examinations.

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

3. Status of Board Sponsored Legislation to Change the Documentation Requirements for Pharmacy Practice Experience, (SB 590, Stone)

Chairperson Veale reported that during its October 2014 Meeting, the board voted to pursue a legislative change to streamline the documentation required for pharmacist practice experience for students that graduate after January 1, 2016 from an ACPE school of pharmacy or a school of pharmacy recognized by the board.

Chairperson Veale stated that Senator Jeff Stone is authoring this bill for the board. The provisions are contained in SB 590, which was introduced on February 26, 2015.

Chairperson Veale reported that board staff received concerns from California Pharmacy Council (a group representing the California schools of pharmacy, associations and the board's executive officer) regarding some of the language contained in the bill. Chairperson Veale explained that based on discussions, staff has requested that clarifying language be amended into the bill to address the comments of the California Pharmacy Council.

Ms. Sodergren explained that many of the proposed amendments were technical in nature. Ms. Sodergren added that the language was modified to clarify that if a student graduated from a school of pharmacy that is accredited by the ACPE or the board they do not have to meet the requirements in subdivision (a) and (b).

President Weisser noted that this section applies to interns, but in the language it says that they must gain experience as a pharmacist (see below).

(3) This pharmacy practice experience shall include 900 hours of pharmacy practice experience in a pharmacy as a pharmacist

Ms. Sodergren clarified that another provision states that an intern can do anything that a pharmacist can do as long as it is under the supervision of a pharmacist.

The committee also discussed the pathway to licensure for out of state pharmacists. The committee acknowledged that this proposed legislation does not change the existing requirements for out of state applicants and no action was taken.

4. NAPLEX Exam Content Outline Updated

Chairperson Veale reported that the NABP recently completed its process to ensure its exam includes the most current standards for safe and effective pharmacy practice. As a result, the NABP has released its new Competency Statements which will go into effect on November 1, 2015. Chairperson Veale reported that this revised competency statement will be evaluated by the board's competency committee as part of its work to evaluate the board's current content outline for the CPJE.

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

5. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chairperson Veale reported that effective February 26, 2015, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

Chairperson Veale explained that this means that there is currently a delay in the release of all CPJE examination scores. This process is done periodically to ensure the reliability of the examination. She added that the board expects to release the scores in May 2015, however, will release exam scores more quickly if the review is completed.

Examination Development

Chairperson Veale reported that the Competency Committee workgroups are meeting several times this year to continue examination development activities. In addition, the committee has completed its review of the revised NAPLEX content outline as a precursor to updating the CPJE content outline. Chairperson Veale concluded that it is anticipated that a recommended revised content outline will be ready for board review and consideration during its October 2015 Board Meeting.

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

6. Review of Statistics Relating to Pharmacy Technician Application Denials

Chairperson Veale stated that during the July 2014 Board Meeting, board members requested further discussion on the basis for denials of pharmacy technician applications. This issue was referred to the Licensing Committee. She explained that as this is the first committee meeting since that discussion, this will be the first opportunity to review this information.

Chairperson Veale reported that in 2014, the board denied 45 pharmacy technician applications. Of those applicants, 73% qualified by completing a technician training program, 18% qualified through certification by the PTCB and 9% earned an associated degree in pharmacy technology.

Chairperson Veale explained that the primary bases for denials include:

- Theft/Forgery, Identify Theft, Fraud
- Multiple DUIs and/or combinations with other violations
- Vandalism, Disorderly Conduct, Obstruction
- Drug Related (possession, under the influence, selling)

The committee discussed if the board should consider raising the qualification requirements for pharmacy technician applicants, noting that the board could focus efforts on technician training programs as a qualifying method or require one hour of drug awareness education either as a condition of licensure or renewal.

The committee commented that there may be value in considering if pharmacy technicians should be encouraged, or required, to continue their education similar to the requirement for pharmacists' renewal.

The committee requested that at a future meeting the committee be provided with information on disciplinary cases for pharmacy technicians, including the qualification methods for their licensure.

The committee also asked that at a future meeting they evaluate the duties of a pharmacy technician and determine if the requirements for licensure are proportionate to their level of responsibility in a pharmacy.

Tony Wong, pharmacist, encouraged the committee to consider continuing education and/or a certification requirement for pharmacy technicians.

The committee again stated the importance of discussing this item at a future meeting. They asked that the future agenda also include more discussion on training, curriculum of technician training programs (including if the programs require a background check as a condition of enrollment) as well as statistics on application denials by the board.

7. Common Deficiencies for Pharmacy Technician Applications

Chairperson Veale reported that the board has processed 4,449 pharmacy technician that were received since July 1, 2014. Of those processed 2,392 (54%) were deficient upon initial review.

Chairperson Veale explained that over the years the board has tried various approaches to reduce the deficiency rate, including updating the application form and instructions to provide more specificity. Regrettably, with these efforts, the deficiency rate is still very high.

Chairperson Veale reported that the most common deficiencies include the following:

- Application not completed in its entirety, including missing signatures and dates, former names, etc.
- Training program affidavit (used to confirm completion of the training program) being completed before the applicant completes the training program or not being completed in its entirety.

- Livescan submission, high school diploma and self-query report provided under different names. Including the AKA on the application would resolve many of these.

Mr. Law asked if the application could be submitted online. Ms. Sodergren responded that the application can be filled out online but it must be printed, signed and mailed to the board.

Ms. Sodergren reported that board staff will be developing a fact sheet that will be included as part of the application materials to assist with educating applicants. She noted that the board's public information officer will also be reviewing the fact sheet and instructions to make them easier for applicants to understand.

8. Common Deficiencies for Pharmacy Applications

Chairperson Veale explained that as the board has discussed recently, the processing times for pharmacy applications is beyond the desired processing time of less than 60 days.

Chairperson Veale reported that applications are currently processed within about 75 days of receipt. While staff is working diligently to reduce this processing time, we have also identified that a large percentage of the applications we receive are deficient upon initial submission which results in further delays in issuing the license.

Chairperson Veale provided a list of common deficiencies:

1. A copy of the approved wholesale credit application is not provided. Many applicants provide a copy of the approval letter, which is not the same thing.
2. The lease is missing information, term of the lease, etc.
3. A Fictitious Name Statement is not provided when the pharmacy is using a "doing business as."
4. Forms are not complete in their entirety.

Ms. Sodergren stated that there is a lot of frustration with the board's current processing times. In an effort to address the frustration, the board is working to educate the public on how to submit a completed application to avoid delays due to deficiencies. She reported that the board will be presenting at the CPhA annual meeting on how to complete the application correctly.

Ms. Sodergren commented that applicants often skip the instructions and begin filling out the application which often leads to incomplete applications. She noted that the instructions will also be reviewed by the board's public information officer for clarity.

Dr. Wong asked how long it takes board staff to respond once a deficient item is received. Ms. Sodergren responded that it takes three to four weeks for staff to process the deficient

items. She added that the hope is by educating the public on filling out a completed application the deficiencies can be avoided.

Ms. Herold reported that the structure of pharmacy ownership has become much more complicated with many layers of limited liability companies and noted that the board often uncovers hidden ownership.

Ms. Sodergren stated that the board could create a video for the board's website on the application process. The committee expressed their support of creating a video for the board's website.

Megan Matix from the California Pharmacist's Association asked what the board's current processing times is for pharmacy applications. Ms. Herold responded that applicants should hear from the board in 60 days of the receipt of their application. She added that if applicants have had no contact with the board in 75 days CPHA can reach out to her for assistance. Ms. Matix offered to post a video and information on their web site.

9. Licensing Statistics

Chairperson Veale reported that following licensing statistics:

Licensing Statistics for July 1, 2014 – February 28, 2015

As of February 28, 2015, the board had 141,998 total licensees, including 45,255 pharmacists and 74,409 pharmacy technicians and 7,334 pharmacies, hospitals and exempt hospitals.

During the first eight months of the fiscal year, the board has issued 10,559 licenses including:

- 1,586 pharmacist licenses
- 1,963 intern licenses
- 5,452 pharmacy technician licenses
- 1,151 pharmacy licenses

Ms. Veale noted that the entire licensing statistics were provided in the meeting materials.

Mr. Law noted the spike of pharmacy licenses issued in one month. Ms. Sodergren explained that there was a change of ownership in a large chain.

President Weisser stated that the board should be aware of the challenges it creates for board staff when a large chain has a change of ownership.

Dr. Wong stated that the board should consider charging an expedite fee for those who want to pay more for their application to be process quicker. Ms. Herold stated that this

would need to go to the legislature and she would be hesitant to highlight the fact the board cannot process applications in a timely manner.

Dr. Wong asked if the board could hire temporary staff when the workload spikes. Ms. Herold responded that because of the analytical detail that is required to process the application, hiring new staff is not ideal.

Mr. Law noted that he was surprised that there were only two centralized packaging licenses issued. Ms. Herold explained some of the current challenges with centralized packaging licensure.

10. Future Committee Meeting Dates for 2015

Ms. Veal reported that the next committee meetings would be held June 17, 2015 and September 10, 2015 in Sacramento.

11. Public Comment for Items Not on the Agenda, Matters for Future Meetings

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

Ms. Veale adjourned the meeting at 10:52 a.m.