



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
MINUTES**

DATE: March 19, 2014

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, Ca 95834

BOARD MEMBERS

PRESENT: Deborah Veale, RPh
Victor Law, RPh
Albert Wong, PharmD
Lavanza Butler, PharmD

**BOARD MEMBERS
NOT PRESENT:** Gregory Murphy, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Michael Santiago, DCA Staff Counsel
Debbie Damoth, SSM1
Laura Hendricks, Staff Analyst

CALL TO ORDER

Chair Veale called the meeting to order at 9:05 a.m.

1. Presentation on the Duties and Operations of Third Party Logistic Providers in the Pharmaceutical Supply Chain

In the newly enacted U.S. Federal Drug Quality and Security Act (enacted November 27, 2013) there are provisions that require that states enact over the next two years appropriate regulation requirements for wholesalers and third party logistic providers. At the January 2014 Board Meeting, the board approved proposed legislation for 2014 that would allow the board

to create a new licensure category of third party logistics providers, and would insert 3PLs into existing requirements in Pharmacy Law that establish requirements for wholesalers and often other board licensees.

Representatives from International Warehouse Logistics Association, UPS Supply Chain Solutions, Exel and Saddle Creek Logistics provided the committee with a presentation on third party logistic providers. Below is a brief overview of the presentation. The entire presentation can be viewed immediately following these meeting minutes.

- 3PLs do not:
 - manufacture the product
 - take title to or own the product
 - engage in the sale of the product
 - arrange for the sale of the product
 - provide care and custody
 - make any decisions about the quality or effectiveness of a product or required storage conditions, nor determine product status or disposition
- 3PLs DO prepare the product for shipment at the direction of the owner
- How the 3PL Differs from the Wholesaler:
 - 3PLs do not manufacture, buy, sell or distribute products.
 - 3PLs do not purchase and then resell products like a wholesaler
 - 3PLs are an extension of manufacturers' operations
 - 3PLs derive their revenue from labor and non-product support services solely dedicated to the movement of products.
 - 3PLs pricing is not predicated on the value of the product, but on the space and labor time it takes to handle/process the movement of the product.
 - 3PLs do not make sales decisions, but often provide labor and support to drive decisions made by the customer (e.g. the manufacturer).
- In the opinion of the presenters there is little potential for diversion from a 3PL facility.
- The 3PL sector is eager to work with California and FDA in the development of national licensing standards for 3PLs with the goal of expeditiously developing and implementing a 3PL licensure framework and standards.

Chair Veale commented that the board's main concern is the potential for diversion in the supply chain. Ms. Herold added that losses often occur during the transport of drugs due to their high value. It was noted by the presenters that the 3PL facility manager is held responsible for any losses by the manufacturer who expect no shrinkage from their 3PLs. It was reported additionally that in the event of a cargo theft, the manufacturers expect the 3PLs to be a part of investigation.

Ms. Herold asked if the DEA issues a 3PL with a permit. It was confirmed that the DEA does issue a permit after inspecting the security and controls.

Ms. Herold commented that the entire supply chain is licensed except 3PLs, the board views this as extremely problematic as it creates a potential for diversion in this unlicensed area.

Ms. Herold asked if 3PLs are involved in the return of drugs in the case of a recall. It was confirmed that 3PLs do assist in the return inventory to manufacturers, however it is not a regular occurrence.

Dr. Wong asked how 3PLs prevent a theft from occurring between the time a driver picks up a shipment and it is delivered to the customer. The presenters responded that while the manufactures actually pick who the carriers will be, the 3PLs ensure that the carriers have security policies in place and have conducted background checks for their drivers.

Chair Veale concluded that the board will continue to work with 3PLs in order to develop the best language for California.

Dr. Steve Gray, representing CSHP, noted that large health systems also deal with 3PLs on the receiving end and offered to help the board in developing language.

2. Presentation by Peter Vlasses, PharmD, Executive Director, Accreditation Council for Pharmacy Education (ACPE), on an Update of Major ACPE Projects

Dr. Vlasses provided an update on the major activities of the Accreditation Council for Pharmacy Education and briefly described the ACPE accreditation process for schools of pharmacy. The entire presentation can be viewed immediately following these meeting minutes.

Mr. Law asked how many new pharmacy schools will be opening in California. Dr. Vlasses indicated that seven schools are in the accreditation application process.

The committee asked if students are aware if a school is in “pre-candidate” status when they apply. Dr. Vlasses responded that all students sign an acknowledgement when they apply to a school that is in “pre-candidate” status.

3. Presentation by Peter Vlasses, PharmD, Executive Director, Accreditation Council for Pharmacy Education (ACPE), on Requirements for Intern Experience in ACPE-Approved School of Pharmacy Curricula

The Licensing Committee was asked by the board to review the requirements for reporting intern hours experience required of students enrolled in ACPE-approved schools of pharmacy. Dr. Vlasses provided a presentation on ACPE’s requirements for intern experience in ACPE-approved schools of pharmacy. Dr. Vlasses highlighted that ACPE accredited schools pharmacy curricula must contain “real world” pharmacy experience. Dr. Vlasses reviewed the process by which students shadow pharmacists and work in

pharmacies to gain hands on practice experience. The entire presentation can be viewed immediately following these meeting minutes.

Mr. Law asked if ACPE pre-screens and continually evaluates preceptors. Dr. Vlasses confirmed that there is an extensive screening and evaluation process in place for all preceptors.

Mr. Law asked if students receive any instruction on drug and alcohol abuse. Dr. Vlasses responded that most pharmacy schools cover drug and alcohol abuse. Dr. Wong noted that perhaps pharmacy schools need to emphasize the dangers more as the board sees numerous cases involving DUIs and drug diversion.

Ms. Butler asked to confirm that ACPE accredited schools ensure that upon graduation students have gained adequate, hands-on knowledge of all areas of pharmacy (community, hospital, acute care, etc.) Dr. Vlasses confirmed pharmacy schools design their curricula so that students enter the field as generalist pharmacy practitioners.

Dr. Steve Gray, individual, asked Dr. Vlasses if ACPE schools require four years of pharmacy education. Dr. Vlasses responded that three years of academic schooling and one year of hands on experience in a pharmacy setting under a preceptor is required.

Dr. Gray commented that some states require preceptors to be registered with the state board of pharmacy. Dr. Vlasses reported that he believes only a small number of states require the registration of preceptors.

The committee recessed for break at 11:20 a.m. and resumed at 11:30 a.m.

4. Presentation by the California Schools of Pharmacy on the Intern Experience Earned by Students in California Schools of Pharmacy and the Reporting of Intern Hours to the California Board of Pharmacy

Over the years, the board has been asked to change the reporting of intern hours to eliminate the specific requirement that 900 hours be earned in a pharmacy. Historically, the board has not agreed that such a change is in the public interest.

Dan Robinson, representing the California Pharmacy Council (CPC), commented that it is difficult for students to get additional intern hours outside of the curriculum, as many of the jobs historically held by interns are now being filled by technicians. Ms. Herold commented that it is the position of the board that the experience an intern gains in a pharmacy should not be equivalent to the work that can be done by a technician.

Mr. Robinson stated that it is the position of the CPC that any student, who has successfully graduated from an accredited school or college of pharmacy after 2007, be deemed as having fulfilled his or her required intern hours through pharmacy practice experiences that

meet the requirements of the Accreditation Council for Pharmacy Education. Ms. Herold noted that if the board accepts CPCs proposal it will need to amend its regulations.

The committee asked Dr. Robinson to confirm that at a minimum, students at an ACPE accredited school will receive 1,740 hours of pharmacy experience. Dr. Robinson confirmed.

Representatives from UCSD and UCSF schools of pharmacy requested the committee to adopt the 1740 experiential hours provided by ACPE accreditation as sufficient for meeting the requirements for application to the CPJE. Representatives from each school briefly described the rotations that students complete to gain the necessary experience hours. It was noted that students could choose electives that would give them more experience in a certain practice area.

Dr. Veale asked if UCSD and UCSF felt that their students graduate with adequate skills and knowledge to practice pharmacy.

Mr. Law asked if there is a certain area of pharmacy (hospital community, etc.) where they have difficulty finding preceptors. Both schools responded that they are always looking for quality preceptors and the one area they often find difficult to fill is institutional pharmacy.

Dr. Ken Schell, from UCSD, noted that the hours completed by students as part of the curriculum occur in licensed pharmacies, under the supervision of a licensed pharmacist as required by current pharmacy law. The change being proposed is to eliminate the need for students to complete additional hours after they graduate.

Chair Veale asked legal counsel if a regulatory change would be required. Mr. Santiago responded that a regulation change would be required to allow the schools to sign off on the entire 1,500 hours. Mr. Law asked if the board could eliminate the 1,500 hour requirement and simply require graduation from an ACPE accredited school. Mr. Santiago confirmed that the board could do this, but it would require a statutory change.

Dr. Wong asked how the schools evaluate the preceptors and if they are paid for their services. UCSD and UCSF briefly described their preceptor evaluation processes. UCSF noted that their preceptors are not paid for their services. UCSD reported that their preceptors are not paid by the school; however Dr. Schell added that he pays preceptors out of the hospitals operational budget.

Student representatives from UCSF attested to the quality of experience they gained from the intern hours obtained through their schooling.

David Carol, Associate Dean of California North State University, expressed his support for the proposal made by USCD, UCSF and CPC.

Steve Gray, of CSHP, stated that CSHP supports changing the intern hour requirements as recommended by the presenters.

5. Review and Discussion of Pharmacist Intern Hour Requirements from Business and Professions Code Section 4209, California Code of Regulations Section 1728, and the Reporting of Hours on the Pharmacy Intern Hours Affidavit Form 17A-29.

Jon Roth, representing CPhA, commented that they would be willing to support the board legislatively to make any statutory changes deemed necessary.

The committee members expressed their desire to ensure that intern hour requirements are the same for all graduates of an ACPE accredited pharmacy program. The committee asked counsel to ensure that any statutory or regulatory changes made achieved equality in intern hour reporting requirements for both in-state and out-of-state applicants.

Motion: Direct staff to work with counsel to develop any statutory and regulatory changes necessary so that graduating from an ACPE accredited school of pharmacy meets the intern hours requirement for the application to the CPJE exam.

M/S: Law/ Butler

Support: 4 Oppose: 0 Abstain: 0

6. Presentation by Alex Adam, Vice President of Pharmacy, National Association of Chain Drugs Stores, on Qualifications to Become an Advanced Practice Pharmacist

Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) makes a number of important changes to the services that pharmacists may perform. One major portion of the law establishes an “advanced practice pharmacist” category of pharmacist licensure, which allows such licensed pharmacists to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers.

Alex Adam, representing The California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS), provided a presentation outlining the two organizations recommendations to the board as it considers implementation of SB 493, which creates a path for APPs.

Dr. Adam stated that both CRA and NACDS share the goal of the legislation to facilitate patient access to high-quality, affordable care and broaden the range of care delivery

options to millions of Californians each year. In order to achieve this desired goal, both associations strongly encourage the board to adopt a multiple pathways approach that includes ACPE-accredited certificate programs, NCCA-accredited certification programs and multidisciplinary certifications. CRA and NACDS believes that the multiple pathways approach will allow the new law to be implemented in a meaningful manner that will offer consumers the benefits that will flow from the APP services.

Dr. Adam's entire presentation can be viewed immediately following these meeting minutes.

Dr. Steve Gray, representing CSHP, expressed his support for the recommendations from CRA and NACDS.

The committee heard comments from the public asking the board to ensure that any certification program approved by the board meets the high standard of practice required by an APP.

Palmer Taylor, dean of UCSD Skaggs School of Pharmacy, commented that the cost of implementing SB 493 should be considered. He added that if the schools of pharmacy are asked to provide the certification programs, the cost should not be passed on to the students.

Dr. Wong stated that the committee does not want to create a sub-par program by rushing the implementation of SB 493.

The committee asked staff to look at states that have similar APP laws to see how they approached implementation and what type of programs they created. Dr. Gray noted that the committee should also examine the shortcomings of APP programs in other states so that California can avoid making the same mistakes.

Dr. Wong asked how nurse practitioners and physician assistants receive their training. Staff offered to collect this information and provide it to the committee.

7. Implementation Schedule for SB 493 (Hernandez, Chapter 469, Statutes of 2013)

Chair Veale reported that at the February Licensing Committee Meeting, the committee discussed other provisions contained in SB 493. Working sessions will be scheduled in April or May to initiate work on the two protocols that the board will develop on hormonal contraception and nicotine replacement products.

8. Questions to Collect "Prior Convictions" on Board Applications

DCA Staff Counsel Michael Santiago is working on this assessment, but it is not ready for presentation to the committee at this time. The topic will be rescheduled to the next Licensing Committee Meeting.

9. Competency Committee Report

Chair Veale reported that effective December 1, 2013, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). The board resumed releasing scores on February 25, 2014.

Mr. Law asked if statistics were available for the CPJE pass rates. Staff responded that statistics are created twice a year on April 1st and October 1st.

The committee has begun to develop a job survey of pharmacists through the oversight of the board's contracted psychometric firm. The information learned from this survey will determine if changes are necessary to the content outline of the CPJE. Pharmacists who completed the job analysis survey in the past have been awarded three hours of CE credit. Staff requests that the board again approve this to acknowledge the important and time-consuming attention needed to review the duties pharmacists perform when assessing each duty listed for importance and frequency the duty is performed.

Motion: Approve three hours of CE credit to pharmacists who complete the job analysis questionnaire.

M/S: Law/Butler

Support: 4 Oppose: 0 Abstain: 0

10. Licensing Statistics for July 2013 – March 2014

Chair Veale reported that the board's licensing statistics for July 2013 to March 2014 were provided in the meeting materials for review.

11. Comments on Items Not on the Agenda

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

Chair Veale adjourned the meeting at 2:00 p.m.