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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: June 22, 2016

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

COMMITTEE MEMBERS PRESENT: Stanley Weisser, Chairperson
Albert Wong, Licensee Member
Allen Schaad, Licensee Member
Victor Law, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Gregory Murphy, Public Member
Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Debbie Damoth, Staff Manager
Laura Freedman, DCA Staff Counsel

1. Call to Order and Establish of Quorum

Chairperson Weisser called the meeting to order at 10:00 am. Roll call was taken with the following members present: Stan Weisser, Allen Schaad, Victor Law and Albert Wong.

Board President Amy Gutierrez administered the oath to newly reappointed board members Victor Law and Albert Wong.

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

A representative from the California Society of Health Systems Pharmacists (CSHP) indicated that CSHP was pleased to see the board and this committee were taking a proactive role on reviewing pharmacy technicians and asked that the board consider its role in hospital setting after implementation of the provisions in Senate Bill 493 (Chapter 469, Statutes of 2013) and Senate Bill 952 (current session) are complete.

A representative from Kaiser requested that the committee consider future discussion on the challenges hospitals face opening a new hospital with the current timing of licensure requirements with the California Department of Public Health.

3. Consideration of Possible Revisions to Regulation(s) Regarding Pharmacy Technician Training Programs (Title 16 CCR §1793.6)

Chairperson Weisser reminded the committee that for several meetings, the committee has been discussing the requirements for licensure as a pharmacy technician. As part of its discussion the committee has reviewed the various pathways to licensure, as well as enforcement actions and denials of applications. The committee has heard presentations about the certification exams used for licensure, presentations by various employers about their training programs, as well as a presentation about upcoming changes to technician training programs accredited by the American Society of Health Systems Pharmacists.

As part of the report, Chairperson Weisser noted that the committee and board have expressed concern about some individuals that are seeking licensure through technician training programs (programs that can be quite costly) that have criminal backgrounds that most likely will result in denial of the application. The committee recognizes that not all such training programs are equal in terms of the quality of the program, but expressed concern that the minimum requirements established in law for these programs may no longer be adequate.

Those in attendance were reminded that during the January 2016 board meeting, the board agreed with the recommendations of the committee in concept to modify Title 16 CCR section 1793.6 to strengthen the requirements of some pharmacy technician programs to include a minimum age requirement at admission (18 years old), a criminal background check and to administer at least one drug test. Further, the program would be required to administer a final examination.

Chairperson Weisser review the proposed language included in the meeting materials.

As part of its discussion, the committee discussed the potential need to increase the experiential training requirements for technician training programs and some of the potential challenges with placing technician trainings in pharmacies to gain such experience. The committee was advised that such a change goes beyond the regulation and would require a statutory change.

The committee discussed the specific regulatory change proposal and heard public comment in support of the proposal. Counsel recommended some minor changes to the language.

MOTION: Recommend that the board approve proposed amendments to section 1793.6 incorporating the changes suggested by counsel (VL/AW) 4-0.

Draft Proposal to Amend Section 1793.6

1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:

- (a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,
- (b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or
- (c) 1 Any other course that provides a training period of at least 240 hours of instruction covering at least the following:
 - ~~1~~ A) Knowledge and understanding of different pharmacy practice settings.
 - ~~2~~ B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.
 - ~~3~~ C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
 - ~~4~~ D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
 - ~~5~~ E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.

(B) Administer at least one drug screening to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine acceptance into the course of training or appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.

(C) Require students to be at least 18 years of age prior to the beginning of instruction.

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

4. Consideration of the Duties of a Pharmacy Technician and Discussion on the Pharmacist to Pharmacy Technician Ratio in the Community Pharmacy Setting

Chairperson Weisser provided an overview of the agenda item including that Business and Professions Code section 4115 specifies that a pharmacy technician may perform packaging, manipulative, repetitive or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist. Further, Title 16 California Code of Regulations section 1793.2 specifies specific duties that may be performed by a pharmacy technician 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

Chairperson Weisser reminded the committee that the board requested the committee discuss the current pharmacist to pharmacy technician ratio. Chairperson Weisser commented that the discussion would focus on the community practice setting first.

Chairperson Weisser highlighted how pharmacy technicians have different roles in various states and that ratio requirements vary by jurisdiction as well. Chairperson Weisser noted that the National Association of Boards of Pharmacy is considering this at the national level.

As part of its discussion the committee discussed if there was a need and/or a demand to change the current ratio. Members noted that a change in the ratio requirement may be appropriate if it makes the pharmacist more accessible to consumers. The committee recognized the benefits of a good pharmacy technician and noted that an increase in the ratio could be a double edged sword. The committee noted that an increase in the number of pharmacy technicians would result in additional prescriptions being filled that will require a final check by a pharmacist.

Public comment heard by the committee included several individuals speaking in support for an increase in the current ratio and that an increase could result in better patient outcomes and implementation of the expanded role of a pharmacist.

The committee was advised that CVS completed a study that indicated that when the ratio is 1:1, a pharmacist spends 72% of his or her time performing technician duties. Many individuals present indicated that they believed that the rate of patient consultation will improve if the ratio is increased.

The committee briefly discussed establishing a workload quota and was advised about the challenges such a quota would present given not all work settings are the same and the variances in the duties as well as skills and abilities among pharmacists.

Public comment suggested that the board could maybe consider changes in the ratio based on a technician's experience.

The committee was advised that the California Pharmacists Association (CPhA) is not asking for a change in the ratio, and that its board of trustees did not support a change in the current ratio. CPhA did note, however, that as the role of a pharmacist is changing to more of a service role, some functions could be transitioned to technicians.

The committee requested information from those present about error rates, noting that even anecdotal evidence would be helpful.

MOTION: Recommend convening a summit to discuss this issue. AS/VL 4-0

5. Consideration of Possible Revisions to Pharmacist Renewal Requirements and Content – Specific Continuing Education (Title 16 CCR §1732.5)

Chairperson Weisser provided background information including reminding the committee that in November 2015, the board initiated a rulemaking to amend section 1732.5 to amend continuing education requirements to specify that six of the 30 hours required for pharmacist license renewal shall be completed in specified areas. This proposal was referred back to the Licensing Committee after the board expressed concern that the proposal may be overregulating the continuing education requirements.

The committee discussed the proposal and noted that many of the specified areas were important, including substance abuse, but noted that the topics many not be relevant for all pharmacists. The committee noted that some of the topics would be appropriate for licensees that are cited for violations.

The committee heard public comment in support of requiring law updates as required continuing education.

MOTION: Recommend withdrawal of the proposed regulation change to 1732.5 VL/AS 4-0.

6. Consideration of Ownership Structures for Pharmacies, Including a Presentation by the Office of the Attorney General Regarding Trusts

Chairperson Weisser indicated that the board tracks the beneficial interest of business owners for pharmacies, whether they be a natural person or an entity. Board regulation specifies the reporting of a transfer in the beneficial interest in the business and specifies the threshold as to when a change of ownership must be submitted to the board.

Chairperson Weisser noted that for some, what is initially reported as (what appears to be) a simple, two- or three-level ownership structure, when staff uncovers details, it often turns out to be multiple levels of ownership with multiple stakeholders. Board staff has identified where (revocable or irrevocable) trust(s) is/are reported as owners of the applicant business. Pharmacy Law does not currently recognize a “trust” as a person to which the board is

authorized to issue a license; however, Mr. Weisser noted that it has sometimes occurred in the past.

Chairperson Weisser stated that as the board was advised at the Board Meeting – as with other ownership structures, trusts can be used as a legitimate form of ownership, however they also can be manipulated to hide ownership. Mr. Weisser recommended that the committee carefully consider this issue and determine if it is appropriate to recommend to the board that a trust be authorized to own a pharmacy and – if so – what information should the board require.

The committee heard a presentation by Matthew Heyn, Deputy Attorney General. Mr. Heyn indicated that the board has a problem with hidden ownership. He noted that lawyers around the world have become more sophisticated in hiding ownership and control of assets. Mr. Heyn referenced a very recent example with the Panama Papers which showed that offshore trusts were the method of choice for nefarious individuals who did not want their ownership interests known. Mr. Heyn noted that as part of the Panama Papers, it was revealed that two foreign-owned pharmacies were owned – one by a husband and the other by a wife in trusts that ultimately allowed them to exert monopoly control using their hidden ownership. The problem faced by the board is that it must keep the ownership of a pharmacy out of the hands of bad players, including felons. Mr. Heyn also indicated that there are other individuals, such as prescribers, who are prohibited from ownership of a pharmacy for public policy reasons. He discussed the need to avoid conflicts of interests. He indicated that hidden ownership makes it difficult to determine who is really the owner and provided an example of a convicted drug dealer setting up a trust to hide the true ownership of the pharmacy. Mr. Heyn noted that trusts are very flexible in how they operate, who controls the trust and who benefits from the trust.

Mr. Heyn highlighted the relevant provisions of pharmacy law and noted that when the board is determining if it can issue a license, it looks at the definition in Business and Professions Code section 4035. He noted that a trust is not included in section 4035. Mr. Heyn refuted the assertion made that a “firm” includes a trust. Mr. Heyn noted that there are legitimate reasons to own a trust. He noted that a trust can’t own things; rather a trust is a relationship between the trustee and the beneficiary. Ultimately, the board needs to know who really owns a pharmacy. Mr. Heyn drew a distinction between trusts and other forms of ownership (e.g., corporations) that are required to register and required to file certain documents that detail the owners, officers, members, etc.

Mr. Heyn indicated that the board will need to identify what information is needed if it decides to issue licenses to trusts and suggested that present beneficiaries should be identified.

Ms. Herold noted that there are several items for consideration before the committee, including if the board should allow trusts to own a pharmacy and, if so, what reporting and disclosure requirements are appropriate. Alternatively should the board determine that it is not appropriate for a trust to own a pharmacy and that the law does not authorize such action.

The committee heard public comment from individuals that provided different opinions on the issue including the determination that the board does not currently have the authority to issue a pharmacy license to the trust as well as the definition of a "person" and whether a trust could be included in the current definition. Comments to the committee indicated that the risk presented by trust ownership is no greater than other types of ownership. Comments included that they are not aware of a single application where the trust owns the pharmacy, rather the applicant and permittee owns the pharmacy, which is not the trust. Comments indicated that the board needs to differentiate between the holder of the license and the additional layers of ownership that may be present. The committee was reminded to be mindful of the difference between a revocable trust and an irrevocable trust, as well as direct owners versus indirect owners.

Public comment indicated that in cases where the board has received an application with a trust included as part of the ownership, there is no attempt to hide the ownership. Comments from the public recognized the need for the board to know who owns a pharmacy. Comments from the public supported the possibility of specifying what information must be reported to the board and indicated that it is not appropriate to require the identity of some beneficiaries including minor children. Commenters indicated that reporting a trustee is appropriate and reporting changes in ownership consistent with current legal requirements is also appropriate.

Committee members spoke in support of allowing trusts to own pharmacies and recognized the important role a trust can play in estate planning. The committee spoke of the need to find common ground.

Ms. Herold reminded the committee that it is important to ensure that the board is operating in compliance with the law and with the concurrence of board attorneys. Ms. Herold noted that this is an emerging issue.

The committee asked DCA counsel to assess the issue. The committee was advised that DCA counsel agrees with the determination of the AG's Office about the definition of a "person." Counsel noted that is an issue that needs to be resolved. Counsel sought clarification asking if it is the policy of the committee and board to allow trusts as part of the ownership.

MOTION: Ask legal counsel to review statutes and regulations and propose a fix to resolve the trust issue and how to regulate the entities within the board's regulatory framework.

VL/AW 4-0

The committee noted that part of the solution will need to address those entities that currently include a trust as part of the ownership structure.

7. Licensing Statistics

Licensing Statistics for July 1, 2015 – May 31, 2016

Chairperson Weisser referenced the licensing statistics included in the committee materials.

The committee was advised that staff continue to closely track the licensing unit's processing times for various application types and efforts are still underway to develop more robust reporting reports. The department is implementing Licensing Performance Measures (LMP) processing times for the boards and bureaus but it is not quite complete.

Staff noted that staff is trying to improve its education to applicants about the requirements and application process and that education on this will be included in the board's newsletter.

8. Future Committee Meeting Dates for 2016

September 21, 2016, is the next scheduled committee meeting. Board staff will be working to secure additional meeting dates. If finalized, these dates will be provided during the meeting.

The meeting was adjourned at 3:16 pm.