

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

DATE:	October 27, 2017
LOCATION:	Department of Consumer Affairs First Floor Hearing Room 1625 N. Market Blvd. Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Amarylis Gutierrez, Board President and Acting Chairperson Ricardo Sanchez, Public Member Debbie Veale, Licensee Member Albert Wong, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Stanley Weisser, Licensee Member, Chairperson Lavanza Butler, Licensee Member, Vice-Chairperson Ryan Brooks, Public Member
STAFF MEMBERS PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Counsel Debbie Damoth, Staff Services Manager

Note: The committee took items out of order during the meeting. For ease of reading, the minutes have been compiled to mirror the agenda.

1. Call to Order and Establishment of Quorum

President Gutierrez called the meeting to order at 10:00 a.m. Roll call was taken with the following members present: Ricardo Sanchez, Debbie Veale, and Amarylis Gutierrez. Member Albert Wong joined the meeting at 10:16. A quorum was established.

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

There was no public comment.

3. Discussion and Consideration of Licensing Requirements of an Advanced Pharmacy Technician (APT)

President Guitierrez explained she participating as Acting Chairperson for the committee in Chairperson Stan Weisser's absence. President Guitierrez reviewed the draft statutory changes approved at the August 22, 2017, Licensing Committee Meeting for Business and Professions Code (BPC) Section 4038.5 to establish a definition for an "Advanced Pharmacy Technician" (APT) and BPC Section 4211 to establish minimum licensing requirements for an individual seeking licensure as an APT.

Dr. Guitierrez explained following the August 2017 Licensing Committee, members of the board's regulated public requested an opportunity to provide additional comments for committee consideration. The committee discussed their opinions. Ms. Veale expressed interest in adding additional pathways to licensure other than an associate degree in pharmacy technology, while Dr. Gutierrez offered the option of verified hours of experience.

Angie Manetti of California Retailers Association (CRA) expressed concern for requiring a separate licensing category to increase the scope of duties for the pharmacy technician in California citing other states requiring training for tech-check-tech but not a separate license category. Assistant Executive Officer Anne Sodergren clarified that liability is part of the change in duties but also noted the committee must determine if the current minimum pharmacy technician qualifications translate to the new duties being established for the advanced pharmacy technician.

Ms. Manetti continued and referenced CRA's proposed licensing requirements for proposed Business and Profession's Code section 4211 requesting additional avenues in addition to the current associate degree avenue to licensure. (A copy of the CRA proposal may be found following these minutes.) Ms. Manetti cited three public community college programs currently available for pharmacy technology. Executive Officer Virginia Herold noted there are approximately 3,000 of the current 70,000 pharmacy technician licensees that qualified for licensure based on the associate degree. Ms. Sodergren added she believed there were also private colleges that offered the associate degree. Dr. Gutierrez requested clarification on the number of private and public associate degrees offered in California.

Dr. Gutierrez inquired if Ms. Manetti was familiar with the ASHP training program. Ms. Manetti stated she believe the ASHP training programs were more enhanced but was not aware of the number of didactic/clinical hours required. Ms. Manetti expressed concern of accessibility to the associate degree programs. Ms. Manetti expressed concern for a required 3,000 hours of experience and preferred 1,500 hours of experience to be in line with other states completing tech-check-tech. Ms. Sodergren reminded the committee the board's proposed APT goes beyond tech-check-tech. Committee member Dr. Wong stated he was in support of a minimum associate degree in pharmacy technology would like to keep the associate degree as a minimum requirement.

(Note: The committee decided to move to the next agenda item to allow for the discussion and consideration of the duties of the APT prior to discussing licensing the requirements of the APT.)

Shane Deselle, a professor of pharmacy at Touro University and president of Applied Pharmacy Solutions and Research Consulting Firm, reiterated support for California creating the additional pathway for licensure. He continued it was extremely successful by mitigating turnover in other states and equally successful. Dr. Deselle expressed concern about keeping the associate degree as the only pathway to licensure. He continued research has proven onthe-job experience is valued greater by pharmacy technicians, employers and other stakeholders and encouraged maintaining a high level of on the job training. Dr. Deselle stated certification is good and he supported the use of board approved training and ASHP training programs. He noted a scarcity of associate degree programs and variance of quality in programs. Dr. Deselle stated he had more faith in ASHP accredited training programs than educational institutions.

Dr. Gutierrez asked Dr. Deselle for his experience and research in the level of expertise required for the next step of expanding their duties. Dr. Deselle indicated experience in on-the-job training and certification are ranked higher and shown to be more effective than other types of educational modules. Research hasn't codified the level of experience. He indicated he thought 2,000-3,000 hours would be sufficient.

Ms. Sodergren asked Dr. Deselle if he was aware of any studies that demonstrated how onthe-job training translates to other workplaces. Dr. Deselle indicated there is a transfer of onthe-job training within similar setting jobs but the transferability within different settings (e.g., retail, hospital, long-term care, etc.) is quite limited.

Ms. Veale indicated it is the responsibility of the employer to make sure that the pharmacy technician has the training needed to perform the job if working in a different setting. Dr. Wong agreed.

Dr. Gutierrez inquired Dr. Deselle of his thoughts on two license types of advanced pharmacy technician: ambulatory and hospital. Dr. Deselle indicated he supported two license types for APT.

The committee heard comments from the public requesting the pathway requirements to licensure be expanded. The committee favored expanding the degree requirement to a minimum of an associate degree in pharmacy technology or a bachelor's degree or above in another field or completion of a board approved training class to expand pathways to licensure. The committee also agreed upon expanding the pathways to licensure by allowing

for 3,000 hours of pharmacy technician experience.

MOTION: Recommend a change to proposed BPC 4211 to the board with the following requirements for licensure as an APT:

- 1. Hold an active pharmacy technician license; and
- 2. Possess certification by a pharmacy technician certifying program (e.g. PTCB or ExCPT); and
- 3. Obtain a minimum of an associate degree in pharmacy technology, or bachelor's or above in another field; or completion of a training program approved by the board; and
- 4. Have completed 3,000 hours of pharmacy technician experience. OR
- 5. Have graduated from a school of pharmacy.

M/S: Wong/Veale

Support: 4Oppose: 0 Abstain: 0

Mark Johnston of CVS Health provided ID as an example of requirements for tech-check-tech. Dr. Gutierrez reminded the committee the board's APT will have more responsibility that tech-check-tech.

4. Discussion and Consideration of the Duties an APT May Perform in a Traditional Community Pharmacy Setting

Dr. Gutierrez reviewed previous work of the committee in developing and voting to recommend to the board pursuing a statutory change to add BPC Section 4115.6 (a) regarding specified tasks of the APT and BPC Section 4115.6 (b) regarding requirements for using an APT in the community setting.

Dr. Wong expressed concern with proposed BPC section 4115.6 (a)(2) that the pharmacist-incharge (PIC) is responsible without being able to verify the work of the APT. Dr. Wong supported adding a way where the PIC can verify the work such as a recording. Ms. Sodergren noted that the committee discussed multiple safeguards in the policies and procedures that could be put in place to help the PIC such as instructing the APT request the purpose of the medication and recording the calls.

Ms. Veale indicated that the PIC would be responsible for determining if this was appropriate for their pharmacy. DCA Counsel Laura Freedman confirmed the PIC has the final authority in the pharmacy to determine if they want to use the expanded role in the pharmacy. She further clarified the licensure establishes the minimum knowledge, skills, and abilities. With the expanded functions of an APT, the responsibility would also shift to include the APT so there is a sharing of the responsibility between the APT and PIC.

Dr. Gutierrez requested clarification on the committees' previous discussion regarding proposed BPC Section 4115.6 (a)(1) about verifying the accuracy of the prescription label before the pharmacist performs the final check. Ms. Sodergren clarified the intent was to catch some errors before the final check by the pharmacist. The committee discussed various

ways that pharmacists in pharmacies conduct first and second check of prescription and when the drug utilization review (DUR) takes place.

The committee agreed the intent of the proposed BPC Section 4115.6 (a) and (b) was to allow for tech-check-tech in a retail pharmacy setting. Ms. Sodergren recommended having staff rework the language to ensure that it better matches the policy of the committee to allow for tech-check-tech where the pharmacist was responsible for the DUR and clinical actions required. The APT is required to check the label, the product and the NDC. The committee discussed the option of updating CCR section 1793.2 in the process.

Danny Martinez of the California Pharmacists Association (CPhA) expressed possible conflict with CPhA's work in trying to get pharmacists reimbursed by Medi-Cal for administering immunizations. Dr. Gutierrez recommended adding to proposed BPC Section 4115.6 (a)(7), "under the supervision of a pharmacist."

Dr. Deselle shared about a paper by Frost and Adams showing safety, efficient operations and accuracy when pharmacy technicians accept new orders in addition to the transfer orders. He also shared there is a paper by Brawn and Napier studying tech-check-tech in the retail setting that shows the pharmacy technician to be effective when the pharmacist is still engaged in the DUR process.

DCA Counsel Freedman requested clarification that DUR refers to verifying the medication prescribed for the patient makes sense for the patient and the committee confirmed this is true.

The committee discussed if the pharmacist should physically hand out the controlled substances if the APT received and filled the controlled substance prescription. Ms. Manetti of CRA expressed concern that proposed BPC 4115.6 (b) (3) may not be the best approach for preventing diversion and encouraged the committee to take a more holistic approach. Ms. Manetti requested clarification that the APT would be able to do the APT duties in addition to the duties approved for a licensed pharmacy technician. The committee confirmed the APT would be able to do the duties assigned to the APT and the duties assigned to a licensed pharmacy technician.

Ms. Manetti presented to the committee CRA's recommended additions to proposed BPC Section 4115.6 (b). CRA requests adding the duty of allowing the APT to check the PDMP and print/present the report for the pharmacist review. The committee discussed only pharmacists are currently allowed to access the PDMP.

CRA also proposed permitting APTs and possibly pharmacy technicians perform technical patient care services such as basic physical assessments (e.g., blood pressure, temperature, CLIA-waived tests) when delegated by a pharmacist subject to the pharmacist review. CRA proposed permitting the APT to compile medication lists by interviewing the patient for medication reconciliation. CRA believes training covers all duties except the immunization.

Dr. Gutierrez requested clarification on proposed BPC Section 4115.6 (b)(9). The committee

decided to hold the discussion until agenda item #5.

Mark Johnston from CVS Health requested an expanded duty of prescription clarification if needed for quantity, etc. The committee discussed adding this to BPC Section 4115.6 (a)(3) to accept new prescriptions or clarifications from a prescriber's offices. Dr. Gutierrez asked Mr. Johnston what he thought would help enhance patient care. Mr. Johnston indicated he would prefer it not to be regulated and provided Idaho as an example where the Idaho board approved and is pending legislature approval prescriptive authority to be written into rules for 22 different categories.

Dr. Gutierrez expressed concern to ensure that the pharmacist can receive some assistance while providing care to the patient. Dr. Gutierrez suggested combining the APT with some type of clinical practice for the pharmacist.

The committee took a break from 12:07 pm to 12:26 pm.

MOTION: Recommend a change to proposed BPC 4115.6 (b)(3) removing "and controlled substances" requirement; replacing with it with language to mirror clinical programs as outlined in CCR 1793.8; and requesting staff to recommend language to define clinical programs to address.

M/S: Gutierrez/Wong

Support: 4 Oppose: 0 Abstain: 0

Members of the public requested the committee consider not delineating the duties of the pharmacist but allow the pharmacist the discretion to serve the patient as needed. The committee discussed the benefit of removing nondiscretionary tasks from the pharmacists to allow the pharmacists the ability to interact more with the patients.

MOTION: Recommend a change to proposed BPC 4115.6 (a) to the board with the following changes to the proposed language:

- 1. Direct staff to combine proposed BPC 4115.6 (a) (1) and (a) (2) to incorporate the aspects of a pharmacist performing the clinical review on drug utilization reports (DURs);
- Add "accept new prescription orders or clarifications...." to the proposed BPC 4115.6 (a) (3);
- 3. Remove and delete proposed BPC 4115.6 (a) (5) to accept refill authorization s from prescriber's office unless authorization requires professional judgment of a pharmacist;
- 4. Remove and delete proposed BPD 4115.6 (a) (9) to initiate post discharge contact with patient upon discharge from a skilled nursing or long-term care facility; and
- 5. Accept CRA's proposed BPC 4115.6 (a) (12) to add compile medication lists by interview the patient for medication reconciliation.

M/S: Gutierrez/Veale

Support: 4 Oppose: 0 Abstain: 0

A member of the public requested clarification of CRA's proposed BPC 4115.6 (a) and clarification was provided by the committee.

Dr. Wong expressed concern with the APT accepting controlled substances for new orders. DCA Counsel Freedman offered bringing that item to the board for direction.

MOTION: Request clarification from the board on proposed BPC Section 4115.6(a)(3) to see if the board wants this to be for all prescriptions/orders or only non-controlled substances prescriptions/orders.

M/S: Gutierrez/Wong

Support: 4 Oppose: 0 Abstain: 0

The committee decided to request clarification from the full board if the board wished to have one general license type for APT or two separate licenses types for APT including a retail license type and an institutional license type.

5. Discussion and Consideration of the Employment of APTs in a Closed-Door Pharmacy Which Provides Pharmacy Services for Patients of Skilled Nursing and Long-Term Care Facilities

Dr. Gutierrez inquired why a separate licensure category was required for closed-door pharmacy when there is not a separate pharmacy license category. Ms. Herold provided it was intended as a topic of discussion for the committee. Ms. Sodergren added both the practice setting and opportunity for patient engagement is different in closed-door pharmacies. Ms. Veale added the closed-door pharmacy has a little different need than the retail/community pharmacy setting.

Dr. Gutierrez inquired if the closed-door pharmacy should be licensed separately. Dr. Gutierrez recommended considering the nuances in long-term care.

Paige Tally of California Council for the Advancement of Pharmacy (CCAP) provided to the committee that skilled nursing facilities contract with the closed-door pharmacy and the closed-door pharmacies contract with a GPO. As a result, the pharmacy can't continue to provide medication when the patient leaves the skilled nursing facility. Typically, the nurses go through the medications with the patients and call the pharmacy if there is a question as the pharmacy is on call 24 hours/day, 7 days/week.

Dr. Gutierrez requested patient consultation for discharge from a long-term care facility be added to a future agenda.

Ms. Freedman pointed out to the committee that a previous motion passed referred to "community" pharmacy. Dr. Gutierrez recommended referring to pharmacies licensed under BPC Sections 4037 and 4029. Ms. Freedman received approval to change the language to remove the "community" portion from the committee.

6. Discussion and Consideration of the Employment of APTs in Inpatient Hospital Pharmacies

Dr. Gutierrez reviewed the meeting materials for the employment of APTs in inpatient

hospital pharmacies including a draft proposal of technical tasks performed by the APT as part of a patient's discharge and a draft proposal of requirements for a hospital using APTs.

Dr. Gutierrez indicated she would like to see this list expanded to include duties such as review and seal crash carts, inspections, and prepackage duties for cassettes, and she requested input from CSHP and other hospital pharmacists. The public generally supported the duties proposed and would like to see the list of duties expanded.

Dr. Gutierrez recommended deferring the item to allow for time for more input from inpatient hospital pharmacists.

7. Discussion and Consideration of the Current Renewal Requirement for Pharmacy Technicians and Possible Changes Thereto

Dr. Gutierrez reviewed the meeting materials. The committee explored options of requiring and offering continuing educations for pharmacy technicians. The committee decided to update the proposed continuing education requirement to remove the specified types of continuing education.

MOTION: Pursue statutory changes to add the continuing education and renewal requirements of an advanced pharmacy technician by adding BPC section 4234 as outlined below

Proposed BPC 4234 (CE/Renewal Requirement)

An advanced pharmacy technician shall complete 20 hours of continuing education each renewal cycle. A licensee must also maintain certification as specified in Section 4211 (a)(2).

M/S: Veale/Gutierrez

Support: 4Oppose: 0 Abstain: 0

8. Future Committee Meeting Dates

The committee reviewed the dates for 2018 as follows:

- January 16, 2018
- April 19, 2018
- June 26, 2018
- September 26, 2018

The meeting adjourned at 1:48 pm.