



**California State Board of Pharmacy
Department of Consumer Affairs
Licensing Committee Meeting Minutes**

Date: October 18, 2022

Location: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.

Board Members

Present: Seung Oh, Licensee Member, Chair
Jig Patel, Licensee Member, Vice-Chairperson
Jessi Crowley, Licensee Member

Board Members

Not Present: India Cameron-Banks, Public Member
Jason Weisz, Public Member

Staff Present:

Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Oh called the meeting to order at approximately 9:00 a.m. As part of the opening announcements, Chairperson Oh reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. Members present: Jig Patel, Licensee Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensing Member. A quorum was established.

Chairperson Oh advised the ownership items discussed at the previous meeting was still under consideration by staff and will be brought to the Committee when finalized.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comment; however, no comments were made.

III. Approval of the July 18, 2022, Licensing Committee Meeting Minutes

Members were provided the opportunity to provide comments on the draft minutes; however, none were provided.

Motion: Approve the July 18, 2022, Licensing Committee meeting minutes

M/S: Crowley/Patel

Members of the public were provided the opportunity to provide public comments; however, no comments were provided.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Crowley	Support
Oh	Support
Patel	Support
Weisz	Not present

IV. Discussion and Consideration of Possible Statutory Proposal to Expand Current Pharmacy Technicians Authorized Duties, Current Pharmacist to Pharmacy Technician Ratio and Possible Changes

Chairperson Oh advised the Committee would be continuing the discussion on pharmacy technicians, including authorized duties, technician ratios and possible changes as well as for the first time to discuss a possible statutory authority change. Dr. Oh noted the proposed language was drafted after considerable opportunities for participation and discussion by both members and stakeholders. Dr. Oh thanked members, stakeholders, and the Licensing Committee's previous Chair Debbie Veale for their robust engagement. Dr. Oh noted the deliberative and thoughtful process used in the Board's efforts is necessary to ensure actions taken by the Board and consistent with the Board's consumer protection mandate and recognized that sometimes policy changes do not move as quickly as some would like.

Chairperson Oh reminded the Committee following initial discussions members convened a series of listening sessions for pharmacists and pharmacy technicians. Dr. Oh stated he was present for all listening sessions. Dr. Oh advised in addition to the listening sessions, the Board also released surveys as another means to solicit feedback. The Committee convened in April 2022 a Pharmacy Technician Summit where the Committee discussed the results of the listening sessions and surveys, information at the national level, and research on various related topics.

Chairperson Oh stated during the discussion in April 2022, the Committee reached consensus on some areas, including some possible new duties for pharmacy technicians including authority to administer vaccinations, authority to receive verbal prescriptions and transfers, and authority to perform some aspects of CLIA-waived testing. Dr. Oh added during the July 2022 Committee meeting, the Committee continued the discussion by considering the policy questions detailed in the report.

Chairperson Oh referenced meeting materials which included a copy of the statutory proposal prepared by staff following the Committee's policy discussions. Dr. Oh stated he reviewed the proposal and believed it was appropriate and consistent with Committee discussions. Dr. Oh believed the proposal served as a compliment to activities underway in other committees including the Medication Error Reduction and Workforce Committee.

Members were provided the opportunity to comment on the draft proposal.

Members discussed increasing ratios to 1:2 in community and hospital settings in general and in relation to when immunizations were occurring. Ms. Sodergren provided current ratio law in the inpatient setting is 1:2 and in the community setting is 1:1 but if a 2nd pharmacist is added, it is 1:2. Members determined the ratio would be addressed separately.

Member Crowley thanked staff for their proposal based on Committee discussion. Dr. Crowley inquired if it would apply to all CLIA-waived testing or specific to the pharmacy. Ms. Sodergren provided it would be determined at the store level by the PIC. Counsel Smiley provided Business and Professions Code (BPC) section 4115 would apply to all CLIA-waived testing with other regulations establishing how policies and procedures

would be done. Ms. Smiley advised the Board needs to obtain the statutory authorization and changes would then be made to the regulations. Ms. Sodergren clarified the authority that is proposed is for the pharmacy technician to do the specimen collection with the policy concept to delegate the determination to the authority to the PIC.

Member Crowley inquired if there was consensus for the pharmacy technicians needing to be nationally certified to perform testing and vaccination. Ms. Sodergren provided as proposed the pharmacy technician doing the expanded duties will be required to be certified pursuant to proposed BPC section 4115 (b)(3) and trained for vaccine requirements in proposed BPC section 4115 (b)(4).

Members were confused as to whether hands on training and which type of certification was required. Ms. Sodergren clarified proposed BPC section 4115 (b)(3) requires certification (PTCB and ExCPT) and maintenance of the certification which requires continuing education (CE). Ms. Sodergren inquired if the preference was for CE through certification or for the Board to require CE. After reviewing CE requirements for PTCB and ExCPT, Members came to a consensus on CE coming from maintaining certification.

Motion: Recommend that the Board pursue a statutory proposal to amend Business and Professions Code section 4115 as presented.

4115.

(a) 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. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(b) In addition to the tasks specified in subdivision (a) a pharmacy technician may administer vaccines, administer epinephrine, perform specimen collection for CLIA waived tests, receive verbal prescriptions, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

1. The pharmacist-in-charge of the pharmacy at which the tasks are being performed has deemed the pharmacy

technician competent to perform such tasks and documented such determination in writing. Documentation must be maintained in the pharmacy.

2. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

3. The pharmacy technician is certified pursuant to Section 4202(a)(4) and maintains such certification.

4. The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

(b c) This section does not authorize the performance of any tasks specified in subdivision (a) & (b) by a pharmacy technician without a pharmacist on duty.

(e d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have not more than one pharmacy technician performing the tasks specified in subdivision (b). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient

of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

~~(g)~~ (h) Notwithstanding subdivisions ~~(a)-(c)~~ and ~~(b)~~, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of

the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f g).

(h i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

M/S: Patel/Crowley

Members of the public were provided the opportunity to comments.

A representative of CVS Health commented the proposed regulations would be more restrictive than federal law and recommended reconsidering proposed BPC 4115 (b) and give authority to the PIC to determine who is trained. The commenter inquired why in proposed BPC 4115 (b)(4) the pharmacy technician would need to complete ACPE approved immunization training if the only other expanded duties were as

listed. The representative inquired for proposed BPC 4115 (b) with the pharmacy technician being able to receive transfers would they be able to initiate prescription transfers. Regarding proposed BPC 4115 (g)(1) one person can count/pour only and one pharmacy technician can do expanded duties; however, if there are no expanded duties, can the pharmacy technician help to count and pour?

The Committee heard a comment about the inpatient pharmacy ratio hoping the Board would consider reviewing due to how the nature of inpatient pharmacy work has changed over the years. The commenter requested reconsideration of the inpatient ratio in the future.

A representative of CSHP commented in support of the expansion of pharmacy technician duties and recommended rather than being specific add the pharmacy technician can do all the nondiscretionary tasks.

A representative from UFCW WSC commented in support of minimum staffing ratio and was concerned of losing the pharmacy technician's assistance to providing immunizations. The comment included concern about how expansive the vaccine authority is where some vaccines require additional training. The commenter requested clarity on oversight with the pharmacist being over the pharmacy technician and confirmation that pharmacy technicians do not provide the services while the pharmacist is on a break. The commenter had a concern with only the PIC determining if a pharmacy technician can do vaccinations as it should include pharmacist on duty being able to make that determination. There should be clarity around what is competent and what that means. The commenter wanted there to be a rebuttable presumption for retaliation.

A pharmacy technician inquired why national certification is required when it isn't required for initial licensure. The pharmacy technician spoke in support of expanded pharmacy technician duties.

A pharmacist representative of Kaiser inquired if the proposed language for proposed BPC section 4115 (g) expressed the intent of the Committee. If the intent is for pharmacy technician to be performing the expanded duties in proposed BPC 4115 (b), then there must also be a scheduled pharmacy technician to do the duties as described in proposed BPC 4115 (a), does that make the new ratio 1:2? The commenter suggested modifying proposed BPC 4115 (g) to add you must have concurrently one

pharmacy technician scheduled to perform the tasks in proposed BPC 4115 (a) to make it clear it is not an “either/or scenario” but an “and” scenario.

A pharmacist inquired about a discussion about how the proposal related to access and social determinants of care would affect the most vulnerable residence of California who may have difficulty accessing care.

Ms. Sodergren suggested looking at CCR 1793.7 (f) where it talks about the higher ratio for the preparation of a prescription for an inpatient licensed health care facility.

Member Patel inquired if that meant in the inpatient setting the first pharmacist can oversee only one pharmacy technician and when the second pharmacist is present there can be a total of three pharmacy technicians.

Ms. Sodergren read CCR 1793.7(f): “For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. . . .”

Members discussed public comment.

Member Crowley addressed the question about why national certification was needed. The pharmacists reported during the pharmacy technician summit an inconsistency with the training of pharmacy technicians. Requiring national certification addresses the inconsistency of training. Dr. Crowley agreed with the pharmacist on duty being able to determine if the pharmacy technician working can perform the advanced duties. Dr. Crowley agreed there was confusion when the ratio changes to 1:2 and was open to adding clarification.

Member Patel agreed clarification was needed in proposed BPC 4115 (g)(2).

Ms. Sodergren requested clarification if Member Patel wanted changes to proposed BPC 4115 (g) also or proposed BPC 4115 (g)(2). Member Crowley indicated the concern was with the addition to proposed BPC 4115 (g)(1) not being clear.

A representative from CRA/NACDS commented in support for expanding pharmacy technician duties including authorization for immunization. Some of the proposed language was limiting and could place greater burden on the workforce than what exists currently. The concern was the proposed language only expands the ratio by one pharmacy technician and only for certain duties and requires an additional pharmacy and requires the pharmacies to have an additional pharmacy technician in the pharmacy in order for the other pharmacy technician to do the additional duties. Expansion should not be limited to certain duties to protect consumers and workforce. The ratio needed more work.

Chairperson Oh noted the proposed BPC 4115 was drafted deliberately based on meetings, listening sessions and stakeholder interests.

Members were provided the opportunity to comment.

Member Crowley addressed the public comment about how the proposed language will affect social determinant and access to health care. Dr. Crowley noted part of reason why the Committee was discussing the expansion of ratios for immunization and expanded duties was that pharmacists felt they were juggling too much and if a pharmacy technician was removed from the workflow to provide these additional services, the pharmacist wouldn't be multitasking and increasing the possibility of medication errors. Dr. Crowley was interested in where the pharmacies were that provide the expanded services.

Ms. Smiley clarified Dr. Crowley wanted the pharmacist and PIC to be able to make the determination but that was not in the motion. Dr. Crowley wanted to add similar language included in the immunization for COVID vaccines so that the pharmacist on duty can determine if the pharmacy technician can perform the additional services. Members discussed and agreed the authority of a pharmacist in the pharmacy to be able to determine what a pharmacy technician can and cannot do.

Ms. Sodergren inquired if the Committee was looking to have staff clarify the nexus in proposed BPC 4115 (g)(1) between the pharmacy technician performing the duties in proposed BPC 4115 (a) and proposed BPC 4115 (b). Members Patel and Crowley agreed to amend the language and motion for clarity.

Motion: Recommend that the Board pursue a statutory proposal to amend Business and Professions Code section 4115 as presented with clarification on the provisions established in Business and Professions Code section 4115 (g) (1).

4115.

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1. The pharmacist-in-charge of the pharmacy at which the tasks are being performed has deemed the pharmacy technician competent to perform such tasks and documented such determination in writing. Documentation must be maintained in the pharmacy.

2. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

3. The pharmacy technician is certified pursuant to Section 4202(a)(4) and maintains such certification.

4. The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

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(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

~~(g h)~~ Notwithstanding subdivisions ~~(a)-(c) and (b)~~, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision ~~(f g)~~.

~~(h i)~~ The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

~~(i j)~~ In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

M/S: Patel/Crowley

Members of the public were provided the opportunity to comment.

A comment was made in response to Member Crowley's response on access and social determinants of care, California was ranked 50th in terms of pharmacists per capita over only Oklahoma.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Crowley	Support
Oh	Support
Patel	Support
Weisz	Not present

V. Discussion and Consideration of Possible State Protocol Consistent with Provisions of Business and Professions Code Section 4052.01 as amended in Senate Bill 1259 (Chapter 245, Statutes of 2022)

Chairperson Oh advised the Board previously considered and established a support position on Senate Bill 1259 which sought to amend BPC section 4052.01 to provide the authority for a pharmacist to furnish federal Food Drug and Administration approved opioid antagonist in accordance with standardized procedures or protocols developed under specified conditions. Dr. Oh reported the Governor signed the measure which will become effective January 1, 2023.

Chairperson Oh noted as required in the statute, the Board and the Medical Board of California must approve the regulation with consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. Dr. Oh noted the statute also specifies areas that must be included in the standardized procedures.

Chairperson Oh referenced meeting materials that provided some history on the initial legislation. Dr. Oh added in 2014 pharmacists were granted authority to furnish naloxone hydrochloride in accordance with standardized procedures established. Dr. Oh recalled following enactment of the statute, the Board was required and developed the regulation necessary to implement the statute. Dr. Oh highlighted access to naloxone has changed since 2014, including additional access points for patients to access naloxone hydrochloride and including authority for pharmacies to furnish naloxone hydrochloride to law enforcement agencies and to school districts, county office of education, or charter schools under specified conditions. Dr. Oh noted this expansion occurred to ensure ready access to this life saving medication and does not appear to create some of the same requirements as the Board's current protocol.

Chairperson Oh stated the required protocol for pharmacists is included in California Code of Regulations (CCR) section 1746.3 and established the requirements of the standardized procedures required for a pharmacist to furnish naloxone hydrochloride pursuant to section 4052.01.

Chairperson Oh noted as products are approved by the FDA it was appropriate to evaluate the Board's current regulation to establish flexibility in the regulation for furnishing of additional opioid antagonists approved by the FDA. Dr. Oh thanked the efforts of Dr. Gasper to assist staff with the development of revisions to CCR section 1746.3. Dr. Oh agreed with the recommendation to amend the regulation to both include the expansion of the provisions related to the authorized product as well as streamlining the process and reflecting the changes in availability of opioid antagonist in communities.

Members were provided the opportunity to comment on the implementation suggested in the meeting materials; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

VI. Discussion and Consideration of Proposal to Establish Requirements for a Pharmacist-in-Charge

Chairperson Oh advised the definition of a “pharmacist-in-charge” (PIC) was defined as a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy’s compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. As required by law every pharmacy must designate a PIC who is responsible for the pharmacy’s compliance with state and federal laws.

Chairperson Oh stated the Board also designated a precedential decision that confirmed a PIC of a pharmacy could be disciplined for a pharmacy’s violation of Section 4081 resulting from a pharmacy technician’s theft of controlled substances without the pharmacist having actual knowledge of, or authorizing, the violations. Dr. Oh recalled one of the strategic objectives established in the Board’s new strategic plan was to determine if the application requirements for a PIC were appropriate to ensure sufficient knowledge, skills and abilities for individuals seeking to serve as a PIC.

Chairperson Oh noted the Committee previously discussed that it was common for investigations to substantiate violations where a pharmacist may be designated as a PIC in name only or the designated PIC fails to exercise appropriate oversight of the operations. Dr. Oh added while the egregiousness of the violations varies, there were many instances where such an individual pharmacist ultimately was disciplined including losing their pharmacist license through the administrative process.

Chairperson Oh advised as part of the January 2022 Board Meeting, the Board previously approved a draft attestation that would be required to be completed by the proposed PIC as part of the approval process. The language of the attestation was included in the meeting materials. Dr. Oh advised members also voted to require completion of a Board-provided training program for a proposed PIC as part of the approval process. These changes were sought through proposed amendments to CCR section 1709.1. Following the Board’s action, the rulemaking materials were submitted to the Department. As part of its review, the Department

suggested additional changes to the language to provide clarification on the attestation statement and process, and to include the name of the training program in the regulation text as included in the meeting materials. Dr. Oh noted being comfortable with the changes recommended.

Members were provided the opportunity to comment and commented in support of the suggested changes to the language. Members agreed of delaying the implementation for six months. Member Crowley suggested discussing have a minimum number of hours for the PIC to work. Chairperson Oh agreed it could be discussed at a future meeting.

Motion: The Board hereby rescinds prior posted text and approves the proposed regulatory text and changes to CCR section 1709.1 as proposed to be amended in the meeting materials, authorize the Executive Officer to further refine the language consistent with the policy discussions and direct staff to submit all approved text to the Director of the Department of Consumer Affairs and Business, Consumer Services and Housing Agency for review. If no adverse comments, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the package, and set the matter for hearing if requested. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at section 1709.1 as noticed for public comment.

Title 16. Board of Pharmacy Proposed Text

Proposed changes to current regulation text are indicated with ~~single strikethrough~~ for deletions and single underline for additions. Recommended proposed additions are indicated in double underline and recommended proposed deletion with ~~double strikethrough~~.

Amend Section 1709.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1709.1. Designation of Pharmacist-In-Charge

- (a) The pharmacist-in-charge (PIC) of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy. Prior to approval of the board, a proposed pharmacist in charge shall complete an attestation confirming their understanding of the roles and responsibilities of a pharmacist in charge and the legal prohibitions of the pharmacy owner to subvert the efforts of a pharmacist in charge, and as part of the application and notice process set forth in Section 1709 of this Division ("application"), a pharmacy shall submit its proposed PIC. The PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course within two years prior to the date of application. The PIC shall complete an attestation statement in compliance with this section. For purposes of this section, a completed attestation statement shall include all of the following: name of the proposed pharmacist-in-charge, the individual's license number, a statement that they have read Sections 4036.5, 4081, 4113, and 4330 of the Business and Professions Code and this section, and a statement identifying the date that the proposed PIC took the board's training course, and a declaration signed under penalty of perjury of the laws of the State of California that the information provided by the individual is true and correct. ~~The proposed pharmacist in charge shall also provide proof demonstrating completion of a Board approved training course on the role of a pharmacist in charge within the past two years.~~
- (b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
- (c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
- (d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.

- (e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
- (f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
- (g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4036.5, 4081, 4113, 4305 and 4330, Business and Professions Code.

M/S: Patel/Crowley

Members of the public were provided an opportunity to comment; however, no comments were provided.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Crowley	Support
Oh	Support
Patel	Support
Weisz	Not present

Members previously commented in support of the six months delayed implementation.

Motion: Include within the rulemaking package for CCR section 1709.1 a request to the Office of Administrative Law for a later effective date that is six months following the date of approval of the amendments to CCR section 1709.1

M/S: Crowley/Patel

Members of the public were provided an opportunity to comment; however, no comments were provided.

Support: 3 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Crowley	Support
Oh	Support
Patel	Support
Weisz	Not present

Chairperson Oh noted the recommendation would be considered at the Board meeting the following week and staff would finalize the training in the interim.

The Committee took a break from 10:27 a.m. to 10:40 a.m. Roll call was taken. Members present included: Jig Patel, Licensee Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum was established.

VII. Discussion and Consideration of Discontinuance of Business by a Pharmacy and Potential Changes to Pharmacy Law to Ensure Continuity of

Patient Care Discussion and Consideration of Committee's Strategic Plan Objectives

Chairperson Oh introduced the Committee's first opportunity to discuss the Board's requirements for discontinuance of business (DOB) referring to the meeting materials for relevant provisions of pharmacy law.

Chairperson Oh advised the Board's current DOB process requires notification to the Board noting the current provisions in the law does not establish conditions for continuity of patient care which Dr. Oh believed to be very problematic and appeared contrary to the Board's mandate. Dr. Oh referenced meeting materials citing two general areas of complaints received related to this issue including scenarios where a pharmacy has closed and a patient cannot receive a refill because they were unable to contact the pharmacy to request a prescription transfer; or where a pharmacy has closed and transferred patient prescription refills to another pharmacy not of the patient's choosing. Dr. Oh agreed in both scenarios, patient care was impeded and patients many times are required to seek a new prescription from their prescriber. Dr. Oh stated belief that the language included in the meeting materials from the Board's Disciplinary Guidelines could serve as a guide to address this issue.

Chairperson Oh advised policy questions to facilitate the policy discussion were included in the meeting materials.

Policy Question #1: Should the Board consider establishing requirements to facilitate continuity of patient care in the event of a pharmacy closure?

Members were provided the opportunity to comment. Members agreed there should be some minimum requirements to ensure for the continuity of care for patients without being too deeply involved in business decisions. Members agreed patients need to know where to get their refills and prescriptions when a pharmacy closes permanently.

Members briefly discussed possible requirements. Ms. Sodergren provided if desired by the Committee, language could be developed to build in timeframes as requested.

Members inquired how this could be enforced. Ms. Sodergren advised the Board retains jurisdiction after the license is canceled and there are avenues for the Board to explore.

Members agreed of the concept moving forward.

Members of the public were provided the opportunity to comment; however, no comments were made.

Policy Question #2: Should the Board consider establishing a timeframe within which notification to patients is required in advance of a pharmacy closure?

Members were provided the opportunity to comment. Members discussed possible required notification as two weeks to 90 days with an emergency caveat for natural disaster. Members discussed methods of notification including emails and letters.

Members of the public were provided the opportunity to comment.

A representative of CVS Health explained when an independent pharmacist sells the pharmacy, the sale price is based on retention. If notification is required too far in advance of closure, it will affect the value of the pharmacy. It was reported most states require two weeks to one month.

The Committee heard a recommendation to have the electronic or paper notification be described as best faith effort to notify.

Policy Question #3:

Should the Board consider specifying some of the elements of such a notification i.e., the process to request a prescription transfer, where pharmacy records will be transferred to and maintained, or any other options the patient does or should be able to provide input?

Members were provided the opportunity to comment. Members did not want to list out requirements but noted it would be helpful to provide patients information on how to transfer prescriptions.

Members of the public were provided the opportunity to comment; however, no comments were made.

Policy Question #4: Should the Board be provided with a copy of the notification?

Members were provided the opportunity to comment. Members agreed the Board should be provided with a copy of the notification.

Members of the public were provided the opportunity to comment; however, no comments were made.

Policy Question #5: Should the Board provide expectations on prescriptions remaining in the will call area and provisions for reversing billing, etc.?

Members were provided the opportunity to comment. Members agreed if the prescription wasn't picked up it should be reversed. It is a standard process and if it is not reversed, it is fraud. Members agreed it should be a given.

Members of the public were provided the opportunity to comment; however, no comments were made.

Policy Question #6: There are some pharmacy transactions where a pharmacy sells a portion of its business to another pharmacy, e.g., sells the portion of the pharmacy operations related to prescription dispensing but maintains the compounding portion of the business. In such an instance, should the Board establish notification requirements to patients in advance of the transaction to ensure patients are aware of the transition in care?

Members were provided the opportunity to comment. Members agreed in a perfect world this would be nice but was not the most crucial element.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Oh noted as there appeared to be agreement that additional regulation in this area is necessary. Dr. Oh recommend that staff develop a proposal consistent with the Committee's discussion for consideration at a future meeting.

VIII. Discussion and Consideration of Legal Requirements for Nonresident Pharmacies include Possible Change to Require Licensure by the Pharmacist-in-Charge

Chairperson Oh advised California law requires any pharmacy located outside of California that provides services into California shall be considered a nonresident pharmacy and requires licensure as a nonresident pharmacy. Dr. Oh noted there are currently no requirements for pharmacists working in these pharmacies to be licensed in California even when providing care to California patients. Additionally, there were no requirements for the PIC of the nonresident pharmacy to be licensed in California. Dr. Oh noted California law currently establishes a prohibition for a pharmacist to provide services to California patients if the pharmacist's license was revoked in California.

Chairperson Oh provided the National Association of Boards of Pharmacy (NABP) establishes model rules for Boards to consider as part of its regulation of the practice of pharmacy. Dr. Oh advised the NABP model rules regarding the regulation of nonresident pharmacies includes a requirement for a pharmacist to be licensed in the state in which it is providing services to patients. Dr. Oh noted states have a range of requirements for licensure of staff working out of state but providing care to their residents.

Chairperson Oh advised the meeting materials provided a few examples of actions taken against nonresident pharmacies. Dr. Oh noted the Board was considering changes to strengthen the requirements for a PIC. Dr. Oh noted it was also appropriate to ensure pharmacists appointed as a PIC in a nonresident pharmacy also have a full understanding of the law to ensure that Californians who receive prescription drugs from nonresident pharmacies have protections that are similar to those received by resident pharmacies in California.

Members were provided an opportunity to comment. Members Oh and Crowley felt at minimum the PIC should be licensed in California. Member Patel noted it would be difficult for some to pass and wondered how many California consumers would be impacted if there was a gap in services available to patients and voiced concern for delayed patient care. Member Patel noted he was unsure about requiring licensure. Dr. Crowley noted a delayed implementation would be needed but ultimately there needs to be some person in the facility who is responsible for compliance if the nonresident pharmacy is providing prescriptions for California residents.

Members discussed the meeting materials indicated the PICs didn't fully understand laws in California (e.g., verify controlled prescription with CURES, performing corresponding responsibility, etc.).

Members discussed how nonresident pharmacies were required to follow California laws. Members also discussed if a nonresident pharmacy is providing prescriptions to a California consumer, the California consumer should receive prescriptions at the same standard regardless of where the pharmacy is located. Requiring the PIC be licensed in California as a pharmacist would provide someone who is responsible for complying with California law in the pharmacy. There was concern about the continuance of care gap if the nonresident pharmacy is unable to provide a PIC licensed in California.

Members of the public were provided the opportunity to comment.

A representative of CVS Health commented about the burden on the pharmacist to become licensed in California as the pharmacist would be required to take the CPJE in California as well as possibly retake the NAPLEX. The representative recommended looking at the Iowa language that requires registration rather than licensure.

A representative from CRA expressed concerns about it possibly impeding access to health care in California as well as the burden on the pharmacists. The representative urged the Committee not to institute the requirement and look at registration rather than full licensure.

Chairperson Oh stated he would work with staff on a possible proposal and bring it back to the Committee for further consideration.

Chairperson Oh noted for the record the CPJE is administered available in California and other states too.

IX. Licensing Statistics

Chairperson Oh referenced meeting materials containing licensing statistics for the first quarter of the fiscal year. Dr. Oh advised during the quarter the Board issued over 3,000 individual licenses and 129 site licenses. The Board also issued 91 temporary licenses, 55 of which are for community pharmacies. The Board received over 4,500 applications during this quarter including 90 applications for community pharmacies, the vast majority of

which are for nonchain pharmacies. The Board received 124 temporary applications during the quarter including 65 for community pharmacies.

Chairperson Oh specifically highlighted the pharmacy workload as this is one area where licensing times are outside of the Board's performance measures. Dr. Oh noted as the Chairperson, he has been monitoring processing times and working with the Executive Officer on this issue. Dr. Oh acknowledged the work the licensing staff perform each day which is extensive with vacancies and recruitment challenges contributing factors to these process times. Dr. Oh noted staff also experience challenges with applicants that provide incomplete or conflicting information during the application process and noted full transparency by entities seeking licensure at the time application would aid staff significantly in reducing processing times.

Members were provided an opportunity to comment; however, no comments were provided.

Members of the public were provided comment. A member of the public requested better communication on the status of applications, access to application status online and acknowledgement of applications received.

IX. Future Committee Dates

Chairperson Oh advised the next meeting was scheduled for January 24, 2022.

X. Adjournment

The meeting adjourned at 11:34 a.m.