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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

LICENSING COMMITTEE REPORT
January 24, 2023

Seung Oh, Licensee Member, Chairperson
Jignesh Patel, Licensee Member, Vice-Chairperson
Indira Cameron-Banks, Public Member
Trevor Chandler, Public Member
Jessica Crowley, Licensee Member
Jason Weisz, Public Member

I. Call to Order and Establishment of Quorum

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

*(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

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

Attachment 1 includes the draft minutes from the October 18, 2022, meeting.

IV. 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) Including Proposed Amendment to Title 16, California Code of Regulations Section 1746.3

Relevant Law
Effective January 1, 2023, amendments to Business and Professions Code section 4052.01 will provide the authority for a pharmacist to furnish federal Food Drug and Administration approved opioid antagonist in accordance with standardized procedures or protocols developed and approved by the Board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. The section further details areas that must be included in the standardized procedures.

California Code of Regulations Section 1746.3 establishes the requirements of the standardized procedures established for a pharmacist to furnish naloxone hydrochloride pursuant to section 4052.01.

Background

In 2014, pharmacists were granted authority to furnish naloxone hydrochloride in accordance with standardized procedures established. Following enactment of the statute, the Board, as required in the statute, developed the regulation necessary to implement the statute.

Subsequent to these authorities, additional access points have been established for patients to access naloxone hydrochloride, 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.

The California Department of Public Health issued a standing order that allows libraries and other community organizations that are currently working with a physician to obtain and distribute naloxone to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist; and allow for the administration of the naloxone.

In April 2021, the FDA announced its approval of higher dose of naloxone hydrochloride nasal spray. The FDA has approved naloxone hydrochloride nasal spray products in 2mg, 4 mg and 8 mg naloxone nasal spray products and noted that naloxone is a medicine that can be administered by individuals with or without medical training to help reduce opioid overdose deaths.

As products are approved by the FDA, it appears appropriate to evaluate the Board's current regulation to establish flexibility in the regulation for the furnishing of additional opioid antagonists approved by the FDA.

As discussed during the October 2022 Meeting, staff worked with Dr. James Gasper, PharmD., Psychiatric and Substance Use Disorder Pharmacist, developing draft of revisions to California Code of Regulations section 1746.3. As required in the statute, on November 18, 2022, the draft regulation language was provided to California Society of Addiction Medicine (CSAM), the Medical Board of California and the California Pharmacists Association. Comments received thus far from CSAM and the Medical Board are supportive of the streamlined regulations. CSAM offered one specific comment, provided below:

- Suggest consideration of moving the 2b statement for overdose reversal earlier.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review the proposed changes. A summary of the changes is detailed below:

1. "Naloxone hydrochloride: is replaced with the generic term "opioid antagonist"
2. Training requirement is updated to allow for completion of training completed in a Board recognized school of pharmacy.
3. Removes the screening criteria. Any individual seeking an opioid antagonist should have access, similar to the expansion of such products in schools and libraries.
4. Product selection should be determined by the pharmacist using professional judgement and not limited to specified forms of an FDA approved product form.
5. Labeling requirements should be consistent with other prescription medications dispensed. The Board should no longer be posting sample labels.
6. Fact sheets are not necessary as the FDA approved medication guide will provide the necessary information.
7. Notification requirements have been updated to only require notification at the request of the patient.
8. Documentation and privacy requirements should be consistent with any other product dispensed by the pharmacy.

Attachment 2 includes a copy of the proposed language.

Following discussion members agree with the proposed changes, the following motion could be used to facilitate incorporation of the change.

> **Possible Motion**: Recommend initiation of a rulemaking to amend CCR section 1746.3 as proposed to be amended. Authorize the executive officer to further refine the language consistent with the policy discussions, including those of the Medical Board of California, and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, 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 1746.3 as noticed for public comment.

V. Discussion and Consideration of Possible State Protocol to Facilitate Pharmacist Provided Medication-Assisted Treatment Pursuant to Business and Professions Code section 4052(a)(14), Including Proposed Addition of Title 16, California Code of Regulations Section 1746.6

Relevant Law
BPC section 4052(a)(14) establishes authority for a pharmacist to provide medication-assisted treatment pursuant to a state protocol, to the extend authorized by federal law.

Background
Medication-assisted treatment (MAT) is used to treat substance use disorders as well as sustain recovery and prevent overdose. Medications used in MAT are approved by the Food and Drug Administration and MAT programs are clinically driven and tailored to meet each patient's needs. As published by SAMSHA, "Research shows that a combination of medication and therapy can successfully treat these disorders, and for some people struggling with addiction, MAT can help sustain recovery. MAT is also used to prevent or reduce opioid overdose."

In 2021, as part of the Board's sunset measure, pharmacist authority was expanded to allow pharmacists authority to provide MAT pursuant to a state protocol.

More recently, President Biden signed legislation to expand access to MAT. Recently SAMHSA has published information about the removal of the DATA Waiver (X-Waiver) Requirement. Information published includes that all practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice site if permitted by applicable state law and SAMHSA encourages them to do so.

For Committee Consideration and Discussion
During the meeting members will have the first opportunity to review a draft protocol developed to facilitate implementation of the MAT authority. The protocol was developed in consultation with experts in the field including:

1. Dr. James Gasper, BCPP, Psychiatric and Substance Use Disorder Pharmacist, California Department of Health Care Services
2. Dr. Talia Puzantian, BCPP, Professor of Clinical Sciences, KGI School of Pharmacy and Health Sciences
3. Dr. Michelle Geier, BCPP, Psychiatric Pharmacy Supervisor, San Francisco Department of Public Health, Behavioral Health Services

Unlike the prior agenda item, development of this protocol resides solely with the Board.

Attachment 3 includes a copy of the proposed language.

Following discussion, should members agree with the proposed protocol, the following motion could be used to facilitate initiation of the rulemaking process.

> **Possible Motion**: Recommend initiation of a rulemaking to add CCR section 1746.6 as proposed. Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, 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 1746.6 as noticed for public comment.

VI. Discussion and Consideration of Pharmacist Provided HIV Preexposure and Postexposure Prophylaxis, Including Presentations

Relevant Law

BPC 4052 generally establishes the scope of practice for pharmacists. Included in the provisions are:

- Authority to initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provide with prescriptive authority.
- Authority to perform procedures or functions in a licensed health care facility as authorized in Section 4052.1.
- Authority to perform procedures or functions as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, and others as specified and as authorized in Section 4052.2.
- Furnish medications as described including HIV preexposure prophylaxis as authorized in Section 4052.02 and HIV postexposure prophylaxis as authorized in Section 4052.03.
- Initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement as specified.

BPC 4052.02 further defines the provisions for pharmacist authority related to initiating and furnishing HIV preexposure prophylaxis as defined. As required by this section, prior to furnishing preexposure prophylaxis a pharmacist must complete specified training. The section explicitly provides that a pharmacist

shall furnish at least a 30-day supply, and up to a 60-day supply under specified conditions, including:

1. The patient is HIV negative.
2. The patient does not report any signs or symptoms of acute HIV infection.
3. The patient does not report taking any contraindicated medications.
4. The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis and the importance of timely testing and treatment as applicable for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy.
5. The pharmacist maintains records.
6. The pharmacist does not furnish more than a 60-day supply as specified.
7. The pharmacist notifies the patient's primary care providers or meets other requirements.

BPC 4052.03 further defines the provisions for pharmacist authority related to initiating and furnishing HIV postexposure prophylaxis under specified conditions including completion of specified training and the following conditions:

1. The pharmacist screens the patient and determines exposure occurred within the previous 72 hours and the patient meets clinical guidelines established by the CDC.
2. The pharmacist either provides testing, or determines the patient is willing to undergoing testing.
3. The pharmacist provides mandatory consultation.
4. The pharmacist notifies the patient's primary care provider or meets other requirements.

CCR Section 1747 establishes the mandatory elements of a training to meet the requirements of Sections 4052.02 and 4052.03.

Background

Senate Bill 159 (Chapter 532, Statutes of 2019) established authorization for pharmacists to furnish preexposure and post exposure HIV prophylaxis (PrEP and PEP) as generally described above. This legislation sought to expand access to life saving HIV prevention medications.

As required by the statute, the Board's emergency regulations became effective April 30, 2020, with permanent regulations becoming effective June 8, 2021.

Following implementation of the regulation the Board and several other entities developed training programs that could be completed to meet the requirements of the statute and regulation.

As part of the October 2022 meeting, members received a presentation on research underway on pharmacists—furnished HIV prevention. The Board will receive a presentation on the outcome of the research when available.

In addition to providing HIV PrEP and PEP under the provisions established in Senate Bill 159, pharmacist may also provide such services under a collaborative practice agreement as well through traditional pharmacist dispensing.

For Committee Consideration and Discussion
During the meeting members will receive presentations on pharmacist-driven models used to expand access to HIV PrEP and PEP.

- Presenters include Dr. Maria Lopez, AAHIVP, President, Clinical Pharmacy Services, Residency Program Director, Mission Wellness Pharmacy.
- Dr. Clint Hopkins, APh, CEO Pucci's Pharmacy / Pucci's LTC Pharmacy

VII. Discussion, Consideration and Possible Action on Discontinuance of Business by a Pharmacy and Potential Changes to Title 16, California Code of Regulations Section 1708.2

Relevant Law
BPC 4333 generally provides in part that all prescriptions filled by a pharmacy and all other records required shall be maintained on the premises and available for inspection. Further, in cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

CCR Section 1708.2 requires any permit holder to contact the Board prior to transferring or selling any dangerous drugs, devices, or hypodermic inventory as a result of a termination of business or bankruptcy proceedings and shall follow official instructions given by the Board applicable to the transaction.

Background
The Board's current discontinuance of business provisions require a licensee to notify the Board and provide specified information; however, there are no provisions established to establish conditions for continuity of patient care.

Related to this, at times staff receive complaints from consumers and policy makers in two general areas:

1. A pharmacy has closed, and a patient cannot receive a refill because they are unable to contact the pharmacy to request a prescription transfer.
2. A pharmacy has closed and transferred patient prescription refills to another pharmacy not of the patient's choosing.

In both such scenarios, patient care is impeded and patients many times are required to seek a new prescription from their prescriber.

The Board's Disciplinary Guidelines establish requirements for continuity of patient care in the event a premises license is surrendered or revoked, yet no similar requirements exist for licenses discontinuing business. Specifically, the guidelines provide:

> Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty days.

<u>Prior Committee Discussion</u>

As part of its last meeting members considered the Board's current discontinuance of business requirements as well as several policy questions detailed below.

1. Should the Board consider establishing requirements to facilitate continuity of patient care in the event of a pharmacy closure?
2. Should the Board consider establishing a timeframe within which notification to patients is required in advance of a pharmacy closure?
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?
4. Should the Board be provided with a copy of the notification?
5. Should the Board provide expectations on prescriptions remaining in the will call area and provisions for reversing billing, etc.
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?

After consideration of the issue and policy questions, members determined changes to the current discontinuance of business requirements was appropriate and requested that staff develop proposed regulation language.

For Committee Consideration and Discussion

During the meeting members will have the opportunity to review the draft regulation language. Below is a summary of the proposed changes:

1. Establish a requirement that the pharmacy provide a written notice in advance of the closure that includes specified information include including:
    a. The name of the patient or representative
    b. The name and address of the pharmacy closing
    c. The name of the pharmacy where patient records will be transferred
    d. Information on how to request a prescription transfer prior to closure of the pharmacy
2. Establish a requirement that all prescriptions for which reimbursement was sought that are not picked up by the patients must be reversed.
3. The Board must be provided a copy of the notice.
4. Requires the pharmacist-in-charge (PIC) or the owner to certify compliance as specified.

In addition to considering the proposed language, it may be appropriate for the committee to consider a few additional policy questions.

1. The time frame within which the notice must be provided to impacted patients.
2. The parameters defining the patients that must receive the notice (i.e., patients that received a prescription filled within the last 365 days.)
3. Does the committee wish to specify the type of written notice (e.g. via email, written correspondence, etc.) is acceptable or does the committee believe any form of written communication is sufficient?

Should the committee believe following consideration of the language and additional policy questions action is appropriate, the following motion could be used to offer a recommendation to the Board for consideration.

Possible Motion: Recommend initiation of a rulemaking to amend CCR section 1708.2 as proposed and further refined by the Committee.

Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, 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 1708.2 as noticed for public comment.

Attachment 4 includes a copy of the proposed amendments to CCR section 1708.2.

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

Relevant Law
BPC Section 4112 provides that any pharmacy located outside this state that provides services into California shall be considered a nonresident pharmacy. Further this section requires licensure as a nonresident pharmacy. The section also established required disclosure of specified information. Subsection (g) provides that a nonresident pharmacy shall not allow a pharmacist whose license has been revoked by the board to provide pharmacy-related services to a person residing in California.

Background
As part of the application process, the nonresident pharmacy is required to provide the name of the designated pharmacist-in-charge. Under current law, the PIC is not required to hold a license in California.

The National Associations of Boards of Pharmacy Model Rules include that, "The 'Practice of Pharmacy in this State' includes shipping Prescription Drugs into this State from another jurisdiction. However, this is not meant to be construed as a licensure requirement for every Pharmacist that is employed at a Nonresident Pharmacy unless they are specifically engaged in the Practice of Pharmacy and provide services to residents in this state."

States have varying provisions related to the licensure requirements for pharmacists providing services into their respective jurisdictions. As an example:

- Oregon law provides that every non-resident pharmacy shall designate an Oregon licensed Pharmacist-in-Charge, who shall be responsible for all pharmacy services provided to residents in Oregon, and to provide supervision and control in the pharmacy.

- Massachusetts is developing regulations to regulate nonresident pharmacies. As part of the proposed rules the nonresident pharmacy will be required to designate a pharmacist that holds a Massachusetts pharmacist license.
- Iowa provides that every nonresident pharmacy is required to have a PIC who is either currently licensed to practice pharmacy in Iowa or who is registered with the Board. If the PIC is not currently licensed to practice pharmacy in Iowa and is not registered with the Board, the PIC must apply for registration as a nonresident PIC. As part of the registration process, the PIC must complete the Board's training module, "Iowa Pharmacy Law Bootcamp: Education for Iowa Nonresident Pharmacists," prior to submission of the application.
- Maryland provides that a nonresident pharmacy shall have a pharmacist on staff licensed by the Maryland Board of Pharmacy who is designated as the pharmacist responsible for providing pharmaceutical services to patients in the state.
- Virginia requires a nonresident pharmacy to designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance.

Over the years the Board has disciplined nonresident pharmacies for violations of California Law. As an example, the Board disciplined Walgreens, including two nonresident pharmacy permits. At times, these nonresident pharmacies have argued that their actions were in accordance with the pharmacy law of the state the pharmacy is located within. The Board has also issued citations against nonresident pharmacies, as an example ESI Mail Pharmacy, Inc., for violations of California law.

Prior Committee Discussion

During its October meeting the Committee noted the Board's efforts to strengthen the requirements for a PIC, to ensure pharmacists appointed as a PIC in California have a full understanding of the requirements of a PIC and to empower such individuals to exercise control over the pharmacy operations. Members also considered if changes were appropriate to the current regulation of nonresident pharmacies is appropriate to ensure that Californians who received prescription drugs from nonresident pharmacies have protections that are similar to those received by resident pharmacies in California.

Members spoke in support of establishing a requirement for a California licensed pharmacist to be the PIC of a nonresident pharmacy providing services to California patients. Members noted some potential challenges with gaps in care if a nonresident pharmacy does not have such an individual to

serve in such a capacity as well as the need for a transition period to allow for nonresident pharmacies to achieve compliance.

For Committee Consideration and Discussion
Subsequent to the meeting, staff developed possible statutory language that could be used to facilitate such a requirement. During the meeting it is recommended that members discuss the language and determine if the solution offered is appropriate.

> **Motion**: Recommend sponsorship of changes to Business and Professions Code section 4112 related to legal requirements for nonresident pharmacies to require licensure by the pharmacist-in-charge consistent with the language presented.

Attachment 5 includes a copy of the draft statutory language.

IX. Discussion, Consideration and Possible Action on Continuing Education Requirements for Pharmacist and Pharmacy Technicians, Including Development of Regulation Language to Facilitate Implementation of Recently Enacted Legislation

Relevant Law
BPC section 4202 establishes the licensure requirements for a pharmacy technician. As recently amended, this section will require a pharmacy technician to complete one hour of continuing education in cultural competency during the preceding renewal.

BPC section 4231 establishes the renewal requirements for pharmacists. As recently amended, this section will require pharmacists to complete at least one hour of continuing education in a cultural competency course as part of the required CE for each renewal cycle.

CCR Section 1732.5 further defines the continuing education renewal requirements for pharmacists.

Background
Assembly Bill 2194 (Ward, Chapter 958, Statutes of 2022) requires, effective January 1, 2024, pharmacists and pharmacy technicians must complete at least one-hour course in cultural competency during the two years preceding the renewal application period. Further, the provisions of the measure prohibit the Board from renewing a pharmacist or pharmacy technician license unless the individual has completed the course.

Prior Discussion

As part of the October 2022 Enforcement and Compounding Committee Meeting members discussed implementation of AB 2194 and recommended that implementation be spearheaded by the Licensing Committee. Members noted the need to amend existing regulation CCR 1732.5 to update the renewal requirements for pharmacists and the need to establish new regulation to define the renewal requirements for pharmacy technicians.

During this discussion, it was noted that the Board's prior action to consolidate all CE related requirements for pharmacists into a single regulation was previously initiated, but subsequently placed on hold in part because of the pending changes in AB 2194.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review the draft regulation language. As proposed, the language amends 1732.5 to implement the provisions of AB 2194 for pharmacists as well as consolidate the various CE requirements for pharmacists performing specified functions.

Additionally, the language establishes new regulations defining the continuing education requirements for pharmacy technicians that mirror the process used for pharmacist renewal.

During the meeting it is suggested that members review the draft regulation to determine if the proposed language is appropriate. Should members believe the proposed language is appropriate, the following motion could be used to offer a recommendation to the Board for consideration.

> **Possible Motion**: Recommend initiation of a rulemaking to amend CCR section 1732.5 and add section 1732.8 as proposed and further refined by the Committee. Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, 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 sections 1732.5 and 1732.8 as noticed for public comment.

Attachment 6 includes a copy of the proposed amendments to CCR section 1732.5 and addition of CCR 1732.8.

X. Discussion and Consideration of Business and Professions Code section 4111
Relevant Law

BPC Section 4111 provides that the Board shall not issue or renew a license to conduct a pharmacy to:

1. An individual authorized to prescribe
2. A person who shares a community or other financial interest with a prescriber.
3. Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership.

This section further specifies that the Board may require any information reasonably necessary for the enforcement of this section.

Background

California is a community property state. This means that generally property acquired by either spouse during a marriage is presumed to be equally owned by both spouses. There are some exceptions, such as prenuptial agreements, where property acquired may not be community property depending on the agreement of the parties to a valid prenuptial agreement. However, the existence of a prenuptial agreement in and of itself may or may not remedy the financial interest that each spouse has in the other's businesses. For example, the money earned by one spouse in their pharmacy would likely be used to support the home, family, or lifestyle of the couple. Therefore, while there may be no specific community property interest as defined in the Family Code, there may still be a community or financial interest that would apply under this code section.

As part of the application process for a pharmacy, the Board requires disclosure of ownership information. To confirm compliance with the above provisions, the Board requests information specifically related to officers and owners of individuals authorized to prescribe in California.

Historically as part of the application process, if an applicant disclosed a familial relationship with a prescriber, the Board would inquire about the nature of the relationship to confirm compliance with Pharmacy Law prior to making a licensing decision. For a number of years, the Board accepted representations from the applicant that the prescriber did not have any financial or community interest in the pharmacy. Unfortunately, this was something of a shallow view of the law and failed to take into account the realities of family life, the requirement of the Family Code that spouses owe a duty of care towards each other, and the conflicts of interest that the statute was designed to protect.

As the Board's application and assessment process evolved, most notably in response to changes in the ownership assessment process, Board staff began looking deeper into the financial arrangements between the applicant spouse and the prescriber spouse and came to the realization and understanding that the pre- or post-nuptial agreements would not necessarily resolve the issue of having a community or financial interest in the pharmacy.

The sole focus on the financial aspects of the property does not take into account policy considerations such as financial incentives for a prescriber to direct prescriptions to their spouses' pharmacy, or pharmacists exercising their duty of corresponding responsibility and whether that duty would be impacted when

reviewing a prescription written by a pharmacist's spouse of the spouse's practice group.

Prior Committee Discussion
During the July 2022 Committee Meeting, members discussed the issue of prohibited ownership related a prescriber's spouse. Following discussions and consideration of possible statutory changes, BPC section 4111 could be made that would continue to meet the legislative intent intact, while creating flexibility for an otherwise authorized individual to own or operate a pharmacy. Members noted agreement with the proposed language and noted support if such a change was pursued.

During that meeting, public comment suggested that the Committee consider further expanding authority for pharmacists that furnish medications be allowed to owner a pharmacy.

For Committee Consideration and Discussion
Subsequent to the July 2022 meeting, staff worked with counsel to develop additional changes to BPC 4111 would be appropriate to expand pharmacist ownership provisions.

Attached for the committee's consideration are potential changes. As drafted, the proposal would expand provisions to allow a pharmacist that is authorized to issue a drug order under specified conditions.

Any change in the provisions, if deemed appropriate, will require a legislative change. Should members believe that the language is appropriate, and it believes it appropriate to sponsor legislation, the following motion could be used:

> **Motion**: Recommend sponsorship of changes to Business and Professions Code section 4111 related to ownership prohibitions consistent with the language presented.

Attachment 7 includes possible language that could be used to facilitate a change in the statute.

XI. Discussion and Consideration of Provisions for Remote Processing

Relevant Law
BPC 4071.1, subdivision (a) permits a pharmacist (or a prescriber or prescriber's agent) to "electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital." This is known as "remote order entry."

Background
As part of the Board's response to the COVID-19 public health emergency

and the initial need for social distancing, a "Remote Processing Waiver" was approved by the Board. This waiver is scheduled to expire May 28, 2023. Under the provisions of the waiver, legal authorization for remote processing was expanded to allow for greater flexibility under pandemic conditions. "Remote Processing" is defined to mean the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy. The Waiver says that, in addition to the provisions of BPC section 4071.1, pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under the Waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The Waiver does not permit dispensing of a drug or final product verification by remote processing. Further, the Waiver expands the provisions of section 4071.1 to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

There are certain limitations and qualifiers regarding the Waiver, including that a pharmacist, pharmacy technician, or pharmacist intern relying on the Waiver must be licensed in California, and must be engaged in processing medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy. The pharmacy must have authorized remote processing and must have appropriate policies and procedures as well as adequate training on those policies and procedures.

Last year the Board voted to sponsor legislation to make certain provisions of the remote processing waiver permanent. The Board sponsored legislation, but the legislation did not move because of significant opposition.

During the October 2022 Board meeting, members received public comment requesting that the Board schedule discussion on the issue.

For Committee Consideration and Discussion

During the meeting members will have the opportunity to consider this issue. To assist the committee in its consideration, the following questions may be appropriate to consider.

1. After May 28, 2023, is there any continuing need for expanded remote processing authority? Should the law revert to the allowance under BPC section 4071.1, subdivision (a), only for "remote order entry" by pharmacists (and prescribers and their agents)? Is even that authority for pharmacist "remote order entry" still necessary? Should this answer depend on the type of prescription, outpatient versus inpatient?
2. What use was being made of the "remote order entry" provision prior to the Waiver, and the pandemic that prompted the Waiver? What do the stakeholders anticipate being the need for remote order entry or remote processing going forward? Is there something beyond what is already permitted by BPC section 4071.1 that will be required?
3. Have operations under the Waiver revealed benefits to expanded remote processing authority that are worth carrying forward into a post-pandemic regulatory environment?
    - Is it desirable to permit pharmacists to also remotely receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V?
    - Is it desirable to permit pharmacists to remotely perform tasks like order entry, other data entry, prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration?
    - Is it desirable to permit pharmacy technicians and pharmacist interns to remotely perform nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders under supervision by a pharmacist that is also remote, using technology that ensures a pharmacist is (1) readily available to answer questions of a pharmacy technician or pharmacist intern; and (2) verifies the work performed by the pharmacy technician or pharmacist intern.
    - Are there other functions that pharmacists or other pharmacy staff should be allowed to perform remotely or from a non-pharmacy location?
    - What does the data reveal about the use to which the Waiver has been put? What can the stakeholders share about perceived benefits and risks of remote processing? What are the technology

solutions that best facilitate remote processing? Have there been advances in technology as a result of expanded authority under the Waiver?

2. If so, in a post-pandemic regulatory environment, under what circumstances should these additional tasks and functions be permitted? Should it be limited only to pharmacists, as is remote order entry under BPC section 4071.1?
3. Should the pharmacist-in-charge be required to authorize or decline use of remote functions for the pharmacy? Should the pharmacist-in-charge be required to declare that remote processing functions are necessary and advisable for the pharmacy's practice, prior to their use?
4. Can a subsequent pharmacist-in-charge make a contrary determination/declaration?
5. Should pharmacy staff members be required to consent to performing remote functions?
6. Should remote order entry and remote processing functions be authorized only for California-licensed pharmacists (or pharmacy technicians and pharmacist interns), and only in connection with California-licensed pharmacies, as per the Waiver? Should it be limited to pharmacy staff also located (not just licensed) in California? Should it apply outside of California? Or should it be left to the states in which out-of-state pharmacies and pharmacy staff are located to decide whether or under what conditions remote order entry/remote processing will be permitted? Should California law specify that non-resident pharmacies must be guided by home state law?
7. If it is not so limited, is there any perceived risk if these remote order entry/remote processing functions are performed in out-of-state or even out-of-country locations?
8. Should there be any "brick and mortar" requirements for remote order entry/remote processing authority? For instance, should these remote functions be allowed at home sites or other sites not licensed by the Board, or should they only be permitted at call centers that are licensed by the Board for this purpose, or are at least registered with the Board for tracking purposes?
9. If remote functions are permitted in home or unlicensed sites, should the law specify that those locations are subject to Board inspection? Would this provoke potential legal challenges?
10. If remote functions are allowed in homes or other unlicensed sites, what should be the record-keeping requirements applicable to the homes or unlicensed sites, versus the pharmacy?

11. Again, should the law specify that any remote site must be located in California?
12. Should there be any limit on the number of pharmacies for which any pharmacist, pharmacy technician, or pharmacist intern can perform functions remotely? Should there be a limit on the number of remote transactions that any pharmacy staff member can perform in a day? Should there be a limit on the geographical distance between the remote site and the pharmacy? Is it acceptable for a pharmacy staff member to work exclusively in a remote location, and to never be required to enter the pharmacy premises? Or should there be a requirement of some level of in-person work in a pharmacy, to balance remote work and prevent atrophy of skills?
13. Are there any perceived risks or problems with a pharmacy staff member in San Diego remotely processing prescriptions or orders for pharmacy patients located in Eureka? Or with a pharmacy staff member remotely processing above a certain threshold number of prescriptions or orders in a day? What about employees exclusively working remotely, and never in a pharmacy?
14. How should the pharmacy be required to track and trace prescription and order processing that is performed remotely, or by a mixture of remote and in-pharmacy staff? What kind of digital audit trail demonstrating the contributions of each pharmacy staff member will be maintained? How will the pharmacy ensure that pharmacy staff members are digitally positively identified, verified, and registered with regard to each processing function performed? How will those systems integrate functions performed remotely with those performed in-pharmacy?
15. What sort of requirements should be written into law for ensuring secure transmissions and maintenance of security and privacy of sensitive information?
16. What sort of records should the Board require that pharmacies produce regarding prescription and order processing that is entirely or partially performed remotely? Should the burden be on pharmacies that utilize remote processing functions to provide the Board with complete data on the pharmacy staff involved in each transaction? How should that be accomplished?
17. Should the pharmacy license or the license of the pharmacist-in-charge be subject to discipline, along with the licenses of the pharmacy staff members involved, in the event of misconduct that is associated with performance of remote processing functions?

18. Should remote processing sites be licensed by the Board, using a license affiliated with the pharmacy license, as with an automated drug delivery system? Or should the pharmacy be required to otherwise identify and register all remote processing sites with the Board?
19. Board investigators have seen instances of pharmacies employing call centers to market directly to patients or prescribers, to cold-call patients, and even to run test prescriptions for patients to test reimbursement, which may result in denials for patients at other pharmacies. If the Board authorizes remote order entry and/or remote processing, how does the Board prevent abuse?

IX. Future Committee Meeting Dates

- April 5, 2023
- July 19, 2023
- October 18, 2023

X. Adjournment

Attachment 1

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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

Date: October 25, 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.

(~~c~~ 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.

(~~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 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 sand 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.

(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.

(~~c~~ 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.

(~~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 <u>single underline</u> for additions. Recommended proposed additions are indicated in <u>double underline</u> 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.

Attachment 2

16 CCR § 1746.3

§ 1746.3. Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~.

A pharmacist furnishing an opioid antagonist ~~naloxone hydrochloride~~ pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(2) "Recipient" means the person to whom ~~naloxone hydrochloride~~ an opioid antagonist is furnished.

(b) Training. Prior to furnishing ~~naloxone hydrochloride~~ an opioid antagonist, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program or equivalent-based training program completed in a board recognized school of pharmacy specific to the use of opioid antagonists for overdose reversal. ~~naloxone hydrochloride such products including in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.~~

(c) Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~.

Before providing an opioid antagonist ~~naloxone hydrochloride~~, the pharmacist shall:

~~(1) Screen the potential recipient by asking the following questions:~~ Make a ~~reasonable inquiry to determine:~~

~~(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);~~

~~(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);~~

~~(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)~~

~~The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.~~

(~~2~~1) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the opioid antagonist ~~antidote naloxone~~.

(~~3~~2) When an opioid antagonist ~~naloxone hydrochloride~~ is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse

effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.
(C) The pharmacist shall answer any questions the recipient may have regarding ~~naloxone hydrochloride~~ the opioid antagonist.
(~~4~~3) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. ~~A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form.~~ A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.
(~~5~~4) Labeling: A pharmacist shall label the ~~naloxone hydrochloride~~ product consistent with law and regulations. The patient shall also receive the FDA approved medication guide. ~~Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website~~.
~~(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the current board-approved fact sheet. The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.~~
(~~7~~5) Notifications: ~~If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.~~
~~If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.~~
~~If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.~~ At the request of the patient, a pharmacist shall notify to the identified primary care provider of the product furnished or enter appropriate information in a shared patient record

system as permitted by the primary care provider. If the patient does not have or does not identify a primary care provider, the pharmacist shall provide the recipient a written record of the drug furnished along with a recommendation to consult with an appropriate health care provider of the patient's choice.
~~(8) Documentation: Each naloxone hydrochloride~~ A ~~product furnished by a pharmacist pursuant to this protocol shall be documented in~~ the pharmacy's ~~a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense in compliance with . The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.~~
~~(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.~~

Credits
NOTE: Authority cited: Section 4052.01, Business and Professions Code.
Reference: Section 4052.01, Business and Professions Code.

Attachment 3

Proposal to Add CCR Section 1746.6 Pharmacist Provided Medication-Assisted Treatment

(a) A pharmacist may initiate, modify, administer, or discontinue medication-assisted treatment pursuant to Section 4052(a)(14) consistent with all relevant provisions of federal law and shall satisfy the requirements of this section.
   a. The pharmacist possesses appropriate education and training to provide such treatment consistent with the established standard of care used by other health care practitioners providing medication-assisted treatment including nationally accepted guidelines.
   b. The pharmacist must ensure a confidential patient care area is used to provide the services. The patient may not waive consultation.
   c. Assessment of the substance use disorder is performed including physical and laboratory examinations for signs and symptoms of substance use disorder. Initial assessment may be waived if the patient is referred to the pharmacist for treatment following diagnosis by another health care provider.
   d. Development of a treatment plan for substance use disorder including referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment is provided as indicated.
   e. Documentation of the pharmacist's assessment, clinical findings, plan of care, and medications dispensed and administered will be documented in a patient record system and shared with a patient's primary care provider or other prescriber, if one is identified.
   f. A pharmacist performing the functions authorized in this section shall do so in collaboration with other health care providers.

(b) For purposes of this section medication assisted treatment includes any medication used to treat a substance use disorder.

Attachment 4

16 CCR § 1708.2

Proposal to Amend § 1708.2. Discontinuance of Business as follows:

(a) Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings (collectively referred to as a “closure”) and shall follow official instructions given by the board applicable to the transaction.
(b)In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure shall complete the following:

(1) Provide written notice to its patients at least [14 days/30 days] in advance of the closure. At a minimum this notice shall include:
(A) the name of the patient and/or legal representative of the patient, if known,
(B) the name and physical address of the pharmacy closure,
(C) the name of pharmacy where patient records will be transferred or maintained, and
(D) information on how to request a prescription transfer prior to closure of the pharmacy.
(2) Reverse all prescriptions for which reimbursement was sought that are not picked up by patients,
(3) Provide the board with a copy of the notice specified in subsection (b)(1),
(4) The pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance along with a pharmacist retained to perform these functions.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4113, 4332 and 4333, Business and Professions Code; and Section 11205, Health and Safety Code.

Attachment 5

ARTICLE 7. Pharmacies [4110 - 4126.10]
(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

4112.
(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, ~~and~~ (4) the name of a California licensed pharmacist designated as the pharmacist-in-charge, and (5) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, pharmacist-in-charge, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall identify a California licensed pharmacist employed and working at the nonresident pharmacy to be proposed to serve as the pharmacist-in-charge, and shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and

ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

(m) Effective date July 1, 2024.

Attachment 6

Proposal to Amend § 1732.5. Renewal Requirements for Pharmacists.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education (CE) in the prior 24 months.
(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal ("required CE hours") shall be completed by participation in a Board provided CE course in Law and Ethics. Further, beginning January 1, 2024, at least one (1) hour of the required CE hours shall be completed by participation in a cultural competency course from an accreditation agency approved by the board pursuant to Section 1732.05, as required by Section 4231 of the Business and Professions Code. ~~Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision~~.
(c) Pharmacists providing specified patient-care services must complete continuing education as specified below.

(1) At least one (1) hour of approved CE specific to smoking cessation therapy, as required by Section 4052.9 of the Business and Professions Code, if applicable.

(2) At least two (2) hours of approved CE specific to travel medicine, as required by Section 1746.5, if applicable.

(3) At least one (1) hour of approved CE specific to emergency contraception drug therapy as required by Business and Professions section 4052.3, if applicable.

(4) At least one (1) hour of approved CE specific to vaccinations as required by Section 1746.4, if applicable.

(d) For a pharmacist who prescribes a Schedule II controlled substance (as defined in Health and Safety Code section 11055), at least one (1) hour of the required CE hours shall be completed by participation in a Board approved CE course once every four (4) years on the risks of additional associated with the use of Schedule II drugs, as required by Section 4232.5 of the Business and Professions Code.
(e) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course demonstrating compliance with the provisions of this section.
(e) "Board approved CE course" shall mean coursework from a provider meeting the requirements of Section 1732.1.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052.3, 4052.8, 4052.9, 4231 ~~and~~ 4232, and 4232.5, Business and Professions Code.

Proposal to Add § 1732.8. Renewal Requirements for Pharmacy Technicians

(a) Beginning January 1, 2024, as a condition of renewal, a pharmacy technician licensee shall submit proof satisfactory to the board that the applicant has completed at least one (1) hour of continuing education in a cultural competency course from an accreditation agency approved by the board pursuant to Section 1732.05 during the two years preceding the application for renewal, as required by Section 4202 of the Business and Professions Code. All pharmacy technicians shall retain their certificate of completion for four (4) years from the date of completion of the cultural competency course demonstrating compliance with the provisions of this section.

(b) If an applicant for renewal of a pharmacy technician license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed the cultural competency course as required, the board shall not renew the license and shall issue the applicant an inactive pharmacy technician license.

(c) If, as part of an investigation or audit conducted by the board, a pharmacy technician fails to provide documentation substantiating the completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacy technician license and issue an inactive pharmacy technician license in its place. A licensee with an inactive pharmacy technician license issued pursuant to this section may obtain an active pharmacy technician license by submitting renewal fees due and submitting proof to the board that the pharmacy technician has completed the required continuing education.

NOTE: Authority cited: Section 462 and 4005, Business and Professions Code. Reference: Sections 462 and 4202, Business and Professions Code.

Attachment 7

Possible amendment to BPC Section 4111

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought unless both the person or persons specified in paragraph (1) and the person seeking a license to conduct pharmacy provide statements disavowing any community or financial interest on behalf of the person or persons specified in paragraph (1) and transmute any such community property under the Family Law Codes of the State of California into the separate property of the person seeking a license to conduct pharmacy. In addition, the pharmacy seeking a license with an owner specified in paragraph (1) if such license is granted, shall be prohibited from filling any prescriptions, emergency or otherwise issued or prescribed by the person or persons specified in paragraph (1) or another prescriber at the same place of business as the person specified in paragraph (1) if the prescriber owns a greater than 10% interest in the practice issuing the prescription.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order ~~pursuant to Section 4052.1, 4052.2, or 4052.6~~ under the following conditions:

1. The pharmacist issuing the drug order offers to provide a prescription to the patient that the patient may elect to have filled by a pharmacy of the patient's choice unless prohibited by the collaborative practice agreement.

2. The pharmacist issuing the drug order must provide a full patient consultation prior to issuing the drug order.