California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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

Date: April 10, 2024

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California State Board of Pharmacy
2720 Gateway Oaks Drive,
First Floor Hearing Room
Sacramento, CA 95833

California State Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

Board Members Present:
Seung Oh, PharmD, Licensee Member, Chairperson
Trevor Chandler, Public Member, Vice Chairperson
Renee Barker, PharmD, Licensee Member
Jessi Crowley, PharmD, Licensee Member
Jason Weisz, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Corinne Gartner, DCA Counsel
Jennifer Robbins, DCA Counsel
Debbie Damoth, Executive Specialist Manager
Sara Jurrens, Public Information Officer

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

Chairperson Oh called the meeting to order at approximately 9:07 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. The following members were present via WebEx: Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Dr. Oh reminded Committee members to remain visible with cameras on throughout the open session of the meeting. Dr. Oh advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their nonappearance when the camera was turned off.

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.

No public comment was made in Sacramento.

Public comment was received via WebEx.

A specialty pharmacist thanked the Board for their continued efforts to find an author to sponsor proposed amendments to the remote processing statute.

A representative of CSHP requested that the Office of Administrative Law (OAL) comments for the ADDS self-assessment regulations on the Legislation and Regulation Committee meeting agenda for 4/11/24 be made public for transparency.

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

III. Approval of the January 22, 2024 Licensing Committee Meeting Minutes

The draft minutes of the January 22, 2024 Licensing Committee meeting were presented for review and approval.

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

Motion: Accept the January 22, 2024 Licensing Committee meeting minutes as presented in the meeting materials.

M/S: Chandler/Crowley

Members of the public were provided the opportunity to comment in Sacramento and via WebEx; however, no comments were made.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Barker	Support
Chandler	Support
Crowley	Support
Oh	Support
Weisz	Support

IV. Presentation Regarding Pharmacy Technician Certification Programs

Chairperson Oh recalled from the January 2024 meeting, the Committee discussed pharmacy technician training programs, including employer-based training programs. The Committee noted at that time what appeared to be great variability in the quality of employer-based programs and suggested perhaps the need for greater oversight of such training programs. The Committee also discussed work being performed by the Department of Consumer Affairs (DCA) Office of Professional Examination Services (OPES), which was performing an occupational analysis for the Board for the pharmacy technician licensure program. Dr. Oh noted the analysis may help inform the Committee in its assessment of training program requirements moving forward.

Dr. Oh added during prior Committee discussions, members suggested it would be helpful to learn more about pharmacy technician programs and accreditation requirements. To that end, Dr. Oh introduced representatives from the Pharmacy Technician Certification Board (PTCB) and National Healthcareers Association (NHA) to provide presentations about their respective pharmacy technician certification programs. Dr. Oh reminded members that certification from either of these organizations was a pathway to licensure as a pharmacy technician in California.

Dr. Oh welcomed PTCB Chief Professional Officer Liza Chapman, PharmD, and PTCB Chief Assessment and Credentialing Officer Levi Boren, PhD.

Dr. Chapman provided a PTCB overview including its mission and vision, and an update on PTCB as of December 31, 2023.

Dr. Boren reviewed the CPhT program content outline, information on the CPhT program job analysis, and CPhT eligibility pathways. Dr. Boren then discussed education and training program recognition for the CPhT program, noting there are 167 PTCB-recognized education/training programs in California as well as online programs available to pharmacy technicians in California. Dr. Boren added approximately 21 programs are ASHP-accredited but noted that program recognition was not the same as accreditation. Next, Dr. Boren discussed the types of programs that could be recognized as a CPhT program (*e.g.*, certificate and degree programs; College of Pharmacy associated programs; employer training; high school programs; and military training programs). Finally, Dr. Boren reviewed California PTCE pass rates for 2021-2023, noting that they were comparable to the national averages for those years.

Dr. Chapman then reviewed the value of PTCB certification, the various credentials available for PTCB-certified pharmacy technicians, and the requirements to earn the CPhT-Adv credential.

Dr. Oh thanked Dr. Chapman and Dr. Boren. Members were provided the opportunity to comment.

Member Chandler asked how the compounding certification has changed as the compounding industry has changed. Dr. Boren advised that changes have been made in accordance with USP changes, and noted that PTCB is constantly assessing and updating the program.

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

Members of the public participating via WebEx were provided the opportunity to comment.

A pharmacist asked about the cost of PTCB certification.

Dr. Chapman provided that the cost of the exam is $129 with a fee of $55 due every two years to maintain the certification. The assessment-based certificate programs cost $89 per exam. The cost for the CSPT exam is $149 with a $50 application fee. Dr. Boren acknowledged awareness of the costs for pharmacy technicians and noted the cost for the PTCE has been the same for 15 years.

Dr. Oh thanked Dr. Chapman and Dr. Boren for their presentation and time.

Dr. Oh next welcomed Jessica Langley, Executive Director of Education and Advocacy for the NHA.

Ms. Langley provided an overview of the Ascend Learning mission and brands, noting that NHA is part of Ascend Learning. Ms. Langley also discussed the background, vision, and mission of NHA.

Ms. Langley next discussed the ExCPT, including pharmacy technician industry research as well as examination statistics and evaluation. Ms. Langley reviewed the test plan and preparation resources as well as updates with the new examination effective in 2025. Ms. Langley noted the current ExCPT exam price was $125 with new prices effective July 1, 2024. Ms. Langley provided updates on resources available, recertification processes, and learning resources.

Dr. Oh thanked Ms. Langley for her presentation. Members were provided the opportunity comment.

Member Chandler asked about the lower passing rates for pharmacy technicians. Ms. Langley provided it could be related to variety of things including a need for a newer exam to align with industry standards, evaluating domain areas, and working with clients.

Member Chandler also asked about the increase of customers from 2022 to 2023. Ms. Langley noted that could be evidence of a couple items such as an increased push for certifications, and/or increased number of states requiring certification as a licensure requirement.

Members of the public participating from Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

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

V. Presentation by the American Society of Health System Pharmacists Regarding Technician Training Program Accreditation

Chairperson Oh referenced meeting materials detailing several relevant sections of pharmacy law including California Code of Regulations (CCR), title 16, section 1793.6, which specifies that a pharmacy technician training program approved by the Board for purposes of licensure as a pharmacy technician includes a training program that is accredited by the American Society of Health-Systems Pharmacists (ASHP). Dr. Oh recalled during the January 2024 Committee meeting, members indicated that a presentation on the pharmacy technician accreditation program would be helpful.

Dr. Oh welcomed to the meeting Lisa Lifshin, Senior Director of Pharmacy Technician Accreditation and Residency Services with the ASHP Office of Accreditation Services, to provide a presentation on the ASHP accreditation program for pharmacy technician training programs.

Ms. Lifshin first provided background on the ASHP/ACPE collaboration to create the Pharmacy Technician Accreditation Commission (PTAC) as well as the process used to update requirements. Ms. Lifshin then reviewed guidance documents and the model curriculum.

Ms. Lifshin advised the application fee for a site was $775 with a fee of $3,100 to start the program. Ms. Lifshin noted there were two levels of programs including entry and advanced programs and reviewed the curriculum length for both types of programs. Finally, Ms. Lifshin provided an overview of the standards used.

Dr. Oh thanked Ms. Lifshin for her presentation. Members were provided the opportunity comment.

Member Chandler asked to what extent the employers cover the cost. Ms. Lifshin clarified that the accreditation is for the program and not the individual.

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

Members of the public participating via WebEx were provided the opportunity to comment.

A pharmacist commented that creating and maintaining an accredited program is a significant cost for the industry.

A representative of CVS Health commented there were five states that currently, or will soon, require ASHP accredited training for pharmacy technicians: South Dakota, Virginia, Louisiana, Illinois, and Utah. Louisiana has proposed a change that would remove the ASHP accreditation requirement as it was seen as a barrier to entry that has caused a tech shortage. Similarly, Utah has received requests to remove the accreditation requirement before it is implemented in 2025.

A representative of Walgreens commented that Walgreens has an ASHP accredited training program, encourages certification for all pharmacy technicians, and pays for the exam, training time, and recertification fees for their employees. The representative commented Walgreens sees a benefit in certification.

The chief executive officer of the PTCB commented that PTCB has a lot of data indicating employers will train pharmacy technicians in-house to lower the cost and barriers to entry. He continued with PTCB certification best success is seen when pharmacy technicians are trained on the job, which keeps costs for the pharmacy technician down.

Before moving on to the next agenda item, President Oh asked members whether a pharmacy-based technician training program should allow participants who are currently not a "pharmacy technician trainee" as defined by Business and Professions Code (BPC) section 4038 to obtain practical experience similar to BPC section 4115.5. Dr. Oh noted this would require expansion of the statutory definition of "pharmacy technician trainee" but might allow more opportunity for pharmacy technician training programs and wanted to see if members were agreeable.

Member Chandler confirmed he would be in favor of expanding options rather than narrowing. Dr. Oh confirmed that was the intent.

Member Crowley requested clarification on the intention on the expansion of the definition. Dr. Oh explained employer-based training programs aren't currently allowed to use pharmacy technician trainees to do the

duties of a pharmacy technician. By expanding the definition, more programs will be able to train in a pharmacy as a pharmacy technician trainee. Ms. Sodergren clarified that the current statute states that to be considered a "pharmacy technician trainee" the person must be enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education. Employer-based training programs or other training programs are not allowed by law to train a pharmacy technician trainee in a pharmacy to gain experience. By expanding the definition of "pharmacy technician trainee," it will increase the number of people who will be able to be trained with hands on learning as a pharmacy technician trainee.

Member Barker commented in support of expanding the definition to include pharmacy-based pharmacy technician training programs for increasing learning, increasing options, and reducing barriers to entry.

The Committee took a break from 10:49 a.m. to 11:05 a.m. Roll call was taken. The following members were present via WebEx: Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

VI. Discussion and Consideration of Survey Results Received Related to Pharmacist to Pharmacy Technician Ratio

Chairperson Oh recalled his intention to focus Committee discussion on strategic objective 1.3 related to the exploration and pursuit of changes in law as appropriate for the authorized duties of a pharmacy technician. Dr. Oh noted an important first step in this evaluation included this Committee convening listening sessions and soliciting feedback from licensees regarding potential changes. The results of these efforts were incorporated in Assembly Bill 1286 which became effective on January 1, 2024.

Dr. Oh reminded members that during the October 2023 meeting, the Committee initiated a review of the Board's ratio requirement. The meeting materials detailed the current law related to ratios and noted members routinely receive public comment indicating that California has one of the most restrictive ratios. Dr. Oh reminded members a review of various state ratios does not necessarily provide an apples-to-apples

comparison, as jurisdictions have varying approaches on provisions for services within a pharmacy, including where some jurisdictions require all pharmacy personnel to be licensed as a pharmacy technician if performing even basic functions such as data entry - which is not the case in California. Dr. Oh highlighted this to remind members that when comments are received, context matters. Dr. Oh noted the meeting materials highlight a few approaches taken by various states.

Dr. Oh recalled during the January 2024 Committee meeting, members reviewed and approved a draft survey to solicit feedback from pharmacists on this topic. The survey was released March 6, 2024, and ended March 25, 2024. During the survey period over 5,100 responses were received. Dr. Oh noted the Board was fortunate to have an extremely engaged licensee population and thanked everyone who participated in the survey.

Dr. Oh thanked Board staff and experts within the DCA Office of Professional Examination Services for working to develop, deploy, and evaluate the survey results. Dr. Oh added included in the meeting materials were the presentation slides with the survey results. Dr. Oh then introduced Ms. Sodergren to provide a summary of the survey results.

Ms. Sodergren provided an overview of the survey population, noting over 5,100 survey responses were received with 4,517 survey responses analyzed as approximately 634 responses could not be used (*e.g.*, not licensed in California, not practicing in California, and incomplete survey responses). Survey questions included asking if the respondent was a pharmacist-in-charge (PIC); currently supervises pharmacy technicians or other personnel in the pharmacy; and uses pharmacy technicians in the pharmacy. Other questions asked about types of worksites utilizing pharmacy technicians; types of clinical services provided at the worksite; whether technology was used in the dispensing process; whether the worksite has pharmacists working overlapping hours; and what the average prescription volume is at the worksite.

Ms. Sodergren continued reviewing responses to questions asking if the current pharmacist to pharmacy technician ratio in noninstitutional settings (currently 1:1) and institutional settings (currently 1:2) was appropriate. For both settings, the majority of respondents thought a 1:2 ratio was appropriate. Over half of the respondents believed they could provide more comprehensive patient care if the number of pharmacy technicians

a pharmacist can supervise increased. When broken down by worksite, over half community chain and nonchain pharmacists believed they could provide more comprehensive patient care if the number of pharmacy technicians a pharmacist can supervise increased, whereas less than half of inpatient hospital pharmacists believed they could provide more comprehensive patient care if the number of pharmacy technicians a pharmacist can supervise increased. In addition, over half of the respondents thought there should be specific determination by the PIC for increasing pharmacist to pharmacy technician ratios and that the pharmacist should be able to refuse to supervise additional pharmacy technicians. Ms. Sodergren continued reviewing survey questions from respondents self-identifying as working in a managerial or administrative position as well as PIC capacity for their employers.

Dr. Oh commented that he found some of the results very interesting, including the responses specifically from pharmacists that identified as either in management positions or serving as the PIC. Dr. Oh also highlighted that as referenced in the meeting materials, there is pending legislation that, if enacted, would change the pharmacist to pharmacy technician ratio to 1:6. Dr. Oh added that this measure was agendized for discussion as part of the April 11, 2024 Legislation and Regulation Committee meeting, and that he wanted to ensure the Licensing Committee's discussion today focused on the survey results. He also noted that the information reviewed by Ms. Sodergren represented summary information, and that if there were additional data points that members thought would be helpful to the Committee, he encouraged members to note those in their comments.

Members were provided the opportunity to comment.

Dr. Crowley commented that she would be interested in data from pharmacists who are not in a management position and what they would want the ratio to be, noting that this would give a different perspective. Dr. Crowley also expressed concern about the issue of liability associated with supervising additional technicians, noting that she wasn't sure pharmacists know that the pharmacy technician isn't held accountable under the law. Dr. Crowley stressed the need to keep the liability issue in the discussion.

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

Members of the public participating via WebEx were provided the opportunity to comment.

A representative for the CPhA commented the survey results seem consistent with feedback CPhA has seen from its members on this issue. The representative agreed with Dr. Crowley that it might be good to know the results from nonmanagement and pharmacists who are not serving as the PIC. The representative also asked if the subgroup analysis for management in institutional and noninstitutional could be broken by worksite.

A representative from CCPC spoke in agreement and support that the 1:1 ratio in a noninstitutional setting was not appropriate. CCPC agreed modifying the ratio to 1:2 or 1:3 would make a significant difference in day-to-day pharmacy operations. The representative commented that data across the country shows that an increase in the ratio would not jeopardize patient care. The representative further noted that a change in the ratio wouldn't have to be a mandate but could be an authorization for pharmacists to supervise additional pharmacy technicians as needed.

A pharmacist commented SB 1365 (Glazer) would allow for an increase in the ratio of pharmacy technicians to pharmacist as 1:6 similar to the ratio in Montana but the definition of pharmacy technician in Montana includes anyone working in a pharmacy including cashiers and clerk typist. The pharmacist commented the Board's survey results and recommendations of the Board would be meaningful to Senator Glazer's office with the possibility to amend the current bill.

A representative of UFCW commented in support of Dr. Crowley's request for further breakdown of the data to hear from nonmanagement pharmacists. The representative noted there was no cap around ancillary staff in the pharmacy and wondered if pharmacists would want a cap for ancillary staff. The representative thought it would be helpful to know what other protections pharmacists and pharmacy staff might want if there was an increase in the ratio (*e.g.*, liability, *etc.*) as well as including the perspective of pharmacy technicians about increasing the ratios.

A pharmacist commented the type of liability (*e.g.*, administrative, civil, *etc.*) needs to be clarified when discussing liability. The pharmacist provided a personal account of the establishment of pharmacy technician duties.

Members were provided the opportunity to comment after having received public comment.

Member Weisz noted that it seemed like the ratio was too low but he would also like to get feedback from pharmacists who were not in management.

Member Chandler thought there was a lot of middle ground, and room for consensus, between the current ratio and the 1:6 ratio proposed in SB 1365.

Chairperson Oh commented that the Committee will continue the discussion at future meetings, with additional data points, and added that this issue will likely be wrapped into the Board's upcoming sunset review.

VII. Discussion and Consideration of Implementation of Senate Bill 339 (Wiener, Chapter 1, Statutes of 2024) Related to HIV Preexposure Prophylaxis (PrEP) and Postexposure prophylaxis (PEP), including Draft Emergency Regulations

Chairperson Oh noted that the meeting materials included background information and relevant law on this agenda item. Dr. Oh advised in response to recently enacted legislation, the Board must pursue emergency regulations to implement the expanded provisions for pharmacist-furnished HIV preexposure prophylaxis. Dr. Oh noted that with recent passage of Assembly Bill 317 related to reimbursement, he was hopeful that some of the barriers to implementation that have previously been identified, including for pharmacist-furnished care such as PrEP and PEP, have been addressed to allow access for patients with commercial health plans.

Dr. Oh thanked the Office of AIDS and the California Department of Health Care Services, pharmacist-experts that have provided input as well as the Medical Board Director Varghese and Medical Board President Dr. Hawkins for their consultation and review of the proposed emergency and permanent regulations. Dr. Oh added that the language included in attachment 4 in the meeting materials incorporated the feedback from many individuals, and that he was informed that the Medical Board had no concerns or edits to the language. Dr. Oh also advised that since emergency regulations were not something the Board generally pursues,

DCA regulation counsel Jennifer Robbins was available to assist the Committee with questions.

Finally, Dr. Oh reminded members and the public to be mindful that pharmacists are routinely providing healthcare in a very prescriptive manner because of specificity provided in the law. Dr. Oh believed as healthcare professionals it was appropriate to start empowering pharmacists to rely on their professional judgement when providing patient care and cautioned members to not be overly prescriptive on the proposed regulation language. Dr. Oh appreciated the proposed draft changes and believed they were appropriate without being overly prescriptive.

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

Motion: As an emergency exists by law, recommend initiation of an emergency rulemaking to amend California Code of Regulations, Title 16, section 1747 as proposed and a regular rulemaking to make the regulation amendments permanent. Authorize the executive officer to further refine the language consistent with the committee's discussion and to make any nonsubstantive changes prior to presenting the proposed emergency and regular rulemakings to the Board.

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PHARMACY

PROPOSED EMERGENCY REGULATORY LANGUAGE
HIV Preexposure Prophylaxis

Legend:	Added text is indicated with an underline. Deleted text is indicated by ~~strikeout~~.

Amend section 1747 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient

pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board, provided by a provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The training program shall satisfy the following criteria:
(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:
(A) HIV preexposure and postexposure prophylaxis pharmacology.
(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.
(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
(D) Patient referral resources and supplemental resources for pharmacists.
(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).
(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.
(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Training obtained as part of an equivalent curriculum-based training program, as identified in (a), can be documented by written certification from the registrar or training director of the educational institution or program from which the licensee

graduated stating that the training is included within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation of training maintained pursuant to this subdivision must be made available upon request of the board.
(c) For the purposes of this section, documentation of preexposure prophylaxis furnished and services provided shall be maintained in patient records, in the record system maintained by the pharmacy, for a minimum of three years from the date when the preexposure prophylaxis was furnished. Such records shall be made available upon request of the Board, consistent with the provisions of Business and Professions Code sections 4081 and 4105.

NOTE: Authority cited: Sections 4005, 4052.02 and 4052.03, Business and Professions Code. Reference cited: Sections 4052, 4052.02, ~~and~~ 4052.03, 4081 and 4105, Business and Professions Code; and Section 120972, Health and Safety Code.

M/S: Chandler/Barker

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented in support of the effort, and of the urgency of the legislation and proceedings. The commenter noted subsection (c) indicates that the records of the treatment of these patients could be maintained for a minimum of three years, and expressed his view that this isn't long enough based on the fact that they are health care treatment records.

Members were provided the opportunity comment after having heard public comment.

Dr. Crowley agreed with the commenter that the retention period should be longer. Dr. Crowley also asked if the language as drafted went beyond the intention of SB 339 (Weiner, Chapter 1, Statutes of 2024). Ms. Sodergren

noted, and Counsel Robbins agreed, that the regulatory language being proposed does not go beyond the statute.

Dr. Oh noted he was in support of expanding the retention period but cautioned that the Board should take a more holistic approach to this issue.

Member Weisz spoke in support of the motion and agreed with taking a holistic approach to retention requirements rather than piece by piece. Dr. Oh and Dr. Crowley agreed. Dr. Crowley requested reviewing it at the Board meeting and asked Board staff to compare record retention for similar boards and bureaus within the Department of Consumer Affairs (DCA).

Member Barker agreed as more latitude is given to the pharmacists and treatments involving patient care, the larger discussion of records retention should be discussed and compared to similar regulatory bodies.

Dr. Oh indicated the Board would need to address record retention as a holistic idea for the sunset report.

Counsel Robbins added in existing CCR section 1707.1 (a)(2) the general records retention requirement is for at least one year.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Barker	Support
Chandler	Support
Crowley	Support
Oh	Support
Weisz	Support

VIII. Discussion and Consideration of Possible Amendment to California Code of Regulations, Title 16, Section 1713, Related to the Use of Automated Drug Delivery Systems

Chairperson Oh refenced meeting materials detailing the relevant laws related to this agenda item and noted BPC section 4427.6 provides specific requirements for the use of automated patient dispensing systems (APDS) and specifically, subdivision (f) provides that all prescribed drugs

and devices dispensed to a patient from an APDS shall be accompanied by a consultation conducted by a pharmacist licensed by the Board via a telecommunications link that has two-way audio and video. This requirement became effective in 2019 as part of SB1447 (Hernandez, Chapter 666, Statutes of 2018). Dr. Oh added CCR, title 16, section 1713, specifically subdivision (d), provides authority for a pharmacy to use an APDS to deliver medications to a patient under specified conditions. One such condition is that an immediate consultation with a pharmacist be provided upon the request of the patient either in-person or via telephone. Dr. Oh noted section 1713 was amended in 2019, to make some conforming changes based on the provisions of Senate Bill 1447; however, the proposed changes to the regulation text at that time did not differentiate the technology requirements consistent with the statutory requirements. The lack of differentiation has led to some confusion among stakeholders about when two-way audio and video is required, consistent with BPC section 4427.6 and the regulation. To provide clarity to the regulated public, it was recommended that the Board amend section 1713(d) to be more specific to licensees and consolidate both technology requirements in a single location to allow for ease of use and ensure a common understanding of the two legal requirements.

Dr. Oh appreciated the recommendation offered by staff and agreed with the proposed changes included in attachment 5 of the meeting materials. Members were provided the opportunity to comment.

Members agreed the language being proposed was awkward. Ms. Sodergren suggested, "A patient shall receive consultation by a pharmacist from an APDS for the first time the prescribed drug is dispensed as specified in BPC section 4427.6 (a), via a telecommunications link that has two-way audio and video. Further, the pharmacy is able to provide an immediate consultation with the pharmacist either in person or via telephone upon the request of the patient." Members agreed the language provided by Ms. Sodergren was clear. Counsel Robbins cautioned on reiterating statute in the regulation as OAL views this as unnecessary duplication of a statute, and noted that the language was drafted as proposed to address that concern. Dr. Oh understood the concern but believed the language proposed by Ms. Sodergren at the meeting would be clearer for the regulated public.

Motion: Recommend initiation of a rulemaking to amend California Code of Regulations, Title 16, section 1713 consistent with the

committee's discussion. Authorize the executive officer to further refine the language consistent with the committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PHARMACY

PROPOSED REGULATORY LANGUAGE
Automated Patient Dispensing Systems Consultation

Legend:	Added text is indicated with an underline. Deleted text is indicated by ~~strikeout~~.

Amend section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use an automated patient dispensing system (APDS) to deliver prescription medications to patients provided:
(1) A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to that patient.

(2) The APDS has a means to identify each patient and only release that patient's prescription medications to the patient or patient's agent.
(3) A patient shall receive consultation by a pharmacist from an APDS for the first time the prescribed drug is dispensed as specified in Business and Professions Code section 4427.6 (a), via a telecommunications link that has two-way audio and video. Further, ~~The~~ the pharmacy is able to provide~~s~~ an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
(4) Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
(e) Any pharmacy making use of an APDS shall maintain, and on an annual basis review, written policies and procedures providing for:
(1) Maintaining the security of the APDS and the dangerous drugs within the APDS.
(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS and for which patients, including when consultation is needed.
(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.
(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS.
(5) Orienting participating patients on use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of prescription medications.
(6) Ensuring the delivery of medications to patients in the event the APDS is disabled or malfunctions.
(f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS.

Credits

NOTE: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4017.3, 4052, 4116, 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7 and 4427.8, Business and Professions Code.

M/S: Crowley/Barker

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented in agreement with the newly proposed language.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Barker	Support
Chandler	Support
Crowley	Support
Oh	Support
Weisz	Support

IX. Discussion and Consideration of Proposal to Establish Authority to Waive the Renewal Fee Requirement for Pharmacists Licensed Over 50 Years

Chairperson Oh recalled that following a request from the public, the Board referred this item to the Committee for consideration. Dr. Oh noted that background information on this agenda item was included in the meeting materials, and added that public comment received suggested that the Board consider development of a step-down licensure process for pharmacists getting ready to retire. It was suggested through public comment that the Board consider the approach used by Nevada. Dr. Oh referenced the meeting materials indicating a pharmacist that has been registered with Nevada for at least 50 years is not required to pay renewal fees after that time.

Dr. Oh added that based on the number of pharmacists that have currently been licensed for over 50 years in California, such a change could result in a loss of annual revenue to the Board of about $250,000. Dr. Oh believed the loss of revenue would not have too significant a negative impact to the Board's fund. Dr. Oh noted if the Committee believed such a change was appropriate, he could work with staff before the July 2024 meeting to develop statutory language. Dr. Oh noted this issue may be appropriate to include in the Board's sunset report.

Members were provided the opportunity to comment.

Member Chandler commented in support in concept but was concerned about loss of revenue. Dr. Oh spoke in alignment with Mr. Chandler.

Member Weisz asked if other approaches were reviewed to achieve similar results. Dr. Oh indicated other avenues were researched but this seemed to be most feasible. Ms. Sodergren noted the distinction between retired and reactivated licenses status. When a pharmacist retires a license, they no longer pay any fees and to restore a license, they must meet all requirements of law at reapplication. When a pharmacist puts a license on inactive status, the pharmacist still pays the fee but does not need to earn continuing education and to reactivate the license, continuing education must be completed. In Nevada, after placing a license on inactive status, the pharmacist must provide proof of having completed continuing education and pass an examination on law provided by the Nevada Board of Pharmacy.

Members discussed reducing the fees for pharmacists who have been licensed for 50 years to allow for pharmacists to maintain license at a lower cost. Members also discussed not adding barriers to reentry in the case of an emergency. Some members were concerned with the fiscal impact to the Board.

Dr. Oh indicated there would be further discussion at the next meeting.

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

Members of the public were provided the opportunity to comment via WebEx.

The Committee received comments from pharmacists and a pharmacy owner who spoke in support of having a reduced or eliminated fee for pharmacists licensed over 50 years or more.

Members were provided the opportunity to comment after having received public comment; however, no comments were made.

The Committee took a lunch break from 12:26 pm to 1:15 pm. Roll call was taken. The following members were present via WebEx: Trevor Chandler, Public

Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

X. Discussion and Consideration of Compounding by Pharmacy Technicians Outside of Pharmacies

Chairperson Oh advised the Enforcement and Compounding Committee referred the discussion of compounding by pharmacy technicians outside of pharmacies to the Licensing Committee. Dr. Oh recalled during previous meetings, the Committee has discussed the requirements for licensure for a pharmacy technician. By definition, pharmacy technicians work in a pharmacy under the direct supervision and control of a pharmacist.

Dr. Oh referenced meeting materials highlighting USP General Chapter 797 describing the minimum requirements that apply to all persons who prepare compounded sterile preparations and all places where sterile preparations are compounded. This includes pharmacists and pharmacy technicians compounding in all places including those areas outside of a pharmacy. Dr. Oh also noted federal law, section 503A of the Food Drug and Cosmetic Act, makes clear that authority to compound a drug preparation is in part predicated on compliance with USP compounding chapters. To assist in its assessment of this issue, the Committee discussed policy questions which may be appropriate to address in the Board's sunset report.

Policy Question #1 - Should the Board seek more explicit authority to inspect locations where pharmacy technicians are performing compounding activities outside of licensed pharmacies? (Note: BPC section 4008 may already provide the Board such authority; however, it may be beneficial to have more explicit authority.)

Dr. Oh appreciated the note included in the meeting materials referencing BPC section 4008, which appears to already provide such authority to the Board. Dr. Oh thought maybe additional educational awareness of the Board's existing authority may be needed. Dr. Oh also noted that there may need to be some improvements on enforcement possibilities for non-licensed areas as currently there was limited actions the Board could take. Dr. Oh would like to improve BPC section 4008 to improve enforcement ability (*e.g.*, add cease and desist, citation and fines, *etc.*) for non-licensed areas.

Members were provided the opportunity to comment.

Mr. Chandler asked for clarification about the problem that needed to be solved. Dr. Oh explained that the Board has become aware of instances where pharmacy technicians are practicing compounding in a non-licensed facility (*e.g.*, IV hydration clinics, doctor's offices, unlicensed infusion centers, *etc.*), with reports that standards are significantly less than what would be required in a pharmacy. Board Supervising Inspector Christine Acosta, who was present via WebEx, clarified that this was a potential patient safety issue because a pharmacy technician can only compound when working in a pharmacy under the supervision of a pharmacist who is responsible for the actions of the pharmacy technician. Ms. Sodergren added that USP 797 was clear on who needs to comply with the compounding standards and this includes pharmacy technicians. Ms. Sodergren noted the Board has found compounding outside of a pharmacy in a less than standard environment. Ms. Sodergren underscored the issue was how can the Board more effectively regulate tin this environment to ensure consumer protection.

Mr. Chandler asked if the compounding was being done with substances not within the Board's jurisdiction. Ms. Sodergren noted that licensees operate in variety of manners and locations, adding that pharmacy technicians were sometimes sought out to compound in some of these locations outside of a pharmacy. Ms. Sodergren added that unlike in pharmacies, at these locations there is no direct supervision and control over the individuals who are also not following USP compounding standards. Ms. Sodergren concluded the Board did not have jurisdiction over the non-licensed site, but the Board has jurisdiction over the Board-licensed individuals.

Dr. Crowley hoped that the Board was able to inspect facilities that were doing compounding regardless of whether they were licensed with the Board. Dr. Crowley asked how the Board knew that pharmacy technicians were being hired for compounding in facilities not licensed by the Board. Dr. Acosta provided the pharmacy technicians are referred to or self-identify as a pharmacy technician.

Dr. Barker added with compounding the environment and how the environment was maintained was of significant importance and she

supported bolstering the Board's existing authority to enable the Board to inspect these locations.

Policy Question #2 – Should the Board develop educational materials to provide to other health care professional Boards and associations reminding such entities of the Board's inspection authority?

Dr. Oh believed this would be appropriate. Dr. Oh recommended referring to the Communication and Public Education Committee to develop a brochure similar to the Board's inspection brochure that inspectors would be able to provide at the time of inspection.

Members were provided the opportunity to comment.

Dr. Crowley agreed educational materials should be developed. Dr. Barker thought educational materials should consist of letting entities know the Board can inspect a location if there was compounding being done at the location, and general information about what was required for compounding. Dr. Oh noted that many people don't realize that compounding is a high risk activity and that there is a potential for patient harm.

Policy Question #3 – Generally, the Board does not inspect facilities where compounding occurs outside of a Board-licensed facility unless requested or referred to the Board for such action by another entity, (e.g., the FDA, FBI, DEA, etc.). Does the Committee wish to provide direction to staff to proactively perform some inspections of such facilities to learn more about compounding practices?

Dr. Oh expressed his strong belief that it would be great to perform inspections to gain a better understanding of compliance of Board licensees with state and federal law and compounding standards, but stated he was also concerned with the increased workload this would create for Board staff.

Mr. Chandler asked if there was a way to work with referring partners, as a way to avoid the need for a statutory fix. Ms. Sodergren noted that other agencies may not have the subject matter expertise in compounding that the Board has, and as a result they look to the Board to provide guidance.

Dr. Crowley inquired about a collaborative effort at the state level with other boards and bureaus. Mr. Chandler indicated it may be more appropriate to receive statutory clarification from the legislature. Dr. Oh believed statutory authority already exists in BPC section 4008. Board Counsel Gartner clarified existing statutory authority in BPC section 4008 (a) where it states that the Board does have inspection authority to inspect during business hours any place where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

Mr. Weisz added in the Board's role to safeguard the health and safety of the public, the Board should proactively go out and investigate within the Board's ability, capacity, and legal authority as well as educate the public of the Board's authority.

Dr. Crowley agreed there needed to be more oversight and wanted to understand what would happen if the Board went into a facility not licensed by the Board, found compounding below USP standards, and what the Board's next steps would need to be (*e.g.*, refer to federal agency, *etc.*).

Policy Question #4 - Does the Committee believe it is appropriate to allow for a pharmacy technician to compound under the direct supervision and control of a pharmacist when outside of a licensed pharmacy?

Dr. Oh thought a way to approach this would be, if the compounding was being done outside of a licensed pharmacy, there should be a pharmacist overseeing the compounding.

Dr. Crowley agreed and from her understanding of the definition of a pharmacy technician, a pharmacy technician should not be compounding if a pharmacist was not there, nor should a tech be compounding outside of a pharmacy. Dr. Crowley added pharmacy technicians may not know they can't be compounding outside of a pharmacy, which underscored the importance of the educational component.

Dr. Barker noted there were so many concerns regarding compounding (*e.g.*, practices, environment, risk, *etc.*) and added that while she understood requiring a pharmacist she also thought the compounding area should be licensed.

Policy Question # 5 - Should the Board consider establishing a requirement for offices, clinics, etc. that are compounding but not currently licensed by the Board to provide notification to the Board that Board licensees are compounding at their location, or alternatively require Board licensees to notify the Board if they are compounding outside of a Board licensed facility?

Dr. Oh was in support of a minimum notification requirement and believed it should be established as a requirement for Board-licensees to notify the Board, as opposed to placing the requirement on the facility itself.

Dr. Crowley thought notification to the Board could be overwhelming to Board staff but the Board did need a baseline to know where to start.

Dr. Barker noted there may be a need to establish a requirement for offices/clinics to complete a self-assessment or attestation to create understanding of what is required.

Mr. Chandler agreed that it was prudent as a baseline to have pharmacy technicians alert the Board when they are performing compounding outside of a licensed facility, but was interested in hearing about staff capacity to absorb this additional notice.

Ms. Sodergren noted the Board could partner with DCA to establish an easy web-based portal and manage notification through an IT solution for minimal staff involvement for that portion. Ms. Sodergren added this would allow the Board to understand the frequency of the practice, and the Board could also do random inspections. The data from the inspections could be used by the Board to help form the Board's policy.

Policy Question #6 - Should the Board develop educational materials reminding pharmacy technicians of the requirements of USP 797 and federal law related to the compounding of drug preparations?

Dr. Oh thought this was appropriate to help educate pharmacy technicians. Dr. Barker also spoke in support of this concept.

Dr. Oh summarized where the Committee had consensus was to provide educational materials for technicians and educational materials for licensees by the Communication and Public Education Committee.

Dr. Oh noted there was not clear consensus to increase inspections of these facilities. If agreeable, the Committee could discuss further at the next Committee meeting, including discussion of what actions and proposals could be included in the sunset report to better protect California consumers who are receiving high risk medication or products from non-licensed facilities.

Mr. Chandler was interested in seeing if there was consensus at the Board level in having pharmacy technicians report to the Board when they are compounding outside of a non-licensed facility.

Dr. Crowley thought this was an urgent issue to address as soon as possible. Dr. Crowley agreed with a notification requirement but wasn't clear on whether facilities or licensees should be asked to provide the notice. The members continued to discuss the notification issue, with no clear consensus reached.

Dr. Oh asked if the Committee would be agreeable to inspecting some facilities in preparation for the sunset report as a way of gathering information to help inform the Board's next steps. Dr. Barker and Mr. Weisz both expressed support for this.

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

Members of the public participating via WebEx were provided the opportunity to comment.

A pharmacist commented that in addition to medical spas and hydration clinics, there are oncology infusion centers where pharmacy technicians are compounding for cancer patients. The pharmacist expressed concern about compounding occurring in this setting and suggested that rather than looking at pharmacy technicians, the Board should focus its attention on the businesses/facilities that are engaging in this high risk practice.

A pharmacist who worked in a licensed sterile compounding pharmacy for cancer treatment was happy to see this as an agenda item. The pharmacist noted this was also an issue with cancer care facilities that only hire pharmacy technicians which is a safety concern and undermines the

pharmacists. The commenter agreed with the previous commenter that these facilities are exploiting a loophole in the law.

A member of the public agreed with the previous commenters and noted that there is confusion in the provider community about whether these locations need and/or can obtain a license from the Board. The commenter thought more education and clarity was needed in this area and agreed that the Board should focus more on the facilities as opposed to the personnel.

A representative of CSHP applauded the Board for the direction it was taking on this issue. The representative didn't want to discourage use of pharmacy technicians in these practice settings, though. The representative thought a pharmacy technician with some training was better than an unlicensed medical assistant with no training, and warned of actions, such as mandated self-reporting, that might discouraged pharmacy technicians from performing these functions.

A pharmacist commented the Board was headed in the right direction. The pharmacist provided a personal account of federal and state laws and compounding terminology.

XI. Presentations on Central Fill Pharmacy Models

Chairperson Oh recalled in January 2024, the Committee began discussions about central fill pharmacies and requested receiving presentations from representatives of companies that currently use a central fill model. Dr. Oh advised the Committee would hear from representatives of Albertsons and Walgreens.

First, Dr. Oh introduced and welcomed Rob Geddes, PharmD, Director, Pharmacy Legislative and Regulatory Affairs with Albertsons.

Dr. Geddes reviewed the components of central fill and the flow of the prescription from the dispensing pharmacy to the central fill pharmacy and back to the dispensing pharmacy. Dr. Geddes advised central fill pharmacies are highly automated environments.

Members were provided the opportunity to comment.

Dr. Crowley asked if Albertsons used central fill in California. Dr. Geddes advised a small number of Albertsons stores in California currently use central fill as a service.

Mr. Chandler asked if Albertsons had studied medication errors through central fill versus non-central fill. Dr. Geddes advised that Albertsons conducts multiple safety checks and has stringent SOPs that function to reduce errors. Dr. Geddes provided examples of safety checks used by pharmacy personnel in a central fill pharmacy. Dr. Geddes advised after six months of operation, there had not been an incident identified where the wrong medication was given to the patient. Dr. Geddes noted Albertsons believed the safety checks and balances built into the processes and systems were very safe and well designed.

Dr. Barker asked how Albertsons determines when a store needs central fill support. Dr. Geddes provided that they use an algorithm that helps determine this based on volume and proximity. Dr. Geddes provided they use the wholesaler to get medications back to the pharmacy and noted that central fill is available to help a store if there is a staffing crisis. Dr. Barker also asked if the prescription was checked by the dispensing pharmacist when the prescription arrives from central fill. Dr. Geddes provided there wasn't a required check by the dispensing pharmacist as both the central fill and receiving pharmacy were licensed by the Board and it was viewed as a corresponding responsibility issue. Dr. Barker asked if the dispensing pharmacist wanted to check the prescription if they were able to. Dr. Geddes provided pharmacists could check the prescriptions but this wasn't required.

Mr. Weisz asked how many prescriptions an average Albertsons fills in a day. Dr. Geddes provided the central fill pharmacy can fill 20,000 prescriptions in an 8-hour shift so that a day consisting of three 8-hour shifts would be 60,000 prescriptions at full capacity. Dr. Geddes noted an average pharmacy fills about 1,000-1,200 prescriptions a week. For a pharmacy using central fill support, approximately 30 percent of the prescriptions are filled by central fill support noting some types of prescriptions such as the maintenance chronic medications that filled by the central fill support. Dr. Geddes advised locations of central fill pharmacies are selected based on wholesaler proximity and maximum number of pharmacies that it could potentially service and encouraged the Board to reconsider and steer away from central fill pharmacies being required to be in California and service only California. Dr. Geddes noted

a central fill for California may be best located in Nevada to best serve California pharmacies.

Mr. Weisz asked if there was any difference between how the central fill model and the direct to consumer model (*i.e.*, mail order) functioned. Dr. Geddes advised Albertsons did not utilize a direct to consumer model, noting there were differences (*e.g.*, label requirements, counseling, *etc.*) but the technology leveraged was similar.

Dr. Crowley asked how the volume in California locations compared to other states. Dr. Geddes provided the California locations do not have as high of a volume as some stores across the country fill up to 4,000 prescriptions a week.

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

Members of the public via WebEx were provided an opportunity to comment.

A representative of CCPC commented on the next agenda item, indicating that CCPC has concerns about the proposed regulatory language.

Dr. Oh next introduced and welcomed Lorri Walmsley, RPh, Director of Pharmacy Affairs with Walgreens.

Ms. Walmsley began her presentation by observing that central fulfillment enables the future of pharmacy. Walgreens currently has 11 central fill pharmacies servicing 32 states. Ms. Walmsley reviewed an infographic explaining the journey for centrally filled prescriptions, and provided samples of prescription record keeping for automation central fill and manual central fill.

Members were provided the opportunity to comment.

Dr. Crowley asked how many Walgreens pharmacies receive central fill service in California. Ms. Walmsley advised that currently there were no Walgreens pharmacies in California that are serviced by central fill. Ms. Walmsley added terms of service for central fill pharmacies were based on

wholesale distribution schedules to minimize carbon footprint and ensure centrally-filled prescriptions arrived with the other medications.

Dr. Crowley also asked if Walgreens had a similar method as Albertsons of determining what pharmacies use central fill and how the volume of prescriptions filled in California compares to the country. Ms. Walmsley provided the goal was to service all of their pharmacies regardless of volume.

Members of the public in Sacramento and via WebEx were provided an opportunity to comment; however, no comments were made.

Dr. Oh thanked Dr. Geddes and Ms. Walmsley for their presentations, noting that he believed it was helpful to inform the Committee about this pharmacy model and will be useful as the Committee continues its assessment of the Board's current central fill regulation.

Dr. Oh surveyed the Committee to see if they received enough information to make decisions for the next agenda item. Members agreed the two presentations were excellent but they wanted to hear from additional companies about their central fill practices including those that were located in California. The Committee agreed to skip agenda item XII until additional information could be obtained for the Committee's review.

The Committee took a break from 3:22 p.m. to 3:45 p.m. Roll call was taken. The following members were present via WebEx: Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

XII. Discussion and Consideration of Proposed Amendment to California Code of Regulations, Title 16, Section 1707.4 Related to Central Fill Pharmacies

This agenda item was not discussed and was postponed to another meeting date.

XIII. Discussion and Consideration of Licensure and Other Requirements for Nonresident Pharmacies

Chairperson Oh expressed concern about the Board's inability to regulate nonresident pharmacies, including mail order pharmacies. Dr. Oh further explained nonresident pharmacies can create unique challenges for

patients, and recalled investigations that resulted in discipline stemming from these challenges that were placing patients at risk. Dr. Ph continued by noting that over the last two years, the Board has referred 11 nonresident pharmacies to the Office of the Attorney General for formal discipline and issued 39 citations. In addition, the Board took disciplinary action on 12 nonresident pharmacies. The underlying violations varied in egregiousness and included extremely serious causes of action including clearly excessive furnishing of controlled substances. Dr. Oh reminded members that there was no current requirement for pharmacists working in these nonresident pharmacies who are providing services to California patients to be licensed in California, and that the Board has previously voted and would be pursuing a statutory change to require the PIC of a nonresident pharmacy to be licensed in California.

Dr. Oh also expressed concern about the actions undertaken by some states to eliminate law and jurisprudence examinations as well as recent actions by Michigan and North Dakota that allow pharmacists licensed in Canada to reciprocate licensure without taking the North American Pharmacist Licensure Examination (NAPLEX).

Policy Question #1
The Committee has previously indicated that inspections should be performed at nonresident pharmacies. Does the Committee wish to establish a minimum frequency for conducting such inspections?

Dr. Oh stated that he believed inspections every four years might be an appropriate frequency and suggested that the Board tie the requirement to the renewal of the license. Dr. Oh noted based on July 2023 statistics, the Board renewed 499 nonresident pharmacy licenses in fiscal year 2022/23. Assuming that number remains constant, the Board would conduct about 125 inspections of nonresident pharmacies annually. Dr. Oh added that he believed a statutory change would be necessary to implement the provisions.

Members were provided the opportunity to comment.

Dr. Crowley thought that inspections every four years might not be frequent enough. She acknowledged the time and the expense to the Board but thought it was necessary and would recommend more frequent inspections.

Mr. Chandler asked what was a common time frame and cost for inspections. Dr. Oh advised the Board inspects pharmacies in California every four years. Ms. Sodergren added based on what the Committee and Board determined, staff would probably recommend pursuing a statutory proposal that would allow the Board to recover the inspection costs similar to the nonresident sterile compounding pharmacy inspections.

Mr. Weisz asked what the precedent was for the Board staff to go out of state for inspections. Ms. Sodergren explained now the Board inspects nonresident sterile compounding pharmacies. Mr. Weisz thought this would be a great expansion for the Board and indicated he was in support of conducting inspections every four years.

Member Barker returned to the meeting at 3:54 p.m.

Policy Question #2
Board staff has recently learned that some states are allowing pharmacists licensed in Canada to secure licensure and/or work in their respective state without taking the NAPLEX and/or law examination. Such individuals could then provide pharmacy-related services to California patients.
a. Does the Committee have concerns with this practice?

Dr. Oh reiterated North Dakota and Michigan recently took action to recognize pharmacists for licensure by reciprocity under specified conditions. Dr. Oh understood in Michigan an applicant for licensure as a pharmacist in Michigan who has passed the Pharmacy Examining Board of Canada Pharmacists Qualifying Examination, completed an educational program accredited by the Canadian Council for Accreditation of Pharmacy Programs, and who has a minimum of 1,600 hours of pharmacy practice either through an approved internship or practice as a pharmacist, would meet requirements for licensure in Michigan. Dr. Oh noted there were 11 nonresident pharmacies located in Michigan and licensed in as a nonresident pharmacy in California. In the 11 nonresident pharmacies, the pharmacist providing services into California has not demonstrated minimum competency on an examination that meets the requirements of BPC section 139.

Members were provided opportunity to comment.

Mr. Chandler asked what the federal role (*i.e.*, FDA) was on licensure. Dr. Oh and Ms. Sodergren provided licensure was at the state level. Members also inquired about licensure requirements for Canadian pharmacists, but the information was not available but could be researched if the Committee desired.

b. Does the Committee wish to prohibit such practice like the approach taken for pharmacist licenses revoked in California?
c. Does the Committee wish to require all pharmacists providing services into California to be licensed in California?

Dr. Oh noted the Board already has a requirement for nonresident pharmacies to ensure that a pharmacist whose license has been revoked in California is prohibited from providing pharmacy services to California patients. Dr. Oh posed the question if the Board should require pharmacists working for nonresident pharmacists to be licensed in California. Dr. Oh thought that might be too far but there may be a prohibition for pharmacists in certain circumstances from being able to practice and verify medications to California patients. The alternative would be to allow pharmacists licensed in Canada to practice in California.

Member were provided the opportunity to comment.

Mr. Chandler understood the issue of reciprocity and agreed there should be a failsafe.

Dr. Oh thought this could be explored further and have some next steps in subsequent meetings. Dr. Oh reminded members that the PIC licensure requirements were already supported by the Board by seeking statutory change through the sunset process.

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

Members of the public via WebEx were provided the opportunity to comment.

A pharmacist representative of Kaiser Permanente encouraged the Board to see what other jurisdictions were doing about inspecting nonresident pharmacies (*e.g.*, submit inspection report from another state or third-party, *etc.*).

A pharmacist commented about where the NAPLEX was accepted and commented in support of the Board inspecting nonresident pharmacies. The commenter was concerned about a license being required by a pharmacist in another state who was only providing clinical services as it would severely limit the options for California residents to get care.

A representative of Walgreens agreed with the comments from the Kaiser Permanente representative as well as recommended focusing inspections on pharmacies with disciplinary action. The representative voiced concern about all pharmacists providing services into California being required to be licensed in California as a pharmacist, noting that this would limit current services being provided to California residents without a patient safety benefit.

A representative of CCPC commented on concern for requiring California licensure for out of state pharmacists. The representative suggested exploring licensure compacts or reciprocity through the sunset report process.

A representative of CVS Health noted that licensure statistics provided at the NABP District Meeting indicated that pharmacy school enrollment and NAPLEX passage rates are both dropping. The representative said the Federal Trade Commission (FTC) was asking states to look at different ways to increase license portability, so the discussion about requiring all nonresident pharmacists to be licensed in California bucks that trend.

Members were provided the opportunity to comment after having heard public comment.

Dr. Crowley noted that she was not comfortable with the suggestion of accepting other states' inspection reports and recommended aiming to have in-person inspections for nonresident pharmacies.

XIV Discussion and Consideration of Proposed Amendments to Pharmacy Law to Transition to a More Robust Standard of Care Model for Some Pharmacist-Provided Patient Care Services

Chairperson Oh referenced relevant laws and regulations that generally detailed the scope of practice for pharmacists. Dr. Oh reminded members that as required by the Board's last sunset review, the Board was required

to evaluate if moving to a standard of care enforcement model was feasible and appropriate for the regulation of pharmacy. Through an ad hoc committee, the Board took a deep dive into the issue and ultimately concluded that the Board's current hybrid approach to the regulation of the practice of pharmacy was appropriate. At that time the Board also noted that based on information received, California patients would benefit from pharmacists gaining additional authority to provide some patient care services consistent with their respective education, training, and experience; however, any such change would require legislation.

Dr. Oh noted that today the Committee had the opportunity to begin discussion of potential statutory language that could facilitate such a transition. Dr. Oh added draft statutory language was prepared to assist the Committee as a place to start the discussion. Dr. Oh believed the basic tenets of the proposal were appropriate. Dr. Oh provided a summary of the proposal:

1. Would expand provisions for pharmacists to perform CLIA waived tests, beyond those currently allowed in BPC section 4052.4.
2. Would allow a pharmacist to perform a therapeutic interchange under specified conditions.
3. Would establish authority for pharmacists to furnish FDA approved or authorized medication that is preventative or does not require a diagnosis under specified conditions.
4. Would expand upon pharmacists' current authority to administer biologics and would allow a pharmacist to furnish an FDA approved or authorized noncontrolled medication for the treatment of minor, nonchronic health conditions or for which a CLIA waived test provides diagnosis and the treatment is limited in duration.
5. Would expand current authority for pharmacists to complete missing information on a noncontrolled medication if there is evidence to support the change.
6. Would expand authority for pharmacists to substitute medications that are generally considered interchangeable (*i.e.*, if insurance will only cover one medication but an interchangeable medication was prescribed.)
7. Would allow for medication therapy management and adjust treatments to manage chronic conditions diagnosed by a prescriber to optimize drug therapy (*i.e.*, adjusting medication dosing in response to laboratory results such as for warfarin, or medication to better control diabetes.)

Dr. Oh acknowledge that for some this proposal may seem too expansive and to others it may not go far enough, but expressed that he believed it provided a good starting place for the discussion.

Members were provided the opportunity to comment but wanted to hear public comment first.

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

Members of the public via WebEx were provided an opportunity to comment.

A pharmacist representative of Kaiser Permanente appreciated that the draft statutory language clarifies that prescriptions issued by a pharmacist pursuant to a collaborative practice agreement pursuant to BPC section 4052(a)(13) are valid prescriptions. The representative encouraged the Committee to recognize that some tasks in the proposed language could also be done pursuant to a collaborative practice agreement and he would want to preserve the ability to do the task under a collaborative practice agreement as well as in the proposed statutory language.

A representative of CPhA thanked the Board for the proposed language, noting its comprehensive nature. CPhA supports the Board in the current approach.

Another representative of CPhA agreed with the prior commenter. The representative spoke in support of the Board's approach, noting that it will release the profession to be able to function in a way with better patient outcomes, and that this would help with the affordability with health care as well as increase equity and access.

A pharmacist agreed with the previous commenters and recommended that the Board also clean up the Health and Safety Code provisions that cross-reference BPC sections that are being amended by this proposal. The commenter stated that the Board should also reconsider whether pharmacists can prescribe for off-label uses.

Members were provided the opportunity to comment having heard public comment.

Mr. Weisz asked about next steps. Dr. Oh explained that no formal action was needed at this time; rather, he is just looking for consensus and any formal action would be taken by the Board as part of the sunset report process in December 2024.

Mr. Chandler recommended making sure the public knows the Board wasn't removing access to these items but expanding pharmacists'; ability to provide certain services, thus making access easier. Dr. Oh agreed.

Dr. Crowley expressed concerns that the language was too expansive. Specifically, under Section 5 regarding "upon patient consent," Dr. Crowley was concerned about not reaching out to the doctor before changing medications as there was information not available in a retail pharmacy (*e.g.*, laboratory results, *etc*.). In addition, under Section 10, Dr. Crowley believed there was too much room for interpretation as well as the definition of "preventative" and that there should be limitations. Dr. Crowley also had a question in Section 16 under question 2 and asked how it differs from what was currently allowed and if it was intended to address emergency use authorization (EUA).

Dr. Oh noted the practice of pharmacy historically had been prescriptive and putting it into the standard of care pharmacy model, there would need to be the understanding that not every practice will be cited by statute or regulation but determined by the practitioner of what is right. Dr. Oh noted this was an opportunity to increase efficiency and provided an example of how this could improve patient care.

Ms. Sodergren believed the language regarding immunizations was consistent with the intent of the prior legislation to cover the COVID vaccines.

Dr. Crowley understood the intention and agreed there was a need for more flexibility, but expressed concern that some pharmacists weren't autonomous enough to actually utilize this model in practice because of employer-imposed policies and procedures.

XV. Discussion and Consideration of Licensing Statistics

Chairperson Oh referenced meeting materials including a summary of the licensing statistics for the first eight months of the fiscal year. Dr. Oh noted the processing times for individual licenses, which as of April 1, 2024, was at

or below 15 days for both initial applications and to process deficiency items. He noted that unfortunately there are some site application processing times well beyond the Board's 30-day processing times. He believed this was in part because of the loss of staff including a manager. Dr. Oh noted the Committee will continue to monitor the progress made by staff.

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

Members of the public were provided the opportunity to comment in Sacramento or via WebEx; however, no comments were made.

XVI. Future Committee Meeting Dates

Chairperson Oh advised the next Licensing Committee meeting was currently scheduled for July 18, 2024.

XVII. Adjournment

The meeting adjourned at 4:47 p.m.