



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: January 22, 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, Chair
Renee Barker, PharmD, Licensee Member
Jessi Crowley, PharmD, Licensee Member
Jason Weisz, Public Member

Board Members Not Present:

Trevor Chandler, Vice Chairperson, Public Member

Staff Present:

Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Corinne Gartner, DCA Counsel
Sara Jurens, Public Information Officer
Debbie Damoth, Executive Specialist Manager

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. The following members were present via WebEx: Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

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 because no members of the public were in attendance in Sacramento.

Public comment was received via WebEx.

A specialty pharmacist thanked the Licensing Committee and Member Weisz for proposing the statutory amendment regarding remote processing. The commenter asked if there was anything that could be done to expedite the process to facilitate obtaining an author, and how the public would be notified once an author was secured.

III. Approval of the October 18, 2023 Licensing Committee Meeting Minutes

Chairperson Oh advised the October 18, 2023 Licensing Committee meeting minutes were presented for review and approval.

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

Motion: Accept the October 18, 2023 Licensing Committee meeting minutes as presented in the meeting materials.

M/S: Crowley/Barker

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

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Chandler	Not Present
Crowley	Support
Oh	Support
Weisz	Support

IV. Discussion and Consideration of Draft Survey Related to Pharmacist to Pharmacy Technician Ratio

Chairperson Oh recalled the Committee's focus 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, noting that an important first step in this evaluation included the 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. At the October 2023 Licensing Committee meeting, the Committee initiated a review of the Board's ratio requirement. Members routinely receive public comment indicating that California has one of the most restrictive ratios. A review of various state ratios would 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 and that was not the case in California. Dr. Oh noted when comments were received, context needed to be considered. The meeting materials highlighted a few approaches taken by various states.

Chairperson Oh recalled that the Committee considered a number of policy questions related to the current ratio and potential opportunities for change at the October 2023 Licensing Committee meeting. Members determined it was appropriate to solicit feedback through a survey from a broader audience of pharmacists after consideration of the policy questions and comments from stakeholders. Chairperson Oh explained that the meeting materials contained draft questions developed by staff with the consultation of a DCA staff member with expertise in survey design who assisted with the development of the questions. After the survey was finalized, staff will continue to work with DCA experts to finalize the survey, develop the introduction and release the survey with results from the survey anticipated to be available no later than the July 2024 Licensing

Committee meeting. Dr. Oh worked with staff on the survey development and believed both the approach and questions were appropriate.

Members were provided an opportunity to comment.

Member Barker clarified with regard to Question #3, the Board was interested in feedback for work done only in California. Dr. Oh agreed and emphasized the survey was for people working in California. Dr. Barker noted Question #7 has an “or” option but only allows for multiple choice responses.

Member Crowley thought the wording of Question #8 was confusing and could be rephrased to be clearer.

Member Weisz thanked staff and believed it was important to note the survey was specifically related to work done in California.

Chairperson Oh indicated the changes could be incorporated before the February 2024 Board meeting.

Motion: Approve the survey subject to changes being made consistent with the Committee’s comments.

M/S: Weisz/Crowley

No public comment was made in Sacramento because no members of the public were in attendance in Sacramento.

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

A pharmacist suggested the Board consider sponsoring legislation to allow for the Board to establish a ratio by regulations rather than having the ratio embedded in a statute.

A representative from Walgreens requested Questions #19 and #20 be amended to add the option to have the pharmacist-in-charge (PIC) determine the ratio.

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

Chairperson Oh asked if Members Weisz and Crowley were open to amending the motion to add the option of allowing the PIC to determine the ratio to Questions #19 and #20. Members Weisz and Crowley were agreeable.

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

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Chandler	Not Present
Crowley	Support
Oh	Support
Weisz	Support

Chairperson Oh noted that the survey, with the changes discussed, will be presented to the Board for approval at the next Board meeting.

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

Chairperson Oh recalled that strategic objective 1.2 calls for the Committee and Board to consider and pursue necessary changes in the law regarding various pharmacy practice settings to ensure variances in the practice were appropriate, and noted that at today's meeting the Committee has the opportunity to continue its discussion and consideration of proposed changes to the Board's regulations regarding central fill pharmacies. The development of the proposed changes reflected the Committee's discussion and consideration of several policy questions contemplated during the October 2023 Licensing Committee meeting. The meeting materials contained a copy of the draft proposed regulation language. Dr. Oh had the opportunity to work with staff on the proposed language and believed it was appropriate, reflected the discussion, achieved the clarity sought by the regulated public, and provided for appropriate consumer protection.

Members were provided the opportunity to comment.

Member Crowley thought the language provided more clarity and was good, but wanted to have a discussion on the review of photographs for final product verification in lieu of physical verification. Dr. Crowley's impression from the Committee's last discussion was at least one pharmacist would actually have tangible final verification and wanted to see what the Committee's thoughts about it were now. Dr. Oh was open to either option. Dr. Barker agreed that some other check was needed but not sure how that check should be done.

Members of the public were provided the opportunity to comment. No public comment was made in Sacramento because no members of the public were in attendance in Sacramento.

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

A pharmacist representative of Kaiser appreciated the additional clarification provided. The representative clarified with the Board that at this time in California Kaiser Permanente does not engage in central refill pharmacy practice to any significant degree. The representative commented in support of allowing pharmacies the flexibility to have varying models for final product verification, including photographs. The representative thought this was consistent with the Board's previous approaches to final product verification in the past. The representative also suggested carrying the term "originating pharmacy" through the regulation to ensure clarity.

A representative of Walgreens appreciated the clarity that new and refill prescriptions were allowed. The representative recommended amending subdivision (a) to allow for a California licensed pharmacy to participate in central fill – not just a pharmacy that was located and licensed in California. The representative stated that while Walgreens does not, other pharmacies may already be doing this practice and it would be unfortunate to disrupt patient services. The representative commented the proposed language in subdivision (a)(5) defeated the purpose of centrally filling a prescription. The representative noted opening the product a second time could introduce another opportunity for error. The representative noted in other workflows in a pharmacy, a pharmacist is not required to check the work of another pharmacist and recommended consistency. Record keeping requirements would allow for accountability for who was responsible for any errors. The representative encouraged the

Committee to bring back for future discussions the issue of final verification for products filled via automation.

A representative of CVS commented that adding a new restriction preventing central fill by pharmacies located outside of California would have severe operational implications without apparent justification. CVS was opposed to draft language that required the originating pharmacy to complete final product verification as it defeated the purpose of central fill. The representative said the draft language may have unintended consequences. The commenter stated central fill pharmacies exist today and the proposed changes will drastically affect current practice.

A pharmacist commented in support of the Committee recognizing how important it was to allow central fill pharmacies to fill new prescriptions. The commenter noted the Committee would need to consider how the proposed language interacts with 16 CCR section 1713 for the delivery of prescriptions. The commenter noted that requiring the pharmacist at the originating pharmacy to perform final product verification was not consistent with how the Board regulates mail order pharmacies. If the proposed language was kept, the commenter recommended adding a record keeping requirement identifying "originating" pharmacy and "delivered to" pharmacy.

A representative of CCPC was in agreement with Walgreens and CVS, noting that limiting central fill to pharmacies that were located in California would be highly problematic given that currently, many CCPC members have central fill happening outside of California. The representative noted the location requirement was not specified in subdivision (b) and requested clarification that central fill could be permitted both within and outside of California by California licensed pharmacies. The representative also requested the draft language requiring final product verification to be performed by the originating pharmacy be modified as it would take away much of the usefulness of central fill pharmacies and.

Members were provided the opportunity to comment after hearing public comment.

Member Weisz expressed concern about disrupting services for California residents.

Chairperson Oh thought it would be helpful to hear from pharmacies that were using this as it was his understanding that it wasn't currently being used much. Dr. Oh added it would be helpful to hear from stakeholders who use central fill pharmacies.

Member Crowley was under the impression that with the use of central fill pharmacies, originating pharmacies were already performing the final product verification. Dr. Crowley wanted more clarification on how many pharmacies were performing this and additional information on the workflow. As it stands, the proposed language seemed to be providing more confusion than clarity.

Member Barker appreciated the comments and agreed with providing more perspective. Dr. Barker agreed with the comment to provide some clarification and using language "originating pharmacy" and to state explicitly in the proposed language. Dr. Barker agreed performing the final product verification needed to be reviewed as duplicate work wasn't needed unless there have been errors that went undetected but would have been caught if a second check was done.

Chairperson Oh indicated the proposed language would go back to staff and opened the item for additional public comment.

No public comment was made in Sacramento because no members of the public were in attendance in Sacramento.

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

A pharmacist recommended keeping the language from (b) that was stricken in the proposed draft. The pharmacist provided a person historical account of central fill.

A representative of Walgreens recommended having presentations about the workflow for central fill pharmacies. The representative was willing to help connect staff with possible presenters.

A representative of CVS agreed with the Walgreen's representative and recommended inviting companies who use central fill models in specialty pharmacy and mail order pharmacy to present to the Committee.

A pharmacist with experience in central fill for several decades was happy to provide information on how prescriptions were processed in California.

Chairperson Oh recommended bringing the item to the next meeting with possible presentations.

VI. Discussion and Consideration of Proposed Definition of Mail Order Pharmacy

Chairperson Oh expressed concern about the Board's inability to regulate nonresident pharmacies, including mail order pharmacies. Dr. Oh noted that mail order pharmacies can create unique challenges for patients and recalled at least one investigation that resulted in discipline stemming from these challenges that placed patients at risk. Based on the discussion at the October 2023 Licensing Committee meeting, there appeared to be opportunities to improve the Board's oversight of mail order pharmacies. As a first step, it appeared appropriate to consider a definition of "mail order pharmacy" to ensure everyone has a common understanding. This could also create opportunities for the Board to address its regulation of this business model more directly. Chairperson Oh directed the Committee's attention to the proposed definition included in the meeting materials.

Member Crowley asked if the 75 percent requirement was for daily, weekly, annual, etc. Dr. Crowley was curious if retail pharmacies had the ability to track that information. Dr. Crowley also wondered if it would affect contracting with PBMs and insurance companies if a pharmacy was not currently classified as a "mail order pharmacy" but would be under this new definition.

Member Barker thought the last sentence about the 75 percent of prescriptions was confusing. A timeframe would be needed.

Members of the public were provided the opportunity to comment. No public comment was made in Sacramento because no members of the public were in attendance in Sacramento.

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

A pharmacist had a question about the delivery service portion of the definition. The pharmacist asked the Committee to consider how this would impact pharmacy delivery services in California and how this differs from payer definitions of mail-order which has considerations of distance greater than 50 miles.

Representatives of CCPC and Kaiser had questions about the 75 percent requirement as it was confusing. The representative of CCPC stated that mail order is an essential service for patients, asked for the rationale for the 75 percent threshold, and expressed concern for unforeseen consequences from the reimbursement perspective even if a timeframe was added.

A pharmacist asked the Committee to consider how this definition interacts with the definition of central fill pharmacies and specialty pharmacies as well as consideration of the 75 percentage.

Member Crowley thanked the commenters and suggested looking at how mail order pharmacies are defined nationally.

VII. Discussion and Consideration of Pharmacy Technician Training Program Requirements

Chairperson Oh noted that the meeting materials detailed relevant laws and regulations regarding pharmacy technician training programs. There are various pathways to licensure for a pharmacy technician applicant, including completion of a pharmacy technician training program that meets specified requirements detailed in regulation. There are different types of pharmacy technician training programs, including those that are accredited by ASHP and employer-based training programs.

Chairperson Oh reported that Board staff have identified some issues with employer-based pharmacy technician training programs. Staff brought this issue to the Committee for awareness but also to allow the Committee to consider if additional parameters were necessary to address some of the common issues identified. Additionally, Board staff were bringing forward for Committee consideration potential changes to the statutory definition of "pharmacy technician trainee." Dr. Oh thanked staff for bringing this issue to the Committee's attention and was concerned by some of the common issues staff have identified. Dr. Oh believed a potential solution could be to require employer-based pharmacy technician training

programs to be accredited by ASHP, but acknowledged that the issue needed to be approached carefully because he does not want to hinder the licensing of pharmacy technicians.

Members were provided the opportunity to comment.

Member Crowley commented that based on her personal experience, employer-based programs vary drastically in quality and needed additional oversight.

Members of the public were provided the opportunity to comment. No public comment was made in Sacramento because no members of the public were in attendance in Sacramento.

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

A pharmacist commented that it is important to realize that when we talk about pharmacy technicians, California is unique across the country. The designation in California gives a technician the authority to do specific tasks. This is not true in other parts of the country, where any non-pharmacist who works in a pharmacy is often called a technician. Some of the nationwide employers have training programs that focus on tasks that do not require a tech license in California. Unnecessary training is an unnecessary cost that ultimately goes back to the public.

A representative from CVS commented that requiring ASHP accreditation would be a barrier and a cost, noting that much of the ASHP training focuses on tasks that do not require a technician license in California. The representative suggested the Committee hear a presentation from ASHP.

A representative of NACDS commented that accredited training programs were unnecessarily burdensome and cost prohibitive for pharmacies. The representative added that employers were in the best position to decide what training was necessary for their workforce. The representative stated there was no evidence that mandating national accreditation would improve patient care in California, and eliminating access to non-accredited programs would leave a critical gap in accessible and affordable employer-based training.

Members were provided the opportunity to comment after hearing public comment.

Member Crowley expressed interest in researching if the national accreditation route was the most appropriate as she recognized the cost to employers. Dr. Crowley agreed employers should decide what training was most appropriate for their employees, but also acknowledged that a baseline for licensure as a pharmacy technician in California was needed.

Chairperson Oh thought a presentation by ASHP would be helpful and asked Ms. Sodergren to share her experiences. Ms. Sodergren referenced meeting materials that detailed issues staff have identified. Ms. Sodergren suggested it may be appropriate to consider the results of the occupational analysis that was in process to help inform the Committee of the minimum requirements for a pharmacy technician license. Ms. Sodergren highlighted that a pharmacy technician license was not a pharmacy-specific or site-specific license; rather, the license allows the individual to perform any of the tasks established in the law. Dr. Oh indicated the item would be brought back for the next meeting, possibly with presentations, and thought there was an opportunity to define pharmacy technician training.

VIII. Discussion and Consideration of Proposed Amendment to California Code of Regulations, Title 16, Section 1793.65 Related to Pharmacy Technician Certification Programs Approved by the Board

Chairperson Oh noted that another pathway to licensure as a pharmacy technician was certification by an agency approved by the Board. The Board's regulation at 16 CCR section 1793.65 listed the two programs currently approved by the Board, which are the Pharmacy Technician Certification Board or PTCB, and the National Healthcareer Association, which administers the ExCPT exam. Section 1793.65 also includes a sunset date of December 31, 2024. Absent action by the Board, the regulation will be repealed on that date.

Chairperson Oh advised that the Board needed to evaluate the examinations used by these two entities consistent with the Department of Consumer Affairs Licensure Examination Validation Policy. The Board has contracted with the Department's Office of Professional Examination

Services (OPES) to perform the work necessary in compliance with the Department's policy; however, that work would not be completed in sufficient time for the Board to consider the results and promulgate regulations as appropriate based on the findings and subsequent Board action. Dr. Oh agreed with the staff recommendation to secure a minimum 18-month extension of the sunset date to allow for the continued use of these two certification programs as a pathway to pharmacy technician licensure while the work was being performed by OPES and any subsequent regulation change was promulgated. Dr. Oh believed this was necessary and appropriate to ensure applicants can continue to avail themselves of this pathway to licensure.

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

Motion: Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, section 1793.65 as proposed to be amended. 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.

Proposed Amendment to 16 CCR § 1793.65 as follows:
§ 1793.65. Pharmacy Technician Certification Programs
Approved by the Board.

- (a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:
- (1) The Pharmacy Technician Certification Board, and
 - (2) The National Healthcareer Association.
- (b) Approval of these programs is valid through ~~December 31, 2024~~ June 30, 2026.

Credits

NOTE: Authority cited: Sections 4005 and 4202, Business and Professions Code. Reference: Sections 4038 and 4202, Business and Professions Code.

M/S: Crowley/Weisz

Members of the public were provided the opportunity to comment. No public comment was made in Sacramento because no members of the public were in attendance in Sacramento.

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

A pharmacist commented in support of the motion and recommended seeing if other organizations could provide the training and subsequently be added to the regulation. The pharmacist also recommended checking with associations to see if they could offer California specific training and could be included in the regulation.

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

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Barker	Support
Chandler	Not Present
Crowley	Support
Oh	Support
Weisz	Support

IX. Discussion and Consideration of Licensing Statistics

Chairperson Oh referenced meeting materials including a summary of the licensing statistics for the first six months of the fiscal year. The Board issued 5,119 licenses to individuals, 382 site licenses, and 207 temporary site licenses. Dr. Oh noted processing times vary and a review of processing

times again shows improvement in several areas. The data report reflects the oldest application of each application type. Dr. Oh highlighted this to remind members that the Board's average processing time is shorter than what was reported. As was projected, with staff vacancies being filled and onboarding, processing times in several areas of operations have improved. The Committee will continue to monitor the progress made by staff. Dr. Oh thanked licensing staff who have demonstrated great commitment to applicants during this time, many of whom are taking time away from family and friends working overtime to address these backlogs.

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

Members of the public were provided the opportunity to comment. No public comment was made in Sacramento because no members of the public were in attendance in Sacramento.

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

A member of the public commented about the Board's involvement with ambulatory surgical clinics. The member of the public was encouraged to contact Board staff and participate in the Enforcement and Compounding Committee meeting scheduled for January 23, 2024.

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

X. Future Committee Meeting Dates

Chairperson Oh thanked participants, noting the next meeting was scheduled for April 10, 2024. Dr. Oh added that Committee meetings would be conducted remotely in 2024 and encouraged all to monitor the Board's website for meeting updates.

XI. Adjournment

The meeting adjourned at 10:40 a.m.