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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: October 18, 2023

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

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION:
WebEx

Board Members Present:
Seung Oh, PharmD, Licensee Member, Chair
Jig Patel, Licensee Member, Vice Chair
Renee Barker, PharmD, Licensee Member
Jessi Crowley, PharmD, Licensee Member
Jason Weisz, Public Member

Board Members Not Present:
Trevor Chandler, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Corinne Gartner, DCA Counsel
Rebecca Bon, DCA Counsel
Sara Jurrens, 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. Members present: Jig Patel, Licensee Member; 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 by meeting participants in the Sacramento location.

Public comment was received via WebEx.

A specialty pharmacist thanked the Board for including specialty pharmacy in the remote pharmacy discussion. The pharmacist shared their observations from returning to the office of the specialty pharmacy including California pharmacists being replaced by out-of-state pharmacists who can work remotely from their states and increased occurrences of pharmacists getting sick from being in the pharmacy as well as shared benefits to patients for specialty pharmacists working remotely.

A representative of CPhA provided an update to the Committee that AB 317, which was sponsored by CPhA and supported by the Board, was passed by the Legislature and signed by the governor. This bill will require health plans to pay pharmacists for pharmacy services within their scope of practice and currently covered for other health care providers. The representative also noted that AB 1286, which was sponsored by the Board and supported by CPhA, was also passed by the Legislature and signed by the governor.

A specialty pharmacist commented in support of allowing remote processing for specialty pharmacists as the pharmacist has to drive over 110 miles to work daily.

Counsel advised this section of the agenda was to add requested items to a future agenda.

III. Approval of the July 19, 2023 Licensing Committee Meeting Minutes

Chairperson Oh advised the July 19, 2023 Licensing Committee meeting minutes were presented for review and approval.

Members were provided the opportunity to comment.

Member Crowley requested page nine, paragraph three be corrected to reflect that Dr. Crowley agreed with the concept Mr. Patel said in terms of an out-of-state licensed pharmacist probably had more training and more reliability than an unlicensed clerk but ultimately Dr. Crowley agreed that any remote processing work should be done by a California-licensed pharmacist.

Motion: Accept the July 19, 2023 Licensing Committee meeting minutes as presented subject to the clarification on page nine, paragraph three.

M/S: Crowley/Patel

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: 1

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

IV. Discussion and Consideration of Provisions for Remote Processing

Chairperson Oh recalled the Committee discussed remote processing during the past several meetings, including during the January 2023 meeting where the Committee considered several policy questions and received significant public comment in support of making permanent provisions for remote processing for pharmacists working in hospitals and community pharmacies while other comments expressed concern with the

Board taking such action. As part of the April 2023 meeting, the Committee reviewed a possible legislative framework. Without quorum at the April 2023 meeting, the Committee was not able to offer recommendations despite significant public comment. At the July 2023 meeting, the Committee reached consensus on a few items so that a legislative proposal could be developed. Dr. Oh recalled at the February 2023 Board meeting, the Board voted to sponsor legislation to make permanent limited provisions related to remote medication chart order review for inpatients which were included in Assembly Bill 1557 signed by the governor. Dr. Oh confirmed members received written comments received related to this agenda item.

Chairperson Oh noted that the services pharmacists provide vary greatly as do their work environments and feedback was important to be considered for the Committee and Board to determine what is best for consumers consistent with the Board's mandate.

Chairperson Oh next reported that based on the discussion at the July 2023 meeting, he worked with staff to develop a legislative proposal, included in the meeting materials, that could serve as an important first step to expanding remote processing. Dr. Oh reviewed the approach being offered. The proposal would provide the Board with the authority to waive both provisions of Pharmacy Law to allow for research and study into new and innovative methods for drug handling under specified conditions. Dr. Oh believed this was an appropriate approach to ensure the Board had means to allow for research into the use of technology (*e.g.*, under the auspices of an accredited school of pharmacy) to allow for evaluation of changes in a controlled, research-driven environment, and to allow future decisions of the Board to be made based on data. Additionally, the language provided the Board with explicit authority to adopt regulations to establish provisions for remote processing beyond those currently allowed. Establishing explicit authority for the Board to promulgate regulations in this area would allow the Board to respond more nimbly to conditions as they change and to respond to findings of research through a public rulemaking process.

Members were provided the opportunity to comment.

Member Crowley asked if the proposed language might be too broad and gave the Board too much authority. Dr. Crowley agreed the majority

of the Board agreed there was remote processing benefits related to specialty pharmacy.

Member Weisz couldn't offer clarification on what the Legislature would do as they are independent elected officials with their own constituents. Mr. Weisz thought the language provided met the Board's needs and consensus.

Member Barker supported the language as proposed and agreed there was an opportunity to not be prescriptive and yet still allow for areas of pharmacy (*e.g.*, specialty pharmacy) to be considered as needed. Dr. Barker agreed the proposed language allowed for rapid change and growth in pharmacy with safeguards in place.

Member Patel thought there should be explicit authorization for all community pharmacists to do remote processing if licensed in California or not. Mr. Patel noted that given the working conditions and consolidations of retail pharmacies, he is concerned about workload in pharmacies and believes remote processing really helps take care of tasks that could be done remotely. Mr. Patel added that putting the requirements of being licensed in California would be a hurdle, and recommended removing the language requiring California licensure for pharmacists.

Members discussed the requirement of having a California-licensed pharmacist. Member Patel offered putting limitations would be going backwards on the work the Board has done to improve workplace conditions, limit California's ability to be prepared for disasters, and increase pharmacy deserts in California. Members Oh and Crowley noted the value in requiring a California licensed pharmacist due to the uniqueness and variances of California pharmacy law and the number of available licensed California pharmacists.

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

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

Members heard from eight specialty pharmacists in favor of allowing specialty pharmacists to work remotely. Specialty pharmacists cited reasons for supporting remote work included preserving California jobs for

California-licensed pharmacists; reducing pollution by decreasing traveling; increasing home/work life balance for pharmacists; increasing accessibility for rural consumers of California; and providing flexibility to pharmacists.

A retired pharmacist spoke in support of developing a new renewal fee structure to allow retired pharmacists to practice if needed.

A former member of the Michigan Board of Pharmacy commented on similar discussions in Michigan noting there were options available to the Board (*e.g.*, NABP certification, etc.) short of requiring California licensure, and added that by requiring licensure in California, the Board was making the profession an occupation.

A representative of CPhA commented in support of requiring a California pharmacist license. The representative noted the Board has worked hard to improve workplace conditions in California and if remote processing was allowed to be outsourced outside of California, where workplace condition protections were not in place, this would undermine the work of the Board. With regard to access to rural communities within California, companies who have remote processing can support the rural areas. The representative requested clarification if remote processing referred to verification, data entry, or both tasks. If considered as both tasks, the Board might want to expand remote processing to pharmacy technicians with verification being limited to pharmacists only.

The Committee also heard comments from pharmacists in community settings expressing concerns including less pharmacist overlap; less hours for pharmacists; and work being outsourced outside of California. Comments also expressed concerns about rushing remote processing provisions through before the results of AB 1286 are fully known, and suggested that the Board consider a confidential survey of community pharmacists to see how they really feel about remote processing in that setting.

A representative of CSHP agreed with the representative of CPhA and spoke in opposition of allowing non-California licensed pharmacists to engage in remote processing as it would compromise the protection of the public in the event of a violation of pharmacy law by a pharmacist not licensed in California.

A pharmacist representative of Kaiser spoke generally in support of the direction of the Committee for a proposal that would allow the Board the authority to write regulations on remote processing. The representative added that the less prescriptive the statutory language is, the better, as this would allow for flexibility to meet the needs of the public that may change over time. The commenter further encouraged the Board to avoid integrating requirements that are protectionist. The representative encouraged the Committee to be cognizant of the timeline (*i.e.*, passing bill and writing regulation, etc.).

A representative of CCPC spoke in support of permanent statutory authority to allow for remote processing in many settings including community pharmacy to allow for better flexibility and less distractions. The representative spoke in favor of not limiting functions to only California-licensed pharmacists to help protect patients and reduce stress in the pharmacy.

A pharmacist commented in support of defining the terms related to the proposal for clarity.

A representative of CVS commented in favor of brief and expansive remote work authorization, noting that most other states already allow for pharmacists and pharmacy technicians to work remotely. The representative suggested looking at Florida's law that allows for remote work without hurdles.

A representative of Albertsons spoke in support of not limiting remote work to only California-licensed pharmacists or California licensed pharmacists located in California to allow for greater flexibility.

A representative of UFCW WSC commented not having an issue with remote processing in specialty pharmacy and saw how there was a need for it. The representative expressed concern with the utilization of remote processing in the retail/chain setting related to outsourcing of jobs, security, enforcement, and liability. If the remote processing could be done at a licensed facility that would help to ease the concern. The representative spoke of concerns about the broadness of the proposal and thought it would have challenges in the Legislature. The representative recommended excluding chain community pharmacies or only allowing remote work in that setting from licensed facilities.

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

Member Crowley noted consumer protection included allowing only California-licensed pharmacists and exercising enforcement of licensees. Dr. Crowley asked if definitions could be provided and what was the basis for (E), wondering if it was necessary. Ms. Sodergren added (E) would allow for studies and research to be completed.

Member Weisz understood the desire for including non-California licensed pharmacists but believed there was a public safety issue to maintain. Mr. Weisz was in support of the proposal as presented.

Motion: Recommend to the Board sponsorship of legislation consistent with the language presented in the meeting materials.

Section 4071.1 of the Business and Professions Code is amended to read:

4071.1.
(a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500).
(b) This section does not reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.
(c) A dangerous drug or dangerous device shall not be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.
(d) (1) A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside of the facility, verify medication chart orders for appropriateness before

administration consistent with federal requirements, as established in the health care facility's policies and procedures.
(2) (A) A health care facility shall maintain a record of a pharmacist's verification of medication chart orders pursuant to this subdivision.
(B) A record maintained pursuant to subparagraph (A) shall meet the same requirements as those described in Sections 4081 and 4105.
(e) In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovate methods for drug handling, or to develop new and better methods or concepts involving the ethical practice of pharmacy the Board may waive the application of this section and applicable provisions of Pharmacy rules and regulations contained in Title 16, California Administrative Code, Chapter 17, if the Dean of said school has filled with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.
(f) The Board may adopt regulations that establish provisions for remote processing of prescriptions. At a minimum, remote processing may only be performed by a California licensed pharmacist, from a location within California. The regulations shall include provisions for security to protect health information, recordkeeping requirements and autonomy for the pharmacist-in-charge to determine when such processing is allowed.

M/S: Weisz/Crowley

DCA Counsel Gartner agreed there was nothing in the proposal addressing the definition of remote processing and added a definition similar to that which was included in the expired remote processing waiver could be added. Ms. Sodergren and Ms. Gartner agreed the definition could be added in regulation. Dr. Crowley asked if it would be a problem with submitting a legislative proposal without a definition. Ms. Gartner was not able to know what the Legislature would do but it was a consideration that the Board would probably want to take under advisement.

Dr. Oh asked Mr. Weisz if he was agreeable to amend the motion to add to the proposal a definition of "remote processing" and authorize the

Chair to work with staff and counsel to refine the language in advance of the November 2023 Board meeting. Mr. Weisz agreed and underscored the urgency to advance forward. Dr. Crowley agreed with the updated motion.

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

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

A pharmacist suggested the committee provide more guidance to the Chair on the definition of remote processing.

A representative of UFCW WSC commented more discussion was needed about the definition, scope, practice settings, and enforcement of remote processing.

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

Support: 5 Oppose: 0 Abstain: 0 Not Present: 1

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

The committee took a break from 10:43 a.m. to 11:00 a.m. Roll call was taken after the break. Members present: Jig Patel, Licensee Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member, and Seung Oh, Licensee Member. A quorum was established.

V. Discussion and Consideration of Pharmacist to Pharmacy Technician Ratio

Chairperson Oh began the discussion by stating his intent to focus Committee discussion on strategic objective 1.3 related the exploration and pursuit of changes in law appropriate for the authorized duties of a pharmacy technician. 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 the governor signed earlier this month. Implementation of that measure would be discussed during the October 19, 2023 Enforcement and Compounding Committee meeting. Dr. Oh noted this was an important first step but additional changes may be appropriate.

Chairperson Oh reported that one area the Board continually receives comments on is the issue of the pharmacist to pharmacy technician ratio. Dr. Oh added members frequently hear public comments indicating that California has the most restrictive ratios; however, the comparison wasn't always equivalent as jurisdictions have varying approaches on provision of 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 reminded participants that context matters when comments are received.

Chairperson Oh noted that the meeting materials contained policy questions to aid the Committee's discussion.

Question 1. Do members generally believe than an increase in the pharmacist to pharmacy technician ratio could be appropriate in additional pharmacy settings than those currently authorized, such as closed-door pharmacies, compounding pharmacies, etc.

Chairperson Oh stated that he believes the answer was yes but as he has previously shared, philosophically, he has a concern with the Board parsing out different rules for different pharmacies, adding that such an approach allows the Board to be more flexible and deliberate in its regulation, but also has the potential to parse out the profession.

Members were provided the opportunity to comment.

Member Patel spoke in support of increasing the ratio to take stress off of pharmacists and allow for more clinical duties by the pharmacist. Mr. Patel

added the pharmacist-in-charge (PIC) could be given the authority based on setting, ratio, ancillary staff, etc. to assist in serving consumers.

Member Crowley was not comfortable expanding ratios in the community setting. Dr. Crowley noted that adding staff didn't always help as staff needed to be supervised. Dr. Crowley pointed out there was already a pharmacy technician shortage and wasn't sure increasing the ratio would help.

Member Barker thought there were pharmacy settings that didn't fall within the categories and the PIC needs to be involved in the decision. Dr. Barker understood the current pharmacy technician shortage but added that wouldn't always be the case. Dr. Barker was in support of increasing the ratio but wasn't sure how to define all of the settings.

Members discussed the PIC having the authority and autonomy to make the decision based on the pharmacy.

Member Weisz looked forward to hearing public comment.

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

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

A representative from CCAP recommended changing the ratios for all closed-door pharmacies.

A representative from CPhA recommended allowing time for AB 1286 to be implemented, monitored, and enforced before making any changes in pharmacy technician ratios. The representative recommended a ratio tied to the volume of work at the pharmacy.

A pharmacist recommended getting feedback from community pharmacists through a survey.

A pharmacist recommended researching with licensees and look at the duties that differentiates a clerk from a pharmacy technician.

A representative from CSHP referenced the increase of ratios related to the administration of administering vaccines.

A representative of CCPC commented in support of increasing consumer care by expanding the ratio, noting states with no ratios have no issues and adding it should be up to the PICs.

A pharmacist manager from Michigan commented Michigan had no ratio and added all stakeholders need to work together to determine what is needed for public safety.

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

Question 2. Do members believe that establishing a ratio of 1:2 could improve patient care in all pharmacy settings that currently do not allow such a ratio?

Chairperson Oh stated that he believes the answer was yes but realized the details were important, adding AB 1286 included some important provisions related to staffing that if implemented correctly could ensure that an across-the-Board ratio increase to 1:2 was possible.

Members were provided the opportunity to comment.

Member Crowley thought it potentially could but depends on the individual and their path of licensure. Dr. Crowley thought the topic was worth expanding on and proposed doing a survey on various practice settings and discuss with the pharmacists the impact with the ratio.

Member Patel commented the 1:2 ratio wouldn't apply to all settings as a closed-door pharmacy could accommodate 1:3. Mr. Patel advocated for letting the PIC decide.

Member Barker agreed with letting the PIC decide. Dr. Barker noted establishing a set number ratio may not serve the pharmacy well.

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

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

A representative of CCAP agreed with Members Patel and Barker as it would depend on the setting.

A pharmacist added there would need to be protection for the PIC and recommended tying to the number of prescriptions the pharmacist has to fill.

A representative of CVS commented there were no issues in Idaho with having a high ratio and provided other states were eliminating ratios. The representative stated increased ratios help public safety.

A pharmacist commented in agreement with an increase in ratio. The commenter read pharmacy law and provided a personal recollection of the history of pharmacy technician ratios.

A commenter stated pushing more pharmacy technicians on pharmacists impacts the pharmacists and recommended looking to how many prescriptions a pharmacist can fill in a day.

A commenter stated increasing the ratio was not a good idea and would just give more power to the large organizations to push more work onto pharmacists. The ratio should stay as is because pharmacists are currently doing too much.

A commenter stated having one pharmacist to one pharmacy technician was difficult in an inpatient setting and in an infusion pharmacy, it was a struggle to get one pharmacist in to allow for the two pharmacy technicians. More pharmacy technicians were needed for each pharmacist.

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

Question 3. Do members believe the Board should have flexibility to have authority to approve a higher ratio on a facility specific basis?

Chairperson Oh stated that he found the concept very intriguing and might provide a path forward by allowing the Board the flexibility to make

a decision based on a specific set of facts for a specific entity. He noted that this approach would be administratively time-consuming to both staff and members, though.

Members were provided the opportunity to comment.

Member Patel recommended checking with North Carolina on how they handle this facility-specific petition method, but the workload on staff and members would need to be considered. Mr. Patel was not in favor.

Member Crowley noted other questions were raised such as criteria, volume, etc. but wasn't opposed to it.

Member Barker thought it would be a challenging approach and wondered what that would look like in reality.

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

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

A pharmacist commented this method had not worked in the past and had unforeseen consequences as well as changes in rules based on Board member and staff turnover. The commenter was in favor of having more pharmacy technicians to help serve consumers.

A pharmacist representative from Kaiser commented about concern in establishing maximum thresholds for the number of tasks a pharmacists can perform in a given time period and was skeptical the Board could be aware of all factors needed to make a decision. The representative discouraged the Board from this path.

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

Question 4. Do members believe the Board should have the authority to increase the ratio via regulation as part of the rulemaking process?

Chairperson Oh thought this would be an easier path to pursue regulation versus sponsoring a legislative proposal. Ms. Sodergren further explained

the Board did not have the current authority to increase the ratio and if changes were identified as needing to be made, changes by regulation would allow the Board with more flexibility.

Members were provided the opportunity to comment.

Member Weisz commented in support of this approach but would like to hear from the pharmacists via a survey as well as see the impacts of AB 1286.

Member Crowley expressed concern of this putting more urgently-needed legislation for remote processing at risk.

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

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

A pharmacist recommended the Board sponsor legislation to take the restriction out of the statute.

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

Chairperson Oh summarized the discussion, noting the Committee wanted to survey pharmacists about the ratio, work settings, and thoughts. Dr. Oh hoped that the survey could be brought back for approval at the next Committee meeting.

A lunch break was taken from 12:09 p.m. to 1:00 p.m. Roll call was taken after the break. Members present: Jig Patel, Licensee 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 Pharmacy Provided CLIA Waived Tests, Including Potential Expansion of Authorized Tests

Chairperson Oh recalled that the Board sponsored SB 409 in 2021 to expand access to pharmacist-provided CLIA-waived tests. This bill

established the general types of tests pharmacists could provide under specified conditions, but left open the potential for additional expansion of authority. Dr. Oh added this to the agenda for open discussion to determine if, in the interest of public safety, the Board should consider expanding pharmacist authority to other tests.

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

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

A representative from the California Medical Association (CMA) commented CMA believed further work needed to be done on the current list of tests before additional tests were added via regulations. CMA wanted to ensure patients were being referred appropriately to their primary care provider for treatment and their assessment.

A pharmacist recommended reaching out to Idaho and Washington to see what other states' pharmacists were testing.

A representative of CVS commented most states defer to federal lists of tests and recommended keeping it broad.

A representative of CPhA commented in support of broad expansions.

Members were provided the opportunity to comment.

Member Crowley thought it was good have the discussion while keeping in mind that staffing levels at the pharmacy affect how much testing can be done, and that the Board might want to wait to see how AB 1286 and AB 317 play out.

Chairperson Oh commented AB 317 if implemented correctly will be a huge opportunity for pharmacies to provide better patient care for the LGBTQ+ community.

Member Patel spoke in support of expanding testing authority as access was a key factor to allow people to get tested on time. Mr. Patel commented the list can grow over time.

Chairperson Oh recommended Ms. Sodergren reach out to the Medical Board.

Member Barker spoke in support of expanding the use of CLIA-waived tests, noting the list was huge. Allowing more tests would provide the public with easy access to help in a decision point. Dr. Barker believed in being less prescriptive.

Chairperson Oh advised he would be working with staff on next steps.

VII. Discussion and Consideration of Central Fill Pharmacies

Chairperson Oh advised that, consistent with strategic objective 1.2 requiring the Committee and the Board to consider and pursue necessary changes in the law regarding various pharmacy practice settings to ensure variances in the practice were appropriate, this discussion was added to the agenda. Dr. Oh first confirmed that members received the written comments that were submitted related to this agenda item. Dr. Oh advised that policy questions would be used to aid the discussion.

Question 1. Should labeling requirements be updated to ensure patient-centered labeling requirements are satisfied? Should the label include the names of both pharmacies?

Chairperson Oh noted that as patient-centered labeling requirements apply to all prescriptions dispensed to California patients, he believes the patient-centered labeling requirements already apply to central fill pharmacies but to ensure licensees had a clear understanding of the requirements, updating the regulations in this area was appropriate. Dr. Oh believed the label should include the names of both pharmacies.

Members were provided the opportunity to comment.

Member Crowley agreed with Dr. Oh. Members discussed the address requirement for the label that required either the address of the central fill pharmacy or the pharmacy where the prescription was picked up. Member Barker agreed a patient should know where their medication was filled.

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

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

A representative of CPhA commented that their membership was requesting clarification and re-endorsement by the Board that central fill pharmacies were allowed by the Board. The representative encouraged engaging with stakeholders including Kaiser, chains, and PBMs on this topic. The representative shared their experience working at Kaiser and central fill pharmacies in the past.

A representative of the CCPC commented in support of the current practice of central fill and encouraged the Board to maintain its existing broad interpretation of central fill and technology assisted final verification services in California. CCPC supported the authorization for a pharmacy to process both the request for refills of prescriptions received by a different pharmacy and new prescriptions as well as that the pharmacy should continue to be able to utilize automated verification technology and that the final verification by dispensing pharmacist should not be required as it takes away the usefulness of central fill. The representative stated labeling requirements should only include pertinent information to take medication. Additional information required on labels may cause confusion for the consumer.

An attorney representative of Quarles & Brady LLP commented as a supporter of many pharmacies engaged in central filling or shared pharmacy services across the country. The representative stated it was common requirement in multiple states for a pharmacy engaged in central fill activities to include the pharmacy information of the filling pharmacy or a unique identifier. The commenter noted sometimes there were two to four pharmacies involved in the processing of the prescriptions with one pharmacy involved in the fulfillment but the patient needs to identify the central fill pharmacy and necessary staff that could be contacted if needed.

A pharmacist representative from Kaiser underscored practices at Kaiser have changed over the years since the CPhA representative worked at Kaiser. The representative agreed the current regulation requires the address of the refill pharmacy and/or the pharmacy receiving the prescription. The representative agreed with the current law and suggested adding a provision that how labeling is completed be specified

in the policies and procedures or contract. The representative had no concerns about the patient-centered labeling being required for central fill pharmacies.

A pharmacist commented central fill has proven to be an improvement in dispensing errors, reducing chaos in the pharmacy, and better overall healthcare. The commenter provided a personal historical recollection of central fill. The commenter was supportive of patient-centered labels and stated this should be enforced.

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

Question 2. Given the number of errors reported from central fill pharmacies, should the regulation require final product review at the dispensing pharmacy before the prescription is released to the patient?

Chairperson Oh referred to the meeting materials, which note that the Board has received QA reports from central fill pharmacies documenting medication errors. Under existing law, both pharmacies are responsible for ensuring the order was properly filled, and it appears that the law envisioned some sort of final product review or verification, but Chairperson Oh noted that he was not certain how that worked in practice.

Chairperson Oh noted that he was more comfortable requiring final verification in some fashion. Dr. Oh added that efficiency and innovation were good, but there were limitations to this, and when consumer protection is considered, there were minimum requirements that should be seeking to ensure the medication and final product was verified by a pharmacist.

Members were provided the opportunity to comment.

Member Patel requested data on errors attributable to central fill pharmacies versus the general trend of errors. Dr. Oh indicated that may need to be gathered with the implementation of AB 1286. Mr. Patel inquired if the errors might be technology versus human. Mr. Patel believed overall, it was working. Dr. Oh indicated the issue was being brought up not necessarily because it's not working, but because there's an opportunity to provide more clarity.

Member Crowley stated that she generally believes the final product should be accessible by a pharmacist to physically open the bottle and look inside. Alternatively, Dr. Crowley was generally comfortable with the idea of having photos to access before dispensing as a substitute for physical verification. She added that she hoped to know more about the errors. Dr. Crowley wasn't opposed to requiring one of the pharmacists (dispensing or central fill) to physically confirm the medication was correct before packaging.

Member Barker thought dispensing pharmacies should have clarity on what they are providing to a patient. If errors are attributable to technology, there needed to be a secondary physical check. The error rate also needs to be clarified and understood.

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

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

An attorney representative of Quarles & Brady LLP commented on behalf of licensees who were seeking confirmation that the Board ultimately defers to the professional judgment of the pharmacist when utilizing technology-assisted prescription verification. The representative referenced materials he had sent to the Board which referenced a 2005 article in *The Script* that stated that it was the pharmacist's responsibility to ensure 100 percent accuracy of a dispensed prescription. The article had indicated that if the licensee seeks to utilize technology for such verification, they may do so pursuant to their professional judgment and at their own risk. Stakeholders were seeking confirmation that the Board still holds the position that the use of the technology is permitted and at the discretion of the pharmacist. The representative requested clarification whether final human verification at the end of the process was required. He added that the manner in which question 2 was framed made unsupported assumptions regarding errors in central fill pharmacies, and he recommended that the Board review peer-reviewed articles demonstrating that technology helps to reduce errors in these systems versus standard human fulfillment.

A representative of Walgreens recommended that the Board visit a central fill facility so they can look at the automation and see firsthand how it works in practice.

A representative of Innovation Associates, which provides technology solutions for central fill pharmacies, recommended that the Board review peer-reviewed studies from ISMP, NABP, and APHA that show the benefits of automation. The representative requested to see the data that was informing the Board's policy decision related to errors.

A pharmacist representative from Kaiser agreed that question 2 seemed framed in a misleading way and encouraged the Board to share data. Kaiser supported the recommendation to reaffirm the position expressed in the 2005 article in *The Script* as the underlying law hasn't changed. The representative saw potential issues with a regulation requiring final product review at the dispensing pharmacy before the prescription was released to the patient if the central fill pharmacy performs the fill and sends it back to the dispensing pharmacy, as the dispensing pharmacy wouldn't have an electronic workflow available to do another product verification.

A pharmacist provided a personal historical account of their experience of central fill at Kaiser. The pharmacist encouraged visiting central fill sites. The commenter advised against having the final review done at the dispensing pharmacy.

A representative of CSHP commented that central fill has improved the ability to counsel the patient. The commenter encouraged members to visit a central fill pharmacy.

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

Member Patel thought a tour of a central fill pharmacy would be helpful for members.

Question 3. Should the regulation be amended to clarify that a central fill pharmacy may dispense both new and refill prescriptions for a pharmacy under contract or under the same ownership?

Chairperson Oh noted that he believes the language as currently written could be interpreted two ways, and that it was important for the Board to

clarify its policy on this issue and to update the language accordingly to ensure the regulated public has a clear understanding of the Board's requirements.

Members were provided the opportunity to comment.

Member Crowley agreed it was unclear and could benefit from clarification.

Member Patel understood the current practice allowed for new and refill prescriptions to be refilled and asked what the benefits were to the consumer if this changed. He also asked why was the Committee wanting to reinvent a wheel that was already working.

Chairperson Oh explained the discussion was to clarify what was unclear and agreed with Member Patel.

Member Weisz requested data from industry before continuing the conversation.

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

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

A pharmacist representative of Kaiser was supportive of clarifying that the regulation allows both new and refill prescriptions. The representative clarified that today Kaiser was not engaging in central fill at the scale that former Kaiser employees were representing today.

A representative of CSHP recommended allowing for new and refill prescriptions for continuity of care.

A pharmacist provided a personal historical account of their experience with central fill.

An attorney representative of Quarles & Brady LLP requested the Board confirm its position on whether a pharmacy may fill new prescriptions on behalf of another pharmacy.

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

Question 4. Should a patient provide consent or receive notification that the prescription will be filled at another pharmacy?

Chairperson Oh stated that he believes the answer to this question was yes as the patient needs to be in control, but that he also understands the dynamic environment and being too restrictive.

Members were provided the opportunity to comment.

Members Crowley and Barker thought it would be confusing for patients and present a barrier to care. Dr. Barker recommended maybe a notification be provided.

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

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

An attorney representative of Quarles & Brady LLP agreed with Members Crowley and Barker and stated it was rare for a state to require prior consent but what was required was to provide notice. The commenter agreed that requiring prior consent was not in the best interest of the patient.

A representative from Innovation Associates agreed with the Quarles & Brady representative.

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

Question 5. Should we limit central fill pharmacies to only operating within California?

Chairperson Oh noted that he was concerned that the Board currently didn't have a good means for assessing nonresident pharmacies for compliance with California law, and that he was inclined to limit central fill provisions to only pharmacies licensed in California but recognized that

may not be possible. Dr. Oh continued that the Board might consider grandfathering in any central fill pharmacies located outside of California but establish some mechanism for inspections of those facilities to ensure compliance with California provisions.

Members were provided the opportunity to comment.

Member Patel asked if currently there were central fill pharmacies located outside of California servicing California patients. Ms. Sodergren responded that the Board's licensing scheme currently does not differentiate.

Some members did not see a problem provided the nonresident pharmacy was licensed in California as a nonresident pharmacy. Some members thought the nonresident pharmacies should be handled the same way as nonresident sterile compounding pharmacies.

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

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

An attorney representative of Quarles & Brady LLP stated California Code of Regulations (CCR), title 16, section 1707.4 (a), specifies "a pharmacy within this state" and agreed the verbiage seemed to permit cross-state arrangements but wanted clarification.

A representative of CSHP noted Business and Professions Code (BPC) section 4112 addressed nonresident pharmacies and posed the question wouldn't it still be a nonresident pharmacy?

A pharmacist commented with their personal historical account of their experience with central fill noting a separate law wasn't needed but a statement or FAQ would be helpful.

A pharmacist representative from Kaiser commented in support of the position that central fill pharmacies can operated outside of California.

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

Question 6. Should the Board define central fill pharmacy?

Chairperson Oh noted that he believes there were pros and cons to such an approach and thought developing a definition to ensure the regulated public has a clear understanding of the Board's application of the requirements might be helpful.

Members were provided the opportunity to comment.

Member Crowley was undecided and Member Patel thought it should be left as is.

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

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

A pharmacist commented that he did not believe it needed to be redefined or defined. The commenter indicated that simply changing the title of 16 CCR 1707.4 might clarify the issue.

A pharmacist representative from Kaiser commented there wasn't any need to define central fill pharmacy.

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

Question 7. Should the regulations for central fill pharmacies be limited to noncontrolled medications only?

Chairperson Oh noted the comment in the meeting materials regarding DEA limitations on transferring controlled substances. He stated that he thought this question was a bit complex and he recommended staff reach out to the DEA for their position on this topic. Dr. Oh further noted that unless members felt strongly that the regulation should be limited to noncontrolled drugs only, his suggestion was to defer the discussion on this question until after clarification was received from DEA.

Members were provided the opportunity to comment.

Chairperson Oh and Member Patel thought there should be no limitations. Mr. Patel noted the DEA has clear regulations on this matter.

Member Crowley thought it should be limited to noncontrolled substances for liability purposes and allowing the PIC to be able to make the decision.

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

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

A pharmacist representative from Kaiser thanked the Board for the discussion and noted the DEA has clear regulations regarding central fill for controlled substances which pharmacies have to meet.

A pharmacist provided the DEA regulation 1306.15 regarding central fill but noted pharmacies decide whether or not they want to fill prescriptions for controlled substances. The pharmacist encouraged the Board to not limit central fill to noncontrolled substances.

A representative of Innovation Associates thanked the Board and offered to be a resource for technology solution questions.

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

Chairperson Oh thought it would be clearer to update the regulation and bring it back to Committee versus developing FAQs to clarify the policy questions. Member Patel didn't believe anything needed to be updated. Dr. Oh noted stakeholders were asking for clarification. Members Crowley and Barker thought clarification was needed and a regulation or update in *The Script* was acceptable.

Ms. Sodergren understood the pros and cons for regulations, policy statements, and FAQs and offered to work with staff and regulation counsel before the Committee's next meeting to determine a path forward. Dr. Oh was agreeable. Member Weisz requested data and a tour of the facility before a decision was made.

Member Weisz left the meeting at 2:43 p.m.

VIII. Discussion and Consideration of the Board's Regulation of Mail Order Pharmacies

Chairperson Oh requested feedback from members on the Board's current regulation of mail order pharmacies and stated that he was concerned about the Board's inability to regulate nonresident pharmacies, including mail order pharmacies. Dr. Oh agreed with the comments in the meeting materials that mail order pharmacies create unique challenges for patients and recalled at least one investigation that resulted in discipline stemming from these challenges that were placing patients at risk. Dr. Oh added that he believes there were opportunities to improve the Board's oversight of mail order pharmacies.

As he opened the matter for general discussion, Chairperson Oh noted that he believes mail order pharmacies may have a place in patient care, but was extremely concerned about what appears to be a transition away from direct pharmacist-patient interaction, which is really contrary to the policy direction of the Board. Dr. Oh reminded members the Board has a legislative proposal to require PICs to be California-licensed pharmacists in nonresident pharmacies or it could be a sunset issue.

Members were provided the opportunity to comment.

Member Crowley asked if there was a definition for mail order pharmacies. Counsel Gartner didn't believe there was a definition on mail order pharmacy. Dr. Crowley thought there should be a good standard for patients for all nonresident pharmacies. Dr. Crowley was hopeful the Board would be able to require California pharmacist licensure for nonresident PICs and hopeful that, with the travel restrictions being lifted, the Board could better monitor the nonresident pharmacies. Ms. Sodergren noted that the travel ban has been lifted; however, the Board currently does not have explicit statutory authority for inspection and recovering costs with respect to nonresident pharmacy inspections as the Board has with the nonresident sterile compounding pharmacies.

Member Crowley thought temperature tracking should be considered due to the extreme temperatures in California.

Chairperson Oh noted most nonresident pharmacies fill millions of prescriptions and should be prioritized. Dr. Oh thought adding an

inspection requirement (*e.g.*, every two to four years) could be a sunset issue.

Member Patel agreed if a nonresident pharmacy was shipping into California an inspection should be done. Mr. Patel noted temperature control was important and inquired if a holistic approach for the entire supply chain should be taken versus isolating nonresident pharmacies shipping into California.

Member Crowley noted in mail order pharmacy, prescriptions can be delayed while sitting in mailboxes or on porches.

Member Barker added maintaining the quality of the drug through extreme temperature fluctuations was a quality issue that should be addressed and was expansive. Dr. Barker agreed nonresident mail order pharmacies should have inspections.

Chairperson Oh added this could be included as a sunset issue due to the size of the change that would be required. Ms. Sodergren noted the sunset process allows for the opportunity to bring issues to the Legislature as well as securing more direct authority and statutory mandate.

Member Crowley agreed having more robust discussion would be helpful so the issue could be addressed as a whole.

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

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

A representative of the CCPC commented the mail order pharmacy service was critical and impacts access for many consumers. The representative noted that requiring temperature monitoring would be problematic and costly without proof that there was a need to do this. The entire supply chain should be considered.

A pharmacist representative from Kaiser encouraged the Board to look at approaches other state boards have taken in regard to inspecting nonresident facilities. Some boards accept home state inspections or inspections conducted by certifying agencies. The representative added

that requiring temperature monitoring in every package would be impractical and suggested that the Board consider a policies and procedures-based approach to regulating mail order pharmacy practice.

A pharmacist asked if patient-centered labeling requirements apply to nonresident (e.g., mail order) pharmacies. Mail order was another mode of delivery being used. The representative added with the increase of mail order pharmacies there was a decrease in patient consultation.

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

IX. Licensing Statistics

Chairperson Oh referred to the meeting materials, which included a summary of the licensing statistics for the year. The Board issued 2,445 licenses to individuals and 182 site licenses, and 96 temporary licenses. Dr. Oh congratulated individuals who received a license during the first quarter, including new graduates of pharmacy schools and those entering pharmacy school.

Chairperson Oh advised that a review of processing times showed improvement in several areas. The data report reflected the oldest application of each application type. Dr. Oh noted that he highlighted that fact so that members understood the Board's average processing time was shorter than what was reported. Dr. Oh further noted that, 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 and working overtime to address these backlogs.

Members were provided the opportunity to comment. Member Patel thanked staff for their efforts.

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

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

A pharmacist requested statistics on remote dispensing site pharmacies and was referred to the meeting materials.

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 January 22, 2024. Dr. Oh added that Committee meetings would be conducted remotely in 2024 and encouraged all to monitor the Board's website for updates.

XI. Adjournment

The meeting adjourned at 3:16 p.m.