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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 5, 2023

Location: Pursuant to the provisions of Government Code

section 11133, neither a public location nor teleconference locations are provided.

Board Members

Present: Seung Oh, Licensee Member, Chair

Trevor Chandler, Public Member Jessi Crowley, Licensee Member

Board Members

Not Present: Jig Patel, Licensee Member, Vice-Chairperson

India Cameron-Banks, Public Member

Jason Weisz, Public Member

Staff Present: Anne Sodergren, Executive Officer

Eileen Smiley, DCA Staff Counsel

Debbie Damoth, Executive Manager Specialist

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

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

Roll call was taken. Members present: Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensing Member. A quorum was not established.

Chairperson Oh advised as the Committee did not have a quorum, consistent with the agenda, Dr. Oh believed it was appropriate that the Committee proceed with the discussion on the agendized items where possible. Dr. Oh advised the at the Board meeting that no Committee recommendations would be offered.

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

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

III. Approval of the January 24, 2023, Licensing Committee Meeting Minutes

Chairperson Oh advised as quorum was not established, the Committee was unable to approve the minutes. Dr. Oh requested staff place this item on agenda for the July 2023 Meeting for consideration and approval as appropriate.

IV. Discussion and Consideration of Provisions for Remote Processing

Chairperson Oh recalled the Committee has discussed remote processing several times over the past year, most recently during the January 2023 meeting as 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.

Chairperson Oh reported during 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. Dr. Oh advised these provisions were included in Assembly Bill 1557.

Chairperson Oh reported the Committee was committed to continue consideration of potential provisions to allow for remote processing for pharmacists working in community pharmacies. During the prior discussion, the Committee did not reach consensus on whether remote processing was appropriate for community pharmacy. Dr. Oh noted the Committee received public comment from pharmacists currently working in a remote capacity under the Board's waiver and potential consequences if provisions were not made permanent.

Chairperson Oh reported the Committee has also received public comment questioning the Board's legal authority for pharmacists beyond remote processing. Dr. Oh referred to the meeting materials outlining the Board's strategic plan includes a strategic objective to evaluate and

change if appropriate, legal requirements for authorized duties that can occur outside of a pharmacy to reflect the dynamic nature of the practice of pharmacy. Dr. Oh believed this was an important discussion that both the Committee and Board must undertake, but the discussion now should remain focused on remote processing.

Chairperson Oh directed staff to prepared draft statutory language to illustrate potential remote processing provisions. Dr. Oh clarified it was intended to merely serve as a starting point for our discussion. Dr. Oh didn't believe the language addressed all of the issues needed to be considered but could provide a basic framework from which to build upon. Dr. Oh believed it was imperative that whatever final decision was made, it must be correct for California consumers and consistent with the Board's mandate. Dr. Oh believed it was possible that the discussion could span multiple meetings.

Chairperson Oh reviewed the concepts in the proposal before accepting member and public comments. Based on the discussion, Dr. Oh would work with staff to incorporate changes for continued consideration at the next meeting.

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

Chairperson Oh advised the first general concept provided that the provisions would be limited to California licensed pharmacists, performing remote functions within California and on behalf of a California licensed pharmacy. Dr. Oh believed it was important if the Board would allow for remote processing in community pharmacies. Dr. Oh noted it was also similar to the approach the Board was taking in Assembly Bill 1557.

Members were provided the opportunity to comment.

Members Crowley and Chandler agreed that was consistent with previous Committee discussions.

Members of the public were provided the opportunity to comment.

The Chief of Pharmacy for UC Health respectfully requested on behalf of the UC Health system to extend the current waiver or exercise enforcement discretion beyond May 28, 2023; ensure any proposed legislation addresses remote functions for pharmacists and pharmacy technicians; and to clearly define each of the remote functions (e.g., insurance processing) in the draft statute. The commentor made specific comments on the draft statutory proposal: (a) allow pharmacy technicians to perform functions outside pharmacy in California; (a) (1) clearly define each of the remote functions and limit the scope of the legislation to activities with the respective scope required by the respective license; (a) (2) requiring the pharmacist-in-charge (PIC) to do an annual certification related to pharmacy staffing was overly burdensome and practice should be the same regardless of the setting; and, (a) (3) designating one location was over overly burdensome where policies and procedures were sufficient.

A pharmacist representative of Kaiser commented in appreciation of commenting on the topic. Based on the favorable experience with remote working, Kaiser continued to believe the current remote processing waiver was the best framework. The more onerous the requirements the less likely organizations will participate. A 2022 study by McKinsey and Company found underrepresented groups have a stronger than average preference for remote or hybrid working. The representative encouraged the Board to consider the diversity, equity, and inclusion (DEI) implications related to the Governor's executive order N-1622. The representative provided comments on (a) recommended to keep the duties limited to pharmacist and pharmacy technician remote work duties using BPC 4007 (b) as a guiding principle for tasks and not limit tasks to pharmacists. The representative encouraged the Board to identify how the proposal would stand apart from the changes proposed in AB 1557 as well as specify these requirements were specific to remote processing outside the hospital or health care facility.

A representative from the California Community Pharmacy Coalition (CCPC) a project of the CRA thanked the Committee for the discussion and commented many members have safety and securely utilized remote processing before the enactment of the waiver. The representative spoke in support of the efforts to ensure remote processing could continue in the community pharmacy setting noting there are pharmacists who do work remotely who will be at risk with the waiver set to end of May 2023. The representative reviewed the benefits for pharmacists and patients when the pharmacist was allowed to work remotely work-life balance and those with disabilities that cannot work in a pharmacy. Duties believed to be allowable for remote work included DUR, prescription order entry, and

remote prescription verification all which reduce workload, interruptions, and errors in the pharmacy. The representative suggested (a)(1) of the draft proposal should include pharmacists licensed in California that were tied to both resident and nonresident pharmacies.

A pharmacist licensed over 40 years spoke as a representative of UCSD Health System, UC Medical Centers and School of Pharmacy and commented about (a)(4) and (a)(5) requesting the Board to look at how to categorize pharmacists not supervised by PICs working in a different setting than community pharmacy. The commentor added standards for remote pharmacists should be similar for pharmacists regardless of practice setting.

Members were provided the opportunity to comment after public comment.

Chairperson Oh thanked the stakeholders for their comments and heard the concerns raised.

Member Crowley inquired if the proposed language would be reviewed. Dr. Oh recommended focusing on policy questions at this meeting.

Member Crowley requested clarification if the specialty pharmacy was part of the community pharmacy. Counsel Smiley commented not being sure if the Board wanted to request a carveout if the Board moves forward with the proposal. Dr. Crowley added a majority of the commenters work in specialty pharmacy and have deeper discussions on what that means. Dr. Crowley also wanted to see additional information on the number of pharmacies these were actually being used in as well as if there was information on the number of community pharmacies versus specialty pharmacies were using it.

Chairperson Oh noted a person who wanted to comment during public comment but disappeared reappeared in the WebEx with a hand raised. Dr. Oh allowed the comment.

A specialty pharmacist commented the specialty pharmacy consists of the front-end pharmacists (e.g., review chart, prescription verification, DUR, consultation, answer stability questions, etc.) and back-end pharmacists (e.g., final product verification). The commentor added the front-end pharmacists and pharmacy technicians had been able to work remotely

without privacy issues for the past three years. Patient care has increased as there are less distractions and less outages due to getting each other sick.

Chairperson Oh reported the second concept would provide that remote processing would only be allowed after the PIC has decided that remote processing is necessary to enable improved direct patient care by pharmacists working in the pharmacy. Dr. Oh believed this was one of the most important concepts as the Board was working hard to ensure PICs were responsible for making the business decisions at the pharmacies for which they were legally responsible.

Members were provided the opportunity to comment.

Member Crowley expressed concern while the community PIC should be involved, the model in community pharmacy doesn't allow for full autonomy in community setting. Dr. Crowley noted many pharmacists and PICs already feel pressured to sign forms to waive lunch breaks and worried the PICs would feel pressured or be threatened. Dr. Crowley expressed concern with the language about staffing issues as now there wasn't transparency and until there was transparency, it would be unable to be proved.

Chairperson Oh inquired how these concerns could be addressed. Dr. Crowley wasn't sure how to get around the fear of retaliation. Dr. Crowley added in chain pharmacies, the PIC was not involved in developing policies and procedures. Dr. Crowley suggested for staffing levels require language for how staffing was determined in order to move to remote processing. Dr. Oh suggested adding there could be a disciplinary action against the pharmacy if the PIC was forced to sign these documents and if the staffing levels were to be reduced after implementation and could be grounds for disciplinary action and unprofessional conduct. Dr. Crowley agreed with the addition of disciplinary action but would have to know how the staffing model works.

Member Chandler agreed with Dr. Crowley and echoed a fear of a race to the bottom in terms of staffing and additional pressure on the pharmacists.

Member Crowley added during COVID extra staffing for pharmacists was needed. Dr. Crowley struggled to understand why many retailers didn't

hire another pharmacist who could have been working remotely in another pharmacy.

Members of the public were provided the opportunity to comment.

A representative of CVS Health commented previous testimony from hospital and community pharmacy described years of experience without issues noting jobs in California will lost. The representative inquired what was meant by proposed (a)(1).

A representative of UFCW commented in agreement with Members Crowley and Chandler about the PIC signing authorization and had concerns from retaliation including demotions, hours cut, floater pharmacist status, being replaced, etc. The commenter added the PIC was required to comment on staffing but asked how that was to be done if the PIC was not privy to the data.

A pharmacist representative of Kaiser commented it was reasonable to ask the PIC to attest to need for pharmacist remote work in the pharmacy but had concerns about the proposal to have the PIC sign a determination under penalty of perjury that reliance on remote work will not be used as a means to or lead to reduced staffing. Business conditions were dynamic and may need changes in staffing at any time for various reasons. The representative agreed with Member Crowley that it would be impossible for the Board to adjudicate the reason that staffing change and recommend the attestation be removed.

A community pharmacist commented on the PIC having the authority to determine whether they have remote processing in their pharmacy or not because they are supposed to be in charge of the pharmacy. The pharmacist noted pharmacists may be concerned with having random pharmacists verifying prescriptions for their pharmacy. The benefit would be for larger pharmacies to be helped by smaller pharmacies. The PIC should be able to determine if additional help was needed. The pharmacist didn't think this would impact pharmacists doing immunization but did think that coercion of PICs would probably exist.

The CEO of CPhA agreed with the previous community pharmacist who testified noting there wasn't a shortage of pharmacists in California but there was a staffing issue that must be addressed. The representative

encouraged the Board to wrestle with the issue until a solution could be found.

Members were provided the opportunity to comment in response to the public comment.

Member Crowley commented it sounded like the remote pharmacists would not be given the opportunity to work from a licensed facility and found that surprising. Dr. Crowley was surprised to hear that the remoted pharmacists weren't given the option to return to a pharmacy to work and hoped employers would consider giving the remote workers the option to return to the pharmacy.

Chairperson Oh added it would be helpful to understand context in terms of numbers of who is working remotely, where they are working remotely, etc. Dr. Oh added it didn't help to just say the remote pharmacists would be shut down. The Committee needed to hear context and recommended providing the information to the Executive Officer.

Chairperson Oh added the next policy concept would specify that a pharmacist performing remote processing must identify the specific location from where the remote processing will be performed. Further, the pharmacist would be required to provide consent for the Board to inspect the location and agreed it was an appropriate concept.

Members were provided the opportunity to comment.

Member Chandler asked if there were inspections for remoted processing locations. Ms. Sodergren provided there were no requirements for the licensee to notify the Board of where the remote processing was occurring. Ms. Sodergren was not aware but would confirm with staff if there had been any investigations stemming from HIPAA violations. Mr. Chandler asked about the Board's ability and cost to inspect remote sites. Ms. Sodergren anticipated investigations being done stemming from a triggering event versus routine investigations unless the Board decided. If the Board decided routine inspections were needed, there would be a cost element.

Member Crowley expressed concern if technology would make it appear that someone was working in California but located elsewhere. Dr. Crowley understood inspection at all remote locations was not feasible but was concerned an inspection would require a catastrophic triggering event.

Members were provided the opportunity to comment.

A pharmacist representative of UC Davis overseeing remote settings wondered about the purpose of the requirements as the practice had been in place for a long time. The commentor wasn't sure what problem the proposal was trying to solve. For remote pharmacists working from home, the commentor wasn't sure how or why the Board would inspect an individual's home. The commentor noted there were policies and procedures in place for pharmacists working remotely from their home or other facility.

A representative from UFCW expressed the proposal had consumer and patient safety protections but was concerned of the point if the Board couldn't enforce it. The representative noted enforcement was difficult (e.g., SB 1442, SB 362) for the current law and was concerned enforcement would only be by triggering events. The commentor was interested in knowing the Board's resources for inspections and had concerns for the enforcement of the proposal.

A pharmacist representative from Kaiser commented and agreed with the UC Davis representative's comment. Kaiser was concerned about having each pharmacists who was performing remote executing consent acknowledging that the Board may inspect their remote work location which could include their home citing the Board was requesting pharmacists to preemptively waive their fourth amendment right against unreasonable searches and seizures. The representative requested the requirement be removed from the proposal.

A pharmacist representative of UCSD Health System made a recommendation for (b)(1) to revise to allow the use of biometrics or equivalent ID verification authentication technology and not prohibit the use of portable electronic devices (e.g., laptops). In (b) (2), the representative believed the standards for remote practice record keeping should be the same for community pharmacies and pharmacists working remotely on behalf of hospitals and clinics.

A representative of CCPC agreed with previous comments noting COVID highlighted the importance of remote work previously done before the

pandemic and the Board maintained tools for enforcement including increased fines for chain store pharmacies. The representative added remote processing assists with the pressure in the pharmacy due to limitations around staffing in California including ratios. While there may not be a shortage of pharmacists, recruitment was difficult and this could help recruitment. The representative urged the Board not to narrow the proposal too much and enable remote processing to continue. The representative would provide statistics regarding remote processing to the Board.

A representative of CVS Health noted the proposal was not in harmony with common practice and provided examples and suggested giving the PIC the right to refuse remote processing. The representative noted the proposal was the opposite of past visionary practices California used to have and implored the Board to save jobs in California. The representative stated there was a large disconnect in clinical services but the law didn't specifically state it. As the representative read the proposal the only that could be done outside the pharmacy were included in (a)(1) but noted immunization or cognitive services weren't included.

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

Member Crowley asked if the proposal contradicted the fourth amendment. Counsel Smiley didn't believe it would and didn't agree with the comment about the fourth amendment.

Member Chandler asked counsel to address the alleged change in the Board's interpretation. Ms. Smiley provided it was not a new interpretation by the Board. The reason the waiver was issued was based on the structure of pharmacy law. Ms. Smiley noted a pharmacist can work inside/outside of a pharmacy as authorized by this chapter. Ms. Smiley added there was no current authority to add the provision for pharmacy technicians. The Board doesn't have the authority outside of 90 days beyond the declared emergency.

The Committee took a break from 10:18 a.m. – 10:30 a.m. Roll call was taken. Members present included Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum was not established.

Chairperson Oh advised the next concept was so that the policies and procedures would specify the authorized functions that could be performed. Dr. Oh noted the proposed statutory language would provide the authorized functions, but the PIC would determine which of those functions could be performed remotely. Dr. Oh noted the policies must include provisions to protect confidentiality of patient information and that training would be provided. Dr. Oh believed this was a good place to start.

Members were provided the opportunity to comment.

Member Crowley commented that a PIC in a chain store setting was not involved in the policies and procedures. Dr. Crowley noted there should be policies and procedures regarding confidentiality. Dr. Crowley added the training was vague noting that sometimes training needs to be specified but because the remote functions may vary and systems are different, the type of training may need to be specified. Dr. Crowley agreed these were required in concept.

Members of the public were provided the opportunity to comment.

A pharmacist representative of UCSD commented with regard to paragraphs (c) recommending revise to require privacy reporting consistent with applicable federal and state and not require separate and independent reporting of privacy incidents to the Board; (d) to clarify the language doesn't restrict or remove other provisions of the BPC code that allow these activities; and (e) any applicable fines or civil penalties fund should be for similar activities within the licensed pharmacy for a pharmacist or pharmacy technician and not more because of the remote function.

Chairperson Oh advised the final two provisions spoke to citation authority specifically related to unauthorized disclosure as well as authority for enforcement action and penalties for violations. Dr. Oh noted the fine amounts would be progressive based on subsequent violations which was a similar approach to provisions related to unauthorized disclosure of medical information established in the civil code. Dr. Oh agreed with the provisions and proposed authority believing the sufficient fine authority was necessary to serve as a deterrent to violations.

Members were provided the opportunity to comment.

Member Chandler commented a lot of work had been done and consistent privacy standards for VPNs noting it was important to have a structure similar to credit cards or other sensitive data companies so that if privacy was breached, the Board and customers are notified.

Member Crowley asked what was meant by "an occurrent" and who was responsible to pay the penalty as one pharmacist may be working at one pharmacy but doing work for another pharmacy. Ms. Sodergren provided as written, it would apply to the entity itself versus corporate ownership and noted the proposed language was a place to start (e.g., progressive fines, etc.). Dr. Crowley spoke in favor of progressive fines but needed more discussion for multiple locations (e.g., if it is happening all at one facility, etc.).

Members of the public were provided the opportunity to comment.

A pharmacist representative of Kaiser commented on (b) regarding the restriction on the use of laptops and requested to clarify the location, not the device. The commenter agreed with the UCSD representative reiterating using existing law rather than establishing new requirements under pharmacy law. The representative clarified the concern with in home inspections of remote workplaces could have an impact on those who wish to work remotely.

A representative of CCPC addressed a question from Member Crowley who asked if after the waiver pharmacies allowing remote work to continue to be allowed from a licensed facility. The representative noted many of the pharmacists working remotely from home have health issues and can't be accommodated to work in a licensed pharmacy but still can do their work from home. The representative added others work too far from a licensed pharmacy.

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

Chairperson Oh expressed a desire to move forward on the issue.

Member Chandler expressed concerned that a previous Board sponsored legislative attempt having failed noting the Board doesn't have the ability

to extend the waiver or put out a statement to waive this issue. Mr. Chandler noted the solution was a legislative matter.

Member Crowley commented on (d) as presented had to do with final product verification stating nothing in the subdivision shall authorize a pharmacist to dispense a drug or perform final product verification via remote connection or without being present. Dr. Crowley expressed concerned with the "or without being present" portion as it made it sound that the pharmacist just had to be within the pharmacy but not doing the check. Dr. Crowley added there would need to be more discussions on specialty versus community setting. Dr. Crowley expressed interest in more data (e.g., where it is occurring, how often it is occurring, if community pharmacies realize remote work is happening in facilities under current waiver, etc.). Dr. Crowley was surprised to see the proposed language as a consensus wasn't reached at the last meeting. Dr. Crowley hoped there was space for pharmacists who were currently working remotely to be given the option for remote position in a facility close.

Chairperson Oh opened the comment period for stakeholders to make global comments.

A pharmacist representative of the University of California expressed concern when wavier expires the ability to provide high quality care will be impaired. The representative added the bill in the legislature or amendments being considered will address the needs but was open to work with the Board to continue to provide pharmacy care.

Chairperson Oh thanked stakeholders for of the comments and will work with staff to update the language based on comments received today. Dr. Oh reminded participants this would be part of a legislative process.

V. Discussion and Consideration of Changes to the Board's Sample CPA Related to MAT to Remove the Data 2000 Waiver Reference

Chairperson Oh referenced meeting materials including some brief background on the development of the sample collaborative practice agreement related to medication assisted treatment. Dr. Oh advised given the recent changes at the federal level, it was appropriate to update the sample CPA to remove the reference to the DATA Waiver requirement.

Chairperson Oh reported confirming with Dr. Gasper that the proposed change is appropriate. Dr. Oh advised as it was a sample CPA. Dr. Oh

didn't believe formal board action was required. Dr. Oh would work with staff to update the sample CPA on the Board's website.

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

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

VI. Discussion and Consideration of Possible Regulations to Implement Government Code Section 16.5 Related to Digital Signatures and Development of Policy State to Facilitate Implementation of Digital Signatures on Applications and Other Notices

Chairperson Oh reported meeting materials detailed the relevant sections of law establishing the provisions for use of digital signatures, including Government Code Section 16.5 which provides authority for a public entity to accept digital signatures under specified conditions. Dr. Oh noted regulations define the two forms of acceptable technology that could be used.

Chairperson Oh advised the Board received public comments seeking alternative means to interact with the Board including alternatives to a "wet signature." Dr. Oh reported the Board was continuing its engagement in business modernization activities to evaluate future technology needs. Dr. Oh added in the interim, there were some steps the Board could consider easing some of the current challenges licensees and applicants repot related to current signature requirements. Dr. Oh noted staff were the use of digital signatures that meet requirements of public key cryptography. Dr. Oh agreed with staff recommendations and the policy statement was appropriate.

Members were provided the opportunity to comment.

Member Crowley inquired if other boards were using this technology. Ms. Sodergren advised other boards have different technology options available as they are on different systems but could survey other boards and bureaus.

Member Chandler spoke in support of digital signatures.

Chairperson Oh thanked Ms. Sodergren for bringing this forward to the Committee. If in agreement, Dr. Oh would work with staff to bring back updated language based on discussion to the Committee but in the interim, the policy statement could be brought to the next Board Meeting as a means to convey the Board's acceptable of digital signatures.

Members of the public were provided the opportunity to comment.

The Committee heard comments in support of the digital signatures from CCPC and Albertson's Companies representatives.

VII. Discussion and Consideration of Licensing Statistics.

Chairperson Oh reported meeting materials include processing times as of March 24, 2023, and included statistics for the first eight months of the fiscal year. The Board received over 9,300 applications and over 300 applications for temporary licenses. The Board issued over 6,300 licenses including over 1,500 pharmacist licenses, almost 2,500 pharmacy technician licensed, and 216 temporary licenses.

Chairperson Oh continued to monitor processing times and reported the licensing unit continued to have a number of staff vacancies. Dr. Oh reported recruitment efforts were ongoing and as new staff were hired/onboarded, Dr. Oh was confident application processing times would improve. Dr. Oh reported the position responsible for processing pharmacy technician applications was now filled. Dr. Oh thanked licensing staff for their efforts to balance all of the various licensing programs through this time with all of the vacancies and noted their efforts were appreciated.

Members were provided an opportunity to comment.

Member Chandler inquired about the surge in clinic applications from July to September and corresponding licensing approval in January to March. Ms. Sodergren advised there could have been a change of ownership and would check with staff. Mr. Chandler asked about trends that should be discussed. Ms. Sodergren advised three-year trending statistics would be provided at the July 2023 Committee Meeting. Ms. Sodergren noted there was decline in intern application received which corresponds to hearing about declining enrollment in schools of pharmacy.

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

VIII. Future Committee Meeting Dates

Chairperson Oh advised the next Licensing Committee Meetings were scheduled for July 19, 2023, and October 18, 2023. Dr. Oh thanked participants for their time and participation.

IX. Adjournment

The meeting adjourned at 11:08 a.m.