



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

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



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

Date: October 20, 2021

Location: Teleconference Public Licensing Committee Meeting Note: Pursuant to the provisions Government Code section 11133, neither a public location nor teleconference locations are provided.

Board Members

Present: Debbie Veale, Licensee Member, Chair
Seung Oh, Licensee Member, Vice-Chairperson
Lavanza Butler, Licensee Member
Jignesh Patel, Licensee Member
Jason Weisz, Public Member

Staff Present: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Sheila Tatayon, DCA Staff Counsel

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

The meeting was called to order at approximately 1:01 p.m. As part of the opening announcements, Chairperson Veale reminded everyone that the meeting was being conducted consistent with the provisions of Government Code section 11133.

Provisions for providing public comment throughout the meeting were reviewed.

Roll call was taken. Members present: Cheryl Butler, Seung Oh, Jignesh Patel, Jason Weisz, Debbie Veale. A quorum was established.

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

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

III. Approval of the July 14, 2021 Licensing Committee Meeting Minutes

Members were provided the opportunity to provide comments on the draft minutes; however, none were provided.

Motion: Approve the July 14, 2021 Licensing Committee meeting minutes.

M/S: Oh/Patel

Members of the public were provided the opportunity to provide public comments; however, none were provided.

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

Board Member	Vote
Butler	Support
Oh	Support
Patel	Support
Veale	Support
Weisz	Support

IV. Discussion and Consideration of Business and Professions Code section 4071.1, Board's Waiver to Facilitate Provisions for Remote Processing and Consideration of Possible Changes to Statute or Regulation to Establish Authority Under Specified Conditions.

Chairperson Veale reviewed the relevant provisions of the law noting that Business and Professions Code (BPC) section 4071.1 establishes the authority for a pharmacy to electronically enter a prescription or an order into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with permission, under specified conditions. Included in these provisions is an explicit prohibition on such authority for controlled substances. Further, this section does not permit pharmacist to perform other steps in the dispensing process, nor does it allow other pharmacy staff to perform functions remotely.

Ms. Veale also noted that BPC section 4038 specifies that pharmacy technicians are wholly and exclusively permitted to practice only within a licensed pharmacy and reminded members that BPC section 4115 specifies that a pharmacy technician may perform packaging, manipulative,

repetitive or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of a pharmacist.

Also, Chairperson Veale highlighted the provisions of BPC section 4023.5 defines "direct supervision and control" to require that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

Chairperson Veale also reviewed the Board's current remote processing waiver stated that the Board's waiver provides that for the purposes of this waiver, "remote processing" means the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy as defined in BPC sections 4029 and 4037.

In addition, the current waiver provisions of BPC section 4071.1(a), also provide pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under this waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The waiver does not include the dispensing of a drug or final product verification by remote processing.

Ms. Veale also reminded members that the Board's waiver further expands the provisions of BPC section 4071.1(a) to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

Ms. Veale advised members that the waiver was approved in response to the COVID-19 pandemic and the early need to promote physical distancing, the Board approved the expanded use of remote processing to facilitate physical distancing while balancing continuity of patient care. As the pandemic has evolved, the waiver was used on both a broad basis and site-specific based on the dynamic conditions at the time. Most recently the Board voted to extend the broad waiver through either December 31, 2021, or 30 days after the declared emergency is lifted, whichever is later.

Ms. Veale noted that it appears appropriate to evaluate the issue and determine what if any actions are appropriate to allow for some form of remote processing or other work on a permanent basis.

Members were provided with a review of the approach taken in Virginia. Ms. Veale reviewed the provisions allowed for pharmacists under Virginia law which was also displayed on the meeting slide. Ms. Veale also reviewed the provisions that a pharmacy must comply with under Virginia law including requirements for policies and procedures and records requirements.

Ms. Veale provided members with an opportunity to comment of the Virginia provisions. Member Butler asked about the staff identified concerns with billing fraud. Ms. Butler noted that she does not believe that there is a need to make the waiver permanent.

Member Oh noted that the Committee needs to separate out what is convenient versus what is safe for consumers. Member Oh indicated that this is a complex issue and noted concerns, suggesting that a very detailed approach is necessary.

The Committee considered several policy questions.

1. Should the Board at this time consider changes in the law to allow for Remote Processing by Pharmacist, Pharmacy Techs and Pharmacy Interns?

Member Oh emphasized that the Committee needs to ensure patients are safe and indicated that review must be very detailed.

Chairperson Veale noted that if the Committee determines it appropriate to move forward, it will occur over multiple meetings and noted that remote processing may be of benefit to consumers.

2. Does remote processing provide improved care for the consumers?

Member Patel noted that consumers could benefit from the provisions noting more health care professionals could work because of resolved child care issues, could allow for completion of additional pharmacy services that could alleviate some pressures in the pharmacy, and could result in improved patient care services because staff would be more available to provide onsite services with the redirection. Member Patel spoke in support of the Committee moving forward on its assessment of the issue and noted the benefit also in response to emergencies.

Member Oh asked if there is objective data on whether it has resulted in improved patient care and if there are any studies available.

Member Weisz requested how long the Virginia law has been in effect and was advised that it appeared the provisions became effective in 2005.

Members of the public were provided with the opportunity to provide public comment about whether the Committee should move forward and what the benefits to consumers would be.

Mark Johnston, CVS Health, stated that 45 states have allowed technicians to work from home under the pandemic. He noted that if the technician is removed from pharmacy they cannot divert. In terms of consumer protections, performing these tasks away from the pharmacy allows for the completion of such tasks free from distraction. Mr. Johnston offered to provide studies in the area.

Paige Talley, California Council for the Advancement of Pharmacy, indicated support for how remote processing is a benefit to consumers.

John Gray, Kaiser, supports the Committee's examination of the issue. Dr. Gray noted that the Board's waiver has allowed pharmacies to be innovative in how it provides care. Dr. Gray noted that they have not identified any quality issues with prescription processing performed remotely. Dr. Gray suggested that the Board use its current waiver. Dr. Gray indicated that benefits include improved flexibility to respond to patient needs, for example through the transition to mail order pharmacies at the patient's choice.

Steven Gray noted that remote processing has existed since 2000. Dr. Gray noted order entry allowed under 4071.1 and stated that the issue should be carefully considered.

Lori Hensic, Scripts Health, spoke in support of prior comments about the benefits to consumers. Their organization supports the transition to remote processing noting that the waiver is allowing pharmacists to focus on more clinical tasks at onsite services with the other functions being performed offsite. Commenter Hensic also suggested that the current waiver would be an appropriate framework

Following public comment, Chairperson Veale stated support for the Committee to continue to consider the issue.

3. What functions in the waiver appear appropriate to be performed, and by who?

Chairperson Veale reviewed the provisions of the current waiver and solicited feedback on the waiver. Member Weisz inquired if the Board has received any complaints and was advised that staff are not aware of complaints received specific to the use of the waiver. Member Oh similarly indicated if any complaints have been received specific to the waiver. Member Butler noted that the current framework appears good, but also requested additional information about complaints received.

4. If either the current waiver or other provisions are made permanent, should the pharmacist-in-charge be explicitly authorized to make the determination if staff are allowed to perform the remote functions? Should remote functions be limited to electronic prescriptions only?

Members spoke in support of the PIC being delegated with the explicit authority to make the decision about staff provisions to perform the remote functions.

Members of the public were also provided with the opportunity to comment on the policy question.

Bob Stein, KGI, provided comments and indicated they did not understand how a pharmacy working remotely would be able to perform the functions remotely unless the prescription is electronic.

Daniel Robinson indicated that according to the American Medical Association website, it has written letters to CMS recommending that all waivers be sunsetted at the end of the declared disaster. Dr. Robinson spoke in support of the gains made.

Dr. John Gray supported the direction of the discussion noting that Kaiser strongly supports considering provisions for pharmacists, pharmacy technicians and pharmacist interns. Further if provisions are allowed for a pharmacy technician, it requested that the Board resolved the issue of a pharmacy technician only working in a pharmacy.

Other public comments expressed concern about potentially limiting provisions to only electronic prescriptions.

Meeting recessed from 2:26 to 2:36. Roll call taken. Members present included Members Butler, Oh, Patel, Weisz and Veale.

Chairperson Veale recommended that the committee focus on a few questions while postponing the discussion in some areas to allow for addition collection.

5. What conditions should exist?
 - a. Appropriate to note in recent years, the Board has conducted investigations, including cases allowing offshoring of the services to countries such as India.
 - b. Should notification to the Board of such practices be required?
 - c. Should any proposal include mandatory notification of any HIPAA breaches.
 - d. Should remote functions be limited to only when the pharmacy is open?

The Committee also considered several other policy questions including if the waiver should expand beyond California licensed pharmacies.

Member Butler noted agreement that the provisions should be limited to California pharmacies, that notification to the Board should be required, and that HIPAA breaches need to be reported. Member Butler indicated an openness to allowing remote processing even when the pharmacy is closed.

President Oh expressed concern about offshoring and wanting to dissect the situation requesting that legal counsel provide what is currently authorized under the law and if the waiver is actually restricting practice. Member Oh commented that remote processing must be done in California.

Member Patel also noted that provision should be limited to California. Member Patel also spoke in support of allowing the remote work to be performed when the pharmacy is closed. Member Patel expressed concern about a requirement to provide notification to the Board.

Member Weisz noted that more data is needed to discuss some of the questions. Member Weisz spoke in support of the work being conducted in California, notification to the Board should be required as well as notification on HIPAA breaches. Further Member Weisz indicated remote functions do not need to be limited to when the pharmacy is open.

Members of the public were provided an opportunity to provide public comment.

Comments included that if notification to the Board is required, the Board should make the notification as easy as possible, e.g., similar to the online notification to change an address and that if notification of HIPAA breaches is required, the Board should could work off of existing law.

Comments also spoke in opposition to allowing offshoring; however, indicated that prohibiting remote processing outside of California could impede current practice.

The Committee considered what elements should be included in a notification. Member Oh stated a preference for more robust notification.

The Committee noted it would resume its discussion at the next meeting.

V. Discussion and Consideration of Requirements to Serve as a Pharmacist-in-Charge

Chairperson Veale highlighted the provisions of relevant law including that BPC section 4036.5 defines a “pharmacist-in-charge” as a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy’s compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. Further Ms. Veale noted that BPC section 4113 provides in part that every pharmacy shall designate a PIC. Further, the PIC is responsible for compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

Chairperson Veale also referenced the Board also a precedential decision ([Sternberg v. California State Board of Pharmacy \(2015\) 239 Cal.App.4th 1159 California Court of Appeal, Second District, Division Eight, Case No. B255865](#)) that confirmed that a pharmacist-in-charge of a pharmacy could be disciplined for a pharmacy’s violation of Section 4081 resulting from a pharmacy technician’s theft of controlled substances without having actual knowledge of, or authorizing, the violations.

Ms. Veale reminded members that during its recent strategic planning session, the Board established a strategic objective to determine if application requirements for a PIC are appropriate to ensure sufficient knowledge, skills and abilities for individuals seeking to serve as a PIC.

Chair Veale commented that It is not uncommon for investigations to substantiate violations where a pharmacist may be designated as a PIC in name only, or the designated PIC fails to exercise appropriate oversight of the operations. Although the egregiousness of the violations varies there are many instances where such an individual pharmacist ultimately is disciplined including losing their pharmacist license through the administrative process.

The Committee considered several questions as part of its discussion including:

1. Are there fundamental knowledge, skills, and abilities that are required for someone to serve as a PIC?
2. Should the Board require or provide a certain type of continuing education or other training as a precursor to assuming the role of a PIC?
3. Should the Board require an attestation from the proposed PIC acknowledging and confirming the legal requirements for a PIC?
4. Should there be a minimum number of hours a PIC should be required to work at the respective pharmacy?

Member Butler spoke in support of continuing education and noted that a PIC should be present at a pharmacy at least one/week.

Member Oh stated belief that there are fundamental knowledge, skills and abilities necessary and spoke in support of training. Member Oh noted that it is very important that the PIC is aware of legal requirements and spoke about the value of a required attestation noting it should be required from both the pharmacy and PIC to ensure the PIC has the power to make a difference. Member Oh spoke in support of a minimum requirement to work one day a week. Member Oh indicated that the Board could establish its own educational program.

Member Patel also indicated that the most relevant policy question is the attestation and spoke in support to such a change. Member Patel indicated concern with the Board's ability to assess if a PIC has the requisite knowledge, skills and abilities. Member Patel suggested the self-assessment could be designed to incorporate the attestation, serving as a reminder every two years. Member Patel spoke in support of a requirement to have the PIC work a few days a week to ensure oversight or suggested a percentage of hours based on the hours of operations of the pharmacy.

Member Weisz, noted that in many hearings, they seem to not be aware of the ramifications. Member Weisz spoke in support of training as well as the attestation.

Chairperson Veale noted that there appears to be consensus that the Board should provide or require training before becoming a PIC. Further there was consensus to require an attestation as well as establishing a minimum number of hours.

Motion: Recommend to the Board that the Licensing Committee pursue a training program for proposed PICs as well as a requirement for an attestation as a precursor to be appointed the PIC.

M/S: Oh/Butler

Members of the public were provided the opportunity to provide public comments.

Public comment including a suggestion that California should consider moving away from a requirement to have a PIC. Further comments suggested that more goes into becoming a PIC than just an awareness of the law and support of a training requirement. Other comments expressed concern of the concept of a required number of hours for a PIC to work and that the attestation could include an educational component.

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

Board Member	Vote
Butler	Yes
Oh	Yes
Patel	Yes
Veale	Yes
Weisz	Yes

VI. Discussion and Consideration of Implementation Plan for Listening Sessions and Pharmacy Technician Summit

Chairperson Veale reminded members that as part of its July 2021 meeting, the Committee voted to convene a pharmacy technician summit. As a precursor to the summit, the Committee determined it appropriate to convene listening sessions, ideally throughout the state and during nontraditional business hours. Such an approach is intended to reach a broad audience to solicit feedback in advance of the summit. During the meeting members stated their intention to convene both the listening sessions and the technician summit in person.

Chairperson Veale stated that given the dynamic nature of the COVID pandemic an alternative approach should be considered. The Committee considered an alternative implementation plan that would allow the Committee to perform its work, but in virtual meetings, while still creating opportunities for broader participation.

Members were advised that Chairperson Veale would attend all sessions and would request comments on the following questions:

1. What duties do you believe a pharmacy technician could perform beyond those currently authorized?
2. Should some functions allow for supervision by another technician (e.g., tech check tech)? If yes, please provide examples.

3. Do you believe as a pharmacy technician you have sufficient oversight by a pharmacist?
4. Do you believe you have appropriate on the job training, education (e.g., community college, etc.) to perform your duties safely, including in the following areas - - pharmacy operations, HIPAA compliance, compounding?
5. Do you believe the level or type of training depends on the functions you perform?
6. What are some of the biggest challenges you face?

Members suggested that separate questions may be appropriate for sessions specific for pharmacists including asking pharmacist what change they believe would be appropriate to aid pharmacists in performing their duties.

Motion: Recommend the Board allowing the convening of listening sessions via WebEx and providing an equal number of sessions for pharmacy technicians and pharmacists with questions intended for each audience. Grant authority to Chair and EO to schedule the sessions accordingly.

M/S: Oh/Patel

Public comment on the motion: Members of the public were provided the opportunity to provide public comment.

Comments spoke in support of the motion but also expressed concern with the suggested questions.

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

Board Member	Vote
Butler	Support
Oh	Support
Patel	Support
Veale	Support
Weisz	Support

VII. Review and Discussion of Licensing Statistics

Chairperson Veale referenced the quarterly licensing statistics in the meeting materials and noted that the materials provide processing times,

noting that data reflects the time from when an application or deficiency response is received by the Board through to the time it is reviewed by licensing staff. The standard performance processing time is within 30 days for initial applications and is within 10 days for deficiency mail. The term "Current" means there are no items to review or staff is currently reviewing the items within 1-5 days for that specific license type.

Processing times are outside of the performance measures established by the Board. The Board's licensing unit has vacancies in various stages of recruitment as well as staff out on unexpected leave. Managers are working with staff to prioritize work. It is anticipated processing times will improve as vacancies are filled and staff return from unexpected leave. Appropriate resources are just part of the challenge. The issue of processing times is also impacted by the number of deficient applications which appear to be a significant percentage of the workload for some application types.

Ms. Veale highlighted some of the actions taken to reduce deficient applications noting that over 50 percent of the pharmacy technician applications received are deficient. The Board has updated both the application and instruction sheets and several years ago made a video. Unfortunately, the Board continues to receive a large number of deficient pharmacy technician applications. Although there is a range of deficiencies, the most common include:

- Applicants submitted a self-query that is either not sealed or the name is spelled wrong or transposed.
- Affidavit of completed coursework is not completely correct or secondary information regarding the identification of the appropriate verifying party is not provided.
- High school transcripts are not received or other appropriate documentation is not provided.

Also, the vast majority of applications received for pharmacies are also deficient. Again, there is a range of deficiencies, but the those most common include:

- Inconsistent information is provided throughout the application and supporting materials
- Forms are not completed correctly
- Ownership information is not disclosed
- Complete financial information is not provided
- Further, nonresident pharmacies many times do not have compliant patient-centered labels. Such an issue must be remedied before a license can be issued.

Although resource intense, staff are piloting a process to schedule phone calls with the authorized contacts for some applicants to discuss the deficiencies and ensure there is an understanding of the requirements and requested items. This is a relatively new process but are hopeful as vacancies are filled such a process will assist applicants and also reduce overall processing times.

IX. Future Committee Meeting Dates

Members were reminded of the upcoming Committee meeting schedule and noted that the schedule did not include the proposed listening sessions or Technician Summit.

X. Adjournment

The meeting adjourned at 4:35 p.m.