



**California State Board of Pharmacy
Department of Consumer Affairs
Public Board Meeting Minutes**

Date: May 27, 2021

Location: Teleconference Public Board Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-29-20, dated March 17, 2020, neither a public location nor teleconference locations are provided.

Board Members

Present: Gregory Lippe, Public Member, President
Debbie Veale, Licensee Member, Vice President
Maria Serpa, Licensee Member, Treasurer
Seung Oh, Licensee Member
Shirley Kim, Public Member
Jignesh Patel, Licensee Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

Staff Present: Anne Sodergren, Executive Officer
Lyle Matthews, Assistant Executive Officer
MaryJo Tobola, Senior Enforcement Manager
Eileen Smiley, DCA Staff Counsel
Dani Rogers, DCA Staff Counsel
Sheila Tatayon, DCA Staff Counsel
Debbie Damoth, Administration Manager

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

The meeting was called to order at 9:03 a.m. As part of the opening announcements, President Lippe reminded everyone that the meeting was being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20.

Provisions for providing public comment throughout the meeting were reviewed.

President Lippe advised those participating in the teleconference the Board would convene in closed session after deliberating on the open session items, except adjournment.

Roll call was taken. Board Members present: Seung Oh, Debbie Veale, Maria Serpa, Jignesh Patel, Albert Wong, Shirley Kim, Ricardo Sanchez, and Greg Lippe. A quorum was established.

Vice President Debbie Veale recognized and thanked President Greg Lippe and Dr. Albert Wong for their work and contributions to the protection of California consumers and the profession of pharmacy during their tenure as Board Members. Ms. Veale provided a summary of Dr. Wong and Mr. Lippe's contributions as Board Members. She noted both Dr. Wong and Mr. Lippe served their terms and grace year period which will end June 1, 2021.

Dr. Wong stated it had been a pleasure working on the Board. He thanked Board Members and Board staff. Dr. Wong thanked Mr. Lippe for his leadership.

Mr. Lippe stated it was an honor to work with and for the Board. He noted admiration to the profession and thanked Board staff.

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

During the meeting members of the public were provided the opportunity to provide public comment on items not on the agenda.

Danny Martinez, CPhA, thanked President Lippe and Member Wong for their service on the Board and appreciated their advocacy for pharmacists.

Robert Stein thanked President Lippe and Member Wong as advocates for consumers and appreciated the work they have done.

Lindsay Gullahorn, CRA and NACDS, thanked President Lippe and Member Wong for their work on the Board showing expertise and dedication to patient safety.

Members Patel, Kim and Sanchez thanked President Lippe and Member Wong.

III. Discussion and Consideration of Request to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code (BPC) section 4062

President Lippe advised there were two recommendations from staff to extend temporary permits beyond the current 180-day timeframe authorized in the law. The motions for agenda items III. (a) and III. (b) were considered and voted at the same time.

a. Consideration of Site-Specific Waiver

1. McKesson Medical-Surgical, Inc, BPC 4161, Temporary License NPL 1274

Mr. Lippe reported the first waiver for consideration would allow for the extension of the Nonresident Third Party Logistics Provider license issued to McKesson Medical-Surgical, INC, license number NPL 1274. As included in the meeting materials, approval of this waiver would allow this facility to continue to distribute vaccines. Mr. Lippe provided staff recommended language to approve an extension of the nonresident 3PL license until January 1, 2022, or until such time as either McKesson Medical-Surgical, Inc., obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.

2. McKesson Corporation dba McKesson Drug Company, BPC 4161, Temporary license, NPL 1277

Mr. Lippe reported the second waiver would allow for the extension of the Nonresident Third Party Logistics Provider license issued to McKesson Corporation, license number NPL 1277. He noted like the previous waiver, approval of this waiver would allow this facility to continue to distribute vaccines. Mr. Lippe provided staff recommend language to approve an extension of the nonresident 3PL license until January 1, 2022, or until such time as either McKesson Medical-Surgical, Inc., obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.

Members were provided with an opportunity to provide comments; however, no comments were made.

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

Motion: Approve an extension of the nonresident 3PL license (NPL 1274) until January 1, 2022, or until such time as either McKesson Medical-Surgical, Inc obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.

Approve an extension of the nonresident 3PL license (NPL 1277) until December 31, 2021, or until such time as either McKesson Medical-Surgical obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.

M/S: Oh/Sanchez

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

Support: 8 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Butler	Not Present
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Not Present
Wong	Yes

IV. Discussion and Consideration of Board Approved Regulation, Title 16 California Code of Regulations Section 1717.5 Related to Automatic Refill Programs to Address Comments by the Office of Administrative Law

Mr. Lippe referred to the meeting materials that included a cover memo providing a brief history of the rulemaking and information regarding why this rulemaking was back before the Board for consideration. He noted the Office of Administrative Law (OAL), through its review, requested that the Board clarify its policy decisions more clearly in the text of the regulation itself with specific changes requested by OAL detailed in the meeting materials. Mr. Lippe also noted that the meeting materials provided excerpts from the October 2020 meeting where the Board voted, as part of its motion memorializing Board's policy. He noted OAL has requested the Board clarify three specific areas:

1. The Board further define "each prescription" in subsection (a)(2).
2. The Board memorialize its policy regarding the need for annual consent.
3. The Board ensure the proposal consistently uses the terms "prescription" and "prescription medication" throughout the text.

Mr. Lippe advised the proposed modified text was provided in the meeting materials. Changes offered were reflected in italicized double underline to reflect new text, and italicized double strikethrough to reflect text recommend being removed.

Mr. Lippe stated based on Board action today, a 15-day comment period would be initiated to provide stakeholders with the opportunity to provide comments on the proposed revisions. He added it is important to note that the scope of the comments

will be limited to just the modified text voted at the meeting. Mr. Lippe stated he believed the Board must act to address the comments provided by the OAL or the regulation will not be approved.

Members were provided an opportunity to comment.

Motion: Approve the amended regulation text and initiate a 15-day comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Office of Administrative Law to complete the rulemaking file.

M/S: Serpa/

Member Patel commented the word “prescriber” should be removed from (a) (2). Dr. Patel stated the word was redundant and could impact consumer protection.

Member Serpa inquired if an additional 15-day comment period would be required if “prescriber” was removed. Counsel Rogers confirmed the 15-day comment period would be required.

DCA Counsel Dani Rogers explained the edits as requested by OAL was to be consistent with current regulation at Title 16 section 1717 (b) (4) related to new prescription. Ms. Rogers expressed concern about removing “prescriber” as she was not sure if OAL’s opinion would change based on the removal of “prescriber.” She noted if OAL has additional concern, it could come back to the Board for reconsideration.

Member Patel noted medication adherence is an issue for patients. He noted automatic refill programs help patients to be healthy. He added prescribers often change for various reasons such as insurance. If the patient must be re-enrolled, patients’ adherence and patients’ health could be in jeopardy. Dr. Patel noted if the word “prescriber” is not removed, the regulation could result as a hurdle with negative impact for the patients’ care.

Member Serpa withdrew her motion.

Member Veale agreed with Member Patel that the prescriber could be a barrier to the automatic refill program and would be a disservice to the public.

Ms. Rogers confirmed removing “prescriber” would be part of a 15-day comment period.

Member Wong commented he heard some automatic refill programs refill without getting permission from the doctor. He wanted to ensure that when a prescription has no refills the physicians are contacted to authorize a refill.

Member Oh agreed with Member Patel. Dr. Oh requested clarification from Ms. Rogers that the change from "prescription medication" to "prescriptions" included prescription items in addition to medications. Ms. Rogers confirmed it meant the paper prescription.

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

Lindsay Gullahorn, CRA/NACDS, commented in support of the motion to strike the word "prescriber" and Board Member comments.

Robert Stein commented in support of the motion. He added the regulation is necessary with pharmacies abusing automatic refills and complaints. He looks forward to it becoming law.

Mark Johnston, CVS, commented requesting the issue be returned to committee.

Motion: Approve the amended regulation text as provided along with the removal of "prescriber" from (a) (2) and initiate a 15-day comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Office of Administrative Law to complete the rulemaking file.

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1717.5. Automatic Refill Programs.

- (a) A pharmacy may offer a program to automatically refill prescriptions ~~medications~~ provided the pharmacy complies with this section.
- (1) The pharmacy shall have written policies and procedures describing the program, which shall set forth, at a minimum, how the pharmacy will comply with this section, ~~as well as a list of medications that may be refilled through the program.~~
- (2) Before a patient enrolls, the pharmacy shall provide a written or electronic notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program. The patient or patient's agent

shall enroll by written, online, or electronic informed consent to participate in the program for each new prescription wherein there is a change in the prescription medication, strength, dosage form, or directions for use.

~~(3)~~ For each prescription to be refilled through the program, the pharmacy shall obtain annual renewal of each prescription from the patient or patient's agent no later than 12 months after the prescription was enrolled in the program.

~~(3-4)~~ The pharmacy shall keep a copy of the written or electronic informed consent to enroll on file for one year from date of dispensing.

~~(4)~~ ~~When a patient enrolls, the pharmacy shall provide a written notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program.~~

~~(5-4-5)~~ The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.

~~(6-5-6)~~ Each time a prescription is refilled through the program, the pharmacy shall provide a written or electronic notification to the patient or patient's agent confirming that the prescription medication is being refilled through the program.

~~(7-6-7)~~ The patient or patient's agent shall at any time be able to withdraw a prescription medication from automatic refill or to disenroll entirely from the program. The pharmacy shall document and maintain such withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and shall provide confirmation to the patient or patient's agent.

~~(8-7-8)~~ The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication refilled through the program if the pharmacy ~~is was~~ notified that the patient did not want the refill, regardless of the reason, ~~and or~~ the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription medication.

~~(9-8-9)~~ A pharmacy shall make available any written or electronic notification required by this section in alternate languages as required by state or federal law.

(b) A licensed health facility, as defined in Health and Safety Code section 1250, that automatically refills prescriptions ~~medications~~ for its patients need not comply with the provisions of this section.

(c) Pharmacies automatically refilling prescriptions ~~medications~~ for inmates of an adult correctional facility or a juvenile detention facility need not comply with the provisions of this section if the facility has written policies and procedures describing how a patient may request that a medication be automatically refilled and how a patient may refuse the medication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

M/S: Patel/Veale

Support: 8 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Butler	Not Present
Kim	Yes
Lippe	Yes
Oh	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Weisz	Not Present
Wong	Yes

V. Petitions for Reinstatement of Licensure, Early Termination of Probation or Other Modification of Penalty.

Administrative Law Judge Jonathan Lew presided over the following petition hearings:

- a. Dina El-Sayed, RPH 43830
- b. Patrick LeRoy, RPH 58396
- c. Hope Pharmacy, PHY 48589
- d. Jadine Mah, RPH 45475
- e. Central Drugs, PHY 49146
- f. Nayan Patel, RPH 48867

Member Kim left the meeting at 11:22 a.m.

The meeting recessed from 11:44 a.m. to 12:30 p.m. Following the recess, a roll call was again taken. Members present included Ricardo Sanchez, Albert Wong, Shirley Kim, Jignesh Patel, Seung Oh, Maria Serpa, Debbie Veale, and Greg Lippe. A quorum was established.

The meeting was in recess from 1:05 p.m. to 1:10 p.m. Upon returning from recess, roll call was taken with the following members present included Debbie Veale, Maria Serpa, Seung Oh, Jignesh Patel, Albert Wong, Ricard Sanchez, and Greg Lippe. A quorum was established.

V. Closed Session Matters

The Board recessed into closed session at approximately 1:57 p.m.

VI. Reconvene Open Session

The Board adjourned after closed session at approximately 2:30 p.m.