

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

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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
Public Board Meeting Minutes

Date: June 17, 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: Seung Oh, Licensee Member, President

Maria Serpa, Licensee Member, Vice President

Lavanza Butler, Licensee Member

Shirley Kim, Public Member

Ricardo Sanchez, Public Member Debbie Veale, Licensee Member Jason Weisz, Public 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. <u>Call to Order, Establishment of Quorum, and General Announcements and Recognitions</u>

The meeting was called to order at 9:04 a.m. President Oh 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 Oh 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 included Maria Serpa, Lavanza Butler, Shirley Kim, Ricardo Sanchez, Jason Weisz, Debbie Veale, and Seung Oh. A quorum was established.

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.

Elizabeth Huber, a faculty member at a university, commented some physicians and pharmacists are being prevented from dispensing therapeutics for COVID-19 including hydroxychloroquine, ivermectin, and budesonide.

The Board heard a public comment from a resident of California who has required both exogenous testosterone and compounded HCG for treatment over the past four years. The commenter stated he understood the Board has decided to disapprove the access to compounded HCG which is needed for his treatment. He wanted to bring this to the Board's attention that many residents in California need access to compounded HCG. He stated he wanted to understand why this was happening and what can be done about it.

Sandra Martinez commented on restrictions being placed on pharmacists to fill medications off-label for COVID-19 patients. She stated concern about future antibody dependent enhancement induced by the COVID vaccines. She stated ivermectin and hydroxychloroquine safely and effective treat COVID, cytokine storm, and blood disorders that accompany COVID as well as problems related to the COVID vaccines and antibody dependent enhancement. She requested the Board rescind restrictions to save lives.

Samuel Plantowksy commented in support of the use of hydroxychloroquine and ivermectin as a beneficial treatment protocol. He stated denial or interference places well beings of patients at risk. He noted the mRNA emergency youth use authorization vaccines will place many at risk through pathogenic priming from spike proteins who would also benefit in the same treatment protocols. He requested the Board let medical professionals treat patients with ivermectin and hydroxychloroquine.

Members were provided the opportunity to include items from public comment on a future agenda item.

Motion: President and executive officer to review if there are restrictions on ivermectin and hydroxychloroquine and determine appropriate

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M/S: Veale/Butler

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

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

Elizabeth Huber commented she understands doctors and pharmacists can provide the medications. However, they are being coerced or living under fear of prescribing and providing hydroxychloroquine, budesonide, and ivermectin. She stated she had COVID and her doctor was afraid to provide these medications where she had to get medical attention from a different doctor.

Sandra Martinez commented pharmacists are afraid to fill these prescriptions. She stated their licenses and businesses have been covertly threatened. She stated she knew one out of every five medications are prescribed off label. She stated hydroxychloroquine and ivermectin as well as budesonide and fluvoxamine are safe in treating COVID and the various symptoms.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Butler	Support
Kim	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support

III. Discussion and Consideration of Adoption of Board Approved Regulation, 16 California Code of Regulations Section 1717.5 Related to Automatic Refill Programs, and Discussion and Consideration of Public Comments Received during the 15-day comment period on the proposed new modifications to the Regulation

President Oh advised during the May 2021 meeting, in response to comments received by the Office of Administrative Law (OAL), the Board voted to further amend the regulation text proposed in section 1717.5 related to Automatic Refill Programs. The proposed modifications were released for an additional 15-day comment period beginning May 28, 2021. The comment period ended June 12, 2021.

President Oh noted as included in the meeting materials, the Board received comments from three individuals during the comment period. Staff prepared recommendations in response to each of the comments which were also provided along with the regulation text. Dr. Oh noted agreement with the recommendations of staff.

Members were provided with an opportunity to provide comments.

Member Veale requested clarification as Dr. Geddes from Albertsons requested an implementation date change from 1/1/2022 to 7/1/2022. Ms. Veale stated she understood the reasoning for the request and noted there was no implementation date in the proposed text. Ms. Veale requested clarification of the implementation date.

Ms. Sodergren provided the effective date is established through communications with the OAL. Ms. Sodergren provided the Board previously voted to delay the implementation to 1/1/2022. After the Board adoption, the regulation was reviewed by control agencies. During the review by OAL, comments were made and brought back to the Board which initiated the 15-day comment period in May 2021 to address the concerns raised by OAL.

Ms. Veale inquired if a change in implementation date to 7/1/2022 would need to be added to the motion. DCA Counsel Rogers confirmed the motion was required. If approved, the Board would need to file an amended Form 400 with OAL.

Motion:

Accept the Board's staff recommended comment responses with the exception of the implementation date to have adjusted to 7/1/2022 and adopt the regulation language as noticed for the 15-day comment on May 28, 2021. Additionally, delegate to the executive officer the authority to make technical or nonsubstantive 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) <u>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.</u>
- (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 <u>or electronic informed</u> 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<u>4</u>-5) The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.
- (65-6) 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.
- (76-7) 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<u>78</u>) 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<u>8-9</u>) A pharmacy shall make available any written <u>or electronic</u> 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 prescription <u>medications</u> 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: Veale/Sanchez

Members of the public were provided with an opportunity to provide comments. The Board heard support of the motion and delay of the implementation date to allow time for implementation from Lindsay Gullahorn of CRA/NACDS and Paige Talley of CCAP.

Support: 7 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Butler	Support
Kim	Support
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support
Veale	Support
Weisz	Support

The Board took a break from 9:31 a.m. and returned at 10:41 a.m. Roll call was taken. Members present included Maria Serpa, Lavanza Butler, Ricardo Sanchez, Debbie Veale, Jason Weisz, Shirley Kim, and Seung Oh.

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

Administrative Law Judge Sawyer presided over the following petition hearings:

- a. Olugbenga Oduyale, RPH 42719
- b. Mohamadali Abolahrar, RPH 47336
- c. Keith Chung, RPH 50486
- d. Maher Kaldas, RPH 39184

Member Kim left the meeting at 10:19 a.m. DCA Counsel Smiley noted with Member Kim's departure, the Board is proceeding as a committee pursuant to Business and Professions Code section 4309(c).

The meeting recessed from 11:06 a.m. to 11:11 a.m. Following the recess, a roll call was again taken. Members present included Maria Serpa, Debbie Veale, Lavanza Butler, Ricardo Sanchez, Jason Weisz, and Seung Oh. DCA Counsel Smiley noted the Board is proceeding as a committee pursuant to Business and Professions Code section 4309(c).

The meeting recessed from 12:18 a.m. to 1:00 p.m. Following the recess, a roll call was again taken. Members present included Maria Serpa, Debbie Veale, Jason Weisz, Ricardo Sanchez, Lavanza Butler, and Seung Oh. President Oh noted the Board is proceeding as a committee pursuant to Business and Professions Code section 4309(c).

V. Closed Session Matters

The Board recessed into closed session at approximately 2:42 p.m.

VI. Reconvene Open Session

The Board adjourned after closed session at approximately 4:28 p.m.