



California State Board of Pharmacy
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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
DRAFT**

Date: March 27, 2020

Location: Teleconference Public Board Meeting
NOTE: Pursuant to the provisions of Governor Gavin Newsom’s Executive Order N-25-20, dated March 12, 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
Ryan Brooks, Public Member
Lavanza Butler, Licensee Member
Shirley Kim, Public Member
Seung Oh, Licensee Member
Jignesh Patel, Licensee Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

Staff Present: Anne Sodergren, Executive Officer
Christine Acosta, Supervising Inspector
Janice Dang, Supervising Inspector
Anne Hunt, Supervising Inspector
Norine Marks, DCA Staff Counsel
MaryJo Tobola, Senior Enforcement Manager
Bob Davila, Public Information Officer
Debbie Damoth, Administration Manager

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

President Gregory Lippe called the meeting to order at 2:00 p.m. President Lippe advised all individuals observing or participating in the meeting that the meeting is being conducted consistent with the provisions of Governor Gavin Newsom’s Executive Order N-29-20.

Department of Consumer Affairs’ staff provided general instruction for the WebEx board meeting for members of the public participating in the meeting.

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

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

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

Jassy Grewal, on behalf of UFCW pharmacists in California, has been in constant communication with pharmacists and pharmacy technician members in California to ensure they are able to perform their jobs safely and efficiently. Ms. Grewal advised the Board that corporate retail pharmacies are asking pharmacists to remove their masks and gloves and administer immunizations in unsafe environments. Ms. Grewal provided pharmacists are scared, stressed and overworked which makes them more susceptible to COVID-19. Ms. Grewal advised UFCW requested the Board require employers to provide the proper personal protective equipment including at minimum gloves, masks and goggles. Ms. Grewal advised pharmacists have been asked to not wear personal protective equipment or have not been provided them. Ms. Grewal provided UFCW requests discontinuing immunizations not related to COVID-19. Additionally, UFCW requests markers be placed on the floors to advise customers of social distancing as well as install sneeze guards at pharmacies to protect pharmacy staff. Ms. Grewal added UFCW requests pharmacists are afforded the opportunity to wash their hands on a regular basis, be provided the necessary sanitation equipment, and sanitize the counter after each patient. Ms. Grewal added pharmacists should be provided adequate resources.

Christine Versichele, Dynalabs, inquired if the current format and agendas will be continued during the pandemic. President Lippe advised processes will be improved over time.

President Lippe took a roll call to inquire if Board Members wanted to add agenda items to a future agenda. There were no future agenda items from Board Members.

III. Election of Treasurer

President Lippe advised the vacancy of the Office of Treasurer with the departure of Board Member Allen Schaad. Mr. Lippe noted that consistent with Board policy, when an officer position becomes vacant, elections are held at the following meeting. He further noted elections will be held at the May Board Meeting for all officer positions, with the term expiring June 1.

President Lippe nominated Board Member Maria Serpa. Board Member Albert Wong nominated Board Member Ricardo Sanchez. There was no public comment.

Board Member Sanchez withdrew his nomination. Board Member Maria Serpa was elected Treasurer.

Board Member	Vote
Brooks	Serpa
Butler	Sanchez
Kim	Serpa
Lippe	Serpa
Oh	Serpa
Patel	Serpa
Sanchez	Withdrew Nomination
Serpa	Abstain
Veale	Serpa
Wong	Sanchez

IV. Determination that Emergency Exists, Pursuant to Government Code section 11125.3

President Lippe advised it came to the attention of the Board after the posting of the agenda that the Board’s policy granting discretion to the Board President for issuing waivers may need to be reviewed in light of a state- and nation-wide declaration of emergency for a pandemic. Mr. Lippe provided the Board may take action on an item of business that was not on the posted agenda upon a determination by a majority vote of the board that an emergency situation exists, defined as (1) a work stoppage or other activity that severely impairs public health or safety, or both; or (2) a crippling disaster that severely impairs public health or safety, or both. That determination must be made by a two-thirds vote of the state body.

President Lippe asked for Board Member comments regarding making such a determination that an emergency exists and the Board must take immediate action to review its policy regarding providing the Board President with the discretion to issue waivers pursuant to Business and Professions Code (BPC) section 4062. He noted that the dynamic nature of this pandemic and response to it, necessitates flexibility in response by the Board and anticipated additional waivers will be necessary both to address site specific issues as well as waivers with broad application. President Lippe stated that he believed an emergency does exist and it is appropriate to review the Board’s policy. He stated if the emergency is established he will also be asking for an extension of the waivers to be increased for up to 90 days.

Motion: Make a determination that an emergency situation exists.

M/S: Veale/Wong

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support

Board Member	Vote
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

V. Review and Possibly Amend Policy Granting President Discretion to Waive Provisions of Pharmacy Law Pursuant to Business and Professions Code section 4062

Motion: Allow for the extension of waivers granted by the Board President pursuant to BPC section 4062 be extended from 30 days to 90 days.

M/S: Veale/Wong

The Board heard comment from a member of the public inquiring if the increase to 90 days would be applied to previously approved waivers. Board Counsel Norine Marks clarified it will apply to waivers moving forward.

The Board briefly discussed the option of voting to make the 90 days retroactive for previously issued waivers but decided against it. (Note: The board later changed this decision.)

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

VI. Discussion and Consideration of Requests to Waive Pharmacy Law Provisions Consistent with the Authority in Business and Professions Code Section 4062

President Lippe provided in response to the Governor's declaration of emergency, and consistent with the provisions of BPC section 4062, the Board has authority to waive provisions of Pharmacy Law or regulations adopted pursuant to it if, in the Board's opinion, the waiver will aid in the protection of public health or provision of patient care. Under the Board's policy, such a determination may be made at the discretion of the Board President for a period of up to 30 days which was amended to 90 days on the day of this meeting. Since that time, the Board President and staff have been approving various waivers for the limited duration allowed. Some of these waivers are limited to a specific site issue, while other waivers have broad application.

President Lippe advised as agenda item, the Board will review several waivers with broad application. These waivers, as approved, have been posted on the board's website and subscriber alerts released. If no action is taken on any waiver, it will expire after 30 days. He advised DCA Counsel Norine Marks, Executive Officer Anne Sodergren, Supervising Inspector Christine Acosta, Supervising Inspector Anne Hunt, and Supervising Inspector Janice Dang are available to answer questions regarding the waivers.

1. Sterile Compounding Renewal Requirements for Facilities Located within a Hospital (BPC sections 4127.1(c) & (d) and 4127.15(b))

President Lippe advised this waiver was requested by Board staff to minimize the Board's impact on hospital operations and is consistent with social distancing recommendations and efforts to preserve limited supplies of personal protective equipment (PPE). Board staff are performing audits and administrative review of operations. Should any issues be identified, Board staff will conduct a physical inspection if needed. As currently approved, the waiver only includes such facilities with an expiration date on or before May 1, 2020. As part of the Board's discussion, President Lippe suggested Board Members may want to consider extending the waiver to apply to such facilities with an expiration date on or before July 1, 2020.

Vice President Debbie Veale inquired if expiration dates were rolling or static. Ms. Sodergren provided expiration dates are rolling, the first day of the month and are staggered throughout the calendar year. Ms. Veale inquired if the Supervising Inspectors had concerns about extending the waiver and protecting the public. Dr. Acosta advised members that as part of the process staff are reviewing prior inspections and collecting records documenting changes in practices, policies & procedures and certifications of hoods as part of the process for the administrative review. Dr. Acosta asked for clarification as it was her understanding that the inspection would be considered the desk audit unless the Inspector or Supervising Inspector overseeing the approval feels there is nefarious behavior requiring an inspection. She noted nothing to date had been brought to her attention that indicates the in-state facilities would require that but she does have concern with nonresident facilities.

Motion: Amended an existing waiver of renewal requirements for sterile compounding pharmacies located within a hospital to apply to pharmacies whose licenses expire on or before

July 1, 2020, under specific conditions (BPC sections 4127.1(c) & (d) and 4127.15(b)).

M/S: Veale/Butler

The Board briefly discussed the option of amending the motion to be for licenses expiring on or before July 1, 2020, or until the emergency declaration is lifted, whichever is sooner. The Board did not amend the motion as a hard stop date was more realistic for operations.

The Board received comment requesting clarification if this will apply to several sterile compounding facilities with renovations completed and are pending inspections. Ms. Sodergren clarified this waiver is specific to the inspection for renewal.

The Board received comment requesting clarification if those pharmacies falling within this time period will have an onsite inspection later or at their next renewal. President Lippe indicated that should issues be identified a physical inspection may be conducted and noted that in general the inspections would resume in advance of the next renewal. Board Member Maria Serpa clarified the administrative audit will take the place of an onsite inspector doing the inspection.

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

2. Prohibited Acts Involving Dangerous Drugs or Devices (BPC sections 4169(a)(1) and 4161(b))

President Lipped suggested consideration to extend the waiver for an additional 120 days effective today, or until the state declaration of emergency is lifted, whichever is sooner. In response to a question, members were advised that an order placed by a pharmacy or wholesaler prior to the end of the emergency or an order that is in transit, could be accepted under the provisions of the waiver. Orders placed after the emergency has ended would not be included in this waiver.

Motion: Extended for 120 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of provisions related to prohibited acts involving dangerous drugs or devices (BPC sections 4169(a)(1) and 4161(b)).

M/S: Lippe/Veale

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

3. Staffing Ratio Provisions (BPC sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations, section 1793.7)

President Lippe reviewed the waiver to allow for an increase in the staffing ratio of pharmacists to pharmacy technicians, to allow for one additional pharmacy technician for each supervising pharmacist under specified conditions.

Motion: Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of provisions related to the staffing ratio of pharmacists to pharmacy technicians under specified conditions (BPC sections 4115(f)(1) and 4127.15(c)(2); and Title 16, California Code of Regulations (CCR), section 1793.7).

M/S: Veale/Butler

President Lippe confirmed this applies to all practice settings and in addition to interns.

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

4. Remote Processing Provisions (BPC section 4071.1(a))

President Lippe provided an overview of the waiver related to “remote processing.” President Lippe noted 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 to the provisions of BPC section 4071.1(a), 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.

The Board discussed including final product verification but members expressed concern as it would expand current practice. Board staff confirmed they believed the request to add final product verification was not included in any of the current waiver requests.

Motion: Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of provisions related to remote processing of medication orders or prescriptions (BPC section 4071.1(a)).

M/S: Veale/Sanchez

In response to a question, President Lippe confirmed the final check is completed by a pharmacist.

Support: 10

Oppose: 0

Abstain: 0

Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

5. Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5)

President Lippe provided as approved, this waiver provides an alternative to the physical the signature requirement in specified situations while still requiring a pharmacist to receive the product.

Motion: Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of the signature requirement for receipt of delivery of drugs, under specific conditions (BPC section 4059.5).

M/S: Veale/Sanchez

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

6. Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6))

President Lippe advised the board that the waived provisions are related to the current prohibition for a prescriber to dispensing medications to an emergency room patient if the medication dispensed is an albuterol inhaler.

Motion: Modify and extend for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of provisions related to prescribers dispensing medication to an emergency room patient if the medications are short-acting, beta-agonist inhalation products, under specific conditions (BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6)).

M/S: Serpa/Wong

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support

Board Member	Vote
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

7. Requirement for Consulting Pharmacist to Perform Visits to Clinic (BPC section 4182(a) & (b) and section 4192(a) & (b))

President Lippe discussed the existing waiver to the requirement for a consulting pharmacist to perform quarterly visit to a clinic under the specified conditions.

Motion: Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver of a requirement for a consulting pharmacist to make quarterly visits to a clinic, under specific conditions (BPC sections 4182(a) & (b)/BPC 4192(a) & (b)).

M/S: Veale/Butler

The Board heard a comment requesting all waivers and time periods be sent out through the notification system to be clearly disseminated. Ms. Sodergren advised as the waivers are issued, the dates are noted and disseminated with the time frame and effective date. Ms. Sodergren advised the Board can send out a subscriber alert if the emergency declaration is lifted.

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

8. USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section 4126.8)

President Lippe reviewed the waiver of USP <797> requirements related to the use of personal protective equipment (PPE) as related to BPC section 4126.8, in that a PPE masks and gowns may be reused by staff performing sterile compounding under the specified conditions. President Lippe

noted that the reason for this waiver was to address the shortage of these items. Dr. Serpa recommended using a hard ending date to allow for the supply chain to be repopulated.

Motion: Extend the waiver related to the use of personal protective equipment (PPE), as related to BPC section 4126.8, to allow for the reuse of PPE masks and gowns by staff performing sterile compounding under specific conditions for 120 days.

M/S: Veale/Butler

The Board heard public comment on the number of times or limitations for use of PPE. Ms. Sodergren advised the conditions are included in the waiver and must be predetermined in policies and procedures in accordance with industry standards. Dr. Acosta advised she anticipated that some PPE may be used for a single shift or until soiled, whichever occurs first. Dr. Serpa added there are national guidelines regarding the reuse of PPE, but such guidelines may change.

The Board heard public comment regarding the remote processing waiver. The commenter indicated there are technologies that exist to allow final approval at a remote location.

The Board heard public comment in support of extending the waiver for a longer period of time, indicating it would be prudent as suppliers have indicated availability of PPE has changed from 4/1/2020 to 6/1/2020. The Board heard additional comment in support and recommended the waiver be extended until the end of the declared emergency at minimum.

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

9. Use of Hand Sanitizer Before Donning Sterile Gloves (Title 16, California Code of Regulations, section 1751.5(a)(5))

President Lippe advised the board that the waiver of CCR section 1751.5(a)(5) allows for hand cleaning with the use of non-persistent activity alcohol sanitizer prior to donning sterile gloves.

Board Members discussed how persistent alcohol sanitizers are difficult to obtain and this waiver allows for any alcohol sanitizers to be used.

Motion: Waive CCR section 1751.5(a)(5) to allow for hand cleaning with the use of non-persistent activity alcohol sanitizer prior to donning sterile gloves for 120 days.

M/S: Sanchez/Brooks

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

10. Expiration of Intern Licenses

President Lippe advised members of a waiver to allow the Board to automatically extend any intern pharmacist license with an expiration on or before April 24, 2020, for an additional six months, if the intern pharmacist license is current and in good standing. The Board discussed extending expiration dates for any intern pharmacist licenses expiring on or before July 1, 2020.

Motion: Allow the Board to automatically extend any intern pharmacist license expiring on or before July 1, 2020, for an additional six months if the license is current and in good standing.

M/S: Veale/Butler

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

11. Staffing Ratio of Pharmacists to Intern Pharmacists (BPC section 4114(b))

President Lippe advised members that this waiver allows for an increase in the staffing ratio of pharmacists to intern pharmacists in specified conditions.

Motion: Extended for 90 days or until the emergency declaration is lifted, whichever is sooner, an existing waiver related to the staffing ratio of pharmacists to intern pharmacists, under specific conditions (BPC section 4114(b)).

M/S: Veale/Sanchez

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

DCA Counsel Norine Marks inquired if the Board would like to revisit the idea of retroactively allowing Board President Lippe the discretion to issue those waivers for the 90 days from the ones that have been issued as Board Members have had the opportunity to see the types of waivers that have been issued.

Motion: Grant the president discretion to extend previously granted waivers for 90 days that were not considered by the Board.

M/S: Brooks/Butler

The Board received a comment requesting clarification if this applies to waivers heard at the meeting or the waivers that have been issued and did not discuss at this meeting. It was clarified that this waiver applies to waivers not heard at the meeting. Counsel Marks clarified the motion is to grant the discretion for those to be issued for a total of 90 days and not an additional 90 days.

Support: 10

Oppose: 0

Abstain: 0

Board Member	Vote
Brooks	Support
Butler	Support
Kim	Support
Lippe	Support
Oh	Support
Patel	Support
Sanchez	Support
Serpa	Support
Veale	Support
Wong	Support

VII. Closed Session Matters

The board recessed to closed session at approximately 4:23 p.m.

VIII. Reconvene Open Session

The board returned to open session at approximately 6:22 p.m.

IX. Adjournment Upon Conclusion of Business

President Lippe adjourned the meeting at approximately 6:22 p.m.