



**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: September 15, 2015

LOCATION: **Staff Location**
Department of Consumer Affairs
Headquarters Building Two
1747 North Market Blvd., Room 186
Sacramento, CA
95834

Additional Teleconference Locations

313 N. Figueroa, Suite 701
Los Angeles, CA 90012

Four Seasons Hotel
2800 Pennsylvania
Washington DC

3848 Carson Street, Suite 212
Torrance, CA 90503

**BOARD MEMBERS
PRESENT:** Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Gregory Murphy, Public Member
Ricardo Sanchez, Public Member
Ryan Brooks, Public Member
Albert Wong, PharmD

**BOARD MEMBERS
NOT PRESENT:** Ramon Castellblanch, Public Member
Lavanza Butler, RPh
Gregory Lippe, Public Member
Rosalyn Hackworth, Public Member
Allen Schaad, RPh
Stanley Weisser, RPh

**STAFF
PRESENT:** Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel

Call to Order

12:00 p.m.

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

President Gutierrez called the meeting to order at 12:00 p.m. Board members present: Amy Gutierrez, Debbie Veale, Greg Murphy, Richardo Sanchez, Victor Law, Ryan Brooks. Note: Albert Wong joined the meeting after roll call.

Laura Freedman, staff counsel, asked if there were any members of the public at the teleconference locations. Members of the board confirmed there were no members of the public in attendance at the any of the teleconference locations.

II. Consideration of the Need for Emergency Board Meeting

Laura Freedman clarified the first item for the board to consider is whether an emergency exists and, if so, whether emergency action is required by the board in response. The board considered that due to the wildfires and the Governor's proclamations, an emergency situation exists that severely impairs public health, safety or both.

There were no comments from the public at any of the meeting locations.

Motion: The board finds, as a result of the current wild files, and proclamations made by the governor, an emergency situation exists that severely impairs public health or safety, or both, that warrants holding the emergency meeting.

M/S: Veale/Sanchez

Support: 6 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law	x			
Lippe				x
Murphy	x			
Sanchez	x			
Schaad				x
Veale	x			
Weisser				x
Wong				x

Board staff explained that, at a prior board meeting, the full board voted that, in the event a quorum of members were not available on an emergency basis to take action pursuant to section 4062 of the Business and Professions Code, it delegated its authority under that section to a committee of three or more board members.

III. Consideration of Specific Requests for Waiver of Requirements During Declared State of Emergency Pursuant to Section 4062 of the Business and Professions Code

a. St. Helena Clearlake Hospital, HSP 43172

President Gutierrez explained that HSP 43172 is a critical access hospital located in Clearlake, California. The board reviewed the request to waive the requirements found in Business and Professions Code sections 4067 and 1705.5. President Gutierrez noted the hospital is requesting a waiver period of September 14, 2015, through September 27, 2015, with the possibility of an extension if evacuations are extended.

Ryan Brooks left the meeting (teleconference) at 12:09 p.m.; there were no members of the public at his location.

The board discussed the possibility of extending the waiver period if needed. Ms. Freedman explained that the board could delegate the authority to extend the waiver to the board’s executive officer.

Albert Wong joined the meeting via teleconference at 12:15 p.m.

Ms. Freedman noted that it had come to her attention that Mr. Law and Dr. Wong were calling in from locations that were not listed on the agenda. Ms. Freedman recommended that Mr. Law and Dr. Wong leave the meeting (disconnect from the call) to avoid potential conflicts with the Open Meetings Act. Mr. Law and Dr. Wong disconnected at 12:17 p.m.

There were no comments from the public at any of the meeting locations.

Motion: Approve waiver request submitted by St. Helena Clearlake Hospital to allow the hospital to dispense medications to outpatients, as well as waive the labeling requirements as requested, for two weeks, and authorize the executive officer to extend the waiver if it is deemed necessary.

M/S: Sanchez/Veale

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler				X
Castellblanch				X
Gutierrez	X			
Hackworth				X
Law				X
Lippe				X
Murphy	X			
Sanchez	X			
Schaad				X
Veale	X			

Weisser				x
Wong				x

b. Lake Pharmacy, PHY 47123

Ms. Sodergren explained that Lake Pharmacy (a retail pharmacy) had not included which specific Business and Profession Code sections it wished waived in their request. Ms. Sodergren added that the pharmacy asked her to articulate to the board that, “there are patients in need and they want to be able to take care of these patients.”

Due to the lack of specificity in the request made by Lake Pharmacy, Ms. Sodergren recommended that the board not take action at this time. She added that the board could come back to this item later in the meeting if they determined action was still required after considering the other items on the agenda.

c. North Lake Medical Pharmacy and North Lake Medication Pharmacy No. 2, PHY 21240 and PHY 41271

President Gutierrez reported that North Lake Medical Pharmacy and North Lake Medication Pharmacy No. 2 are both requesting a waiver from Business and Professions Code section 1116.2 (c) to allow pharmacists to fill a prescription for a controlled substance, based on a written prescription that does not fully conform to California security prescription requirements, for a clinic or licensed health care facility involving less than 25 prescribers.

Ms. Herold noted the board’s emergency waiver authority only applies to the Business and Professions Code. As the sections that North Lake Medical Pharmacy and North Lake Medication Pharmacy No. 2 are requesting a waiver from refer to the Health and Safety Code, DCA legal counsel is of the opinion that the board does not have the authority to grant the waiver.

Ms. Herold stated she would encourage the pharmacies to turn the prescriptions into oral prescriptions, if the prescription is for a Schedule III-IV drug. Other board members expressed agreement with this recommendation.

There was no public comment at any of the meeting locations.

Motion: Deny the waiver request because the board does not have the authority to waive Health and Safety Code requirements.

M/S: Veale/Murphy

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			

Hackworth				x
Law				x
Lippe				x
Murphy	x			
Sanchez	x			
Schaad				x
Veale	x			
Weisser				x
Wong				x

IV. Discussion and Consideration from the Board to, Pursuant to Section 4062 of the Business and Professions Code, Waive Application of Provisions of Pharmacy Law During the Declared State of Emergency in Lake, Napa, Amador, and Calaveras Counties That Will Aid in the Protection of Public Health or the Provision of Care

- a. **Grant of a waiver in areas affected by the states of emergency, by proximity to state of emergency, with or without a request by the pharmacy, for example, to allow:**
- i. **A hospital pharmacy the ability to provide medication to outpatients**
 - ii. **A pharmacy providing medication for seven days when there is no underlying prescription available**
 - iii. **With or without a medication container**
 - iv. **Any limitations to such waivers, for example, relating to controlled substances**

Ms. Herold noted that item iv above should be removed from the list, as the board does not have the authority to waive Health and Safety Code requirements.

Ms. Sodergren stated that the list provided on the agenda was not meant to be all inclusive, rather to give the board a starting point to begin the discussion.

The board discussed how patients, in the specified counties, without an available underlying prescription would be dispensed medication.

President Gutierrez stated that the dispensing of medication without an underlying prescription should not be a requirement; rather, a pharmacist should be allowed to use their professional judgement. Other board members expressed agreement with President Gutierrez’s recommendation.

Ms. Veale stated that the medication must be medically necessary for the pharmacist to dispense it without an underlying prescription. Other board members expressed agreement with the recommendation.

The board discussed the need for documenting the dispensing. Ms. Veale stated that the pharmacist could document the emergency order by using a format similar to a phone order. The board also discussed the need for the pharmacist to attempt to contact the prescriber to notify them that an emergency supply of medication had been dispensed to their patients.

President Gutierrez asked if the waivers could also be applied to veterinary medicine. Ms. Freedman confirmed that the waiver could be applied to veterinary practices.

President Gutierrez asked if compounded medications would be included in the waiver. After discussion, the board decided that the waiver would not include sterile compounded medications.

The board discussed the quantity of medication that should be given to the patient. After discussion, the board decided to allow the pharmacists to provide the patients with a thirty-day supply.

Ms. Sodergren asked how long the board would like the waiver to be in effect. After discussion the board decided that the waiver shall remain in effect until the removal of the declaration of emergency by the governor or otherwise subsequently modified by the board.

There was no public comment at any of the meeting locations.

Motion: Under the circumstances described below, the board grants waiver to a pharmacy in the counties of Lake, Napa, Amador, Calaveras, as well as the immediately adjacent counties, when the pharmacy is providing services to residents impacted by the wild fires. If a pharmacist, in his or her professional judgment, believes it is in the best interest of a patient to receive medically necessary medication, the pharmacist may provide the medication without full compliance with pharmacy law. This waiver will not apply to controlled substances. This waiver applies to both human and veterinary drugs.

Pharmacists must use their professional judgment prior to dispensing a medically necessary medication without an underlying prescription, ensuring that the benefits outweigh the risks. Patients need to identify their prescriber. The pharmacy shall document the prescription by creating an order similar to a phone order as an emergency dispense. Sterile compounded drugs and controlled substances are not covered in this waiver. The prescription is not to exceed a 30-day supply, at the judgment of the pharmacist. Pharmacists should make an attempt to validate the dispensing history through commercially available methods. After the emergency medication is dispensed the pharmacy shall attempt to contact the prescriber.

M/S: Veale/Sanchez

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law				x
Lippe				x
Murphy	x			
Sanchez	x			
Schaad				x
Veale	x			

Weisser				x
Wong				x

The board discussed the waiver requirements for hospitals.

President Gutierrez recommended that hospital pharmacies should be allowed to dispense to outpatients irrespective of the 1 percent limit. The board agreed with the recommendation.

The board decided medications dispensed to patients under the waiver must have a label that includes the same elements that the hospital would provide a patient being discharged from the hospital.

There were no public comments at any of the meeting locations.

Motion: Add the additional provisions below to the language voted on above:

- a. Hospital pharmacies may dispense to outpatients irrespective of the 1% limit. Such dispensing is exempt from the prescription label that must include the same elements it would provide to a patient being discharged from the hospital.
- b. The waiver remains in effect until removal of the declaration of emergency by the governor or otherwise subsequently modified by the board.

M/S: Sanchez/Veale

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law				x
Lippe				x
Murphy	x			
Sanchez	x			
Schaad				x
Veale	x			
Weisser				x
Wong				x

b. Delegation of Authority to Issue, or Extend, Waivers to the Executive Officer, a Board Member, or Some Combination Thereof

Ms. Freedman explained that the board needed to decide whether to delegate authority to extend the time frame or geographic location of the waivers related to the current fires.

The board asked if legal counsel would recommend delegating authority solely to the executive officer, or if board members should be involved. Ms. Freedman responded that either way is legally acceptable. She added she would not recommend requiring approval from more than one board member to make it easy to issue the extension.

Joyia Emard, staff from the Department of Consumer Affairs, asked in the event a new fire broke out if the board would need to adjourn another meeting to grant additional waivers. Ms. Freedman responded that new fires would require the board to hold additional meetings to grant waivers.

Motion: In the unfortunate event the fire spreads to additional counties, delegate to the executive officer the authority to expand or extend these waivers to those counties.

M/S: Sanchez/Veale

Support: 4 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler				x
Castellblanch				x
Gutierrez	x			
Hackworth				x
Law				x
Lippe				x
Murphy	x			
Sanchez	x			
Schaad				x
Veale	x			
Weisser				x
Wong				x

The board directed staff to contact the pharmacies notifying them of the outcome of their waiver requests.

It noted that the waiver approved under agenda item IV would address the request from Lake Pharmacy, thus there was no need to return to the agenda item for further discussion.

V. Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings

Ms. Herold noted that at a future board meeting the full board would have a broader discussion of the board’s emergency response policy.

There was no public comment from any of the meeting locations.

President Gutierrez adjourned the meeting at 1:18 p.m.