



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**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
Lavana 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

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 Stated 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.



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GOVERNOR EDMUND G. BROWN JR.

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

DATE: September 30, 2015

LOCATION: University of Southern California – Orange County Center
2300 Michelson Drive
Irvine, CA 92613

BOARD MEMBERS

PRESENT: Amy Gutierrez, PharmD, President
Victor Law, RPh, Treasurer
Gregory Murphy, Public Member
Allen Schaad, RPh
Lavanza Butler, RPh
Albert Wong, PharmD
Ramon Castellblanch, Public Member
Stanley C. Weisser, RPh

BOARD MEMBERS

NOT PRESENT: Greg Lippe, Public Member
Deborah Veale, RPh, Treasurer
Rosalyn Hackworth, Public Member
Ryan Brooks, Public Member
Ricardo Sanchez, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Janice Dang, Supervising Inspector
Desiree Kellogg, Deputy Attorney General
Debbie Damoth, Staff Manager
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting may be found at:

<http://www.pharmacy.ca.gov/about/meetings.shtml>

Wednesday, September 30, 2015

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

President Gutierrez called the meeting to order at 9:07 a.m. Board members present: Stanley Weisser, Allen Schaad, Amy Gutierrez, Victor Law, Ramon Castellblanch, Gregory Murphy, Lavanza Butler, and Albert Wong.

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

A pharmacist stated that the board should be more pharmacist friendly and that pharmacists should be given the ability to use more professional judgement. The pharmacist stated that the board should hold pharmacy technicians more accountable for their actions. He added that pharmacists should not be required to take lunch breaks. The pharmacist concluded by stating that the board should use an electronic renewal system.

Rich Kruzynski, from PharMEDium, asked if there would be an update on SB 619. Ms. Herold stated that during the Legislation and Regulation section of the next board meeting there would be an update.

Robert Stein, representing KECK School of Pharmacy, asked the board to agendaize a future discussion on possible conflicts in the law regarding naturopathic medicine.

Ray Varble, Pharm.D, asked the board to consider the use of electronic automation technology to validate intravenous drugs. He provided an example of a medication error that occurred in Bend, Oregon, that could have been prevented with the use of automation.

Dr. Varble also encouraged the board to educate the public on the consultation they should expect from the pharmacists when they receive a new prescription. In response to Dr. Varble's comment regarding consultation, a pharmacist in the audience stated that if the board mandates consultation they should also mandate software that would require the pharmacist to perform the consultation.

III. Closed Session

The board recessed to closed session at 9:43 a.m. to consider the preparation, approval, grading and or administration of one or more licensing examination(s).

The board returned to open session at 11:49 a.m.

IV. Approval of the July 27-29, 2015 Board Meeting Minutes

There were no comments from the board or from the public.

Motion: Approve the July 27-29, 2015 Board Meeting minutes.

M/S: Weisser/Law

Support: 8 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			

V. Consideration of Waivers Previously Granted by the Board Pursuant to Business and Professions Code section 4118 Relating to Centralized Hospital Packaging Licenses

President Gutierrez explained that in 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license. The legislation would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are barcoded. President Gutierrez noted that the specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012).

President Gutierrez reported that included in the provisions of this measure was the requirement that the unit dose medications prepared a licensed centralized hospital packaging pharmacy be barcoded to be readable at an inpatient’s bedside. The law also specifies the information that must be retrievable when the barcode is read. President Gutierrez stated that the board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have to reduce medication errors that occur in hospitals. Specifically, the board’s letter to the Governor included the following:

“...Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient’s chart and a patient’s wristband the right medication, in the right dose will be ensured at the patient’s bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events....”

President Gutierrez reported that since January 2014, the board has considered and approved seven requests from hospitals seeking an exemption to allow them to secure a

centralized packaging license – where the board has interpreted the barcode requirements specified in Section 4128.4 more broadly to allow additional time following licensure for the hospitals to fully comply with the requirements of the statute.

President Gutierrez explained that recently Assembly Bill 486 (Bonilla, Chapter 241, Statutes of 2015) was signed by the Governor on September 2, 2015. AB 486 contained an “Urgency” clause whereby upon the Governor’s signature and upon filing with the Secretary of State, the new law was effective, thereby making the waivers unnecessary.

President Gutierrez stated that the Licensing Committee discussed the issue at its September 10 meeting and made the following recommendation: Direct staff to prepare correspondence advising appropriate parties that because of changes in the law, the waiver is no longer necessary. Include as part of the correspondence that the board encourages development in technology to address the current limitations and to ultimately achieve all of the bar coding requirements originally envisioned in AB 377 (Solorio, Chapter 687, Statutes of 2012).

Jonathon Nelson, from CSHP, expressed support of the Licensing Committee’s recommendation and offered to disseminate educational material on centralized hospital packaging in CSHP’s newsletter.

Committee Recommendation (Motion): Direct staff to prepare correspondence advising appropriate parties that because of changes in the law, the waiver is no longer necessary. Include as part of the correspondence that the board encourages development in technology to address the current limitations and to ultimately achieve all of the bar coding requirements originally envisioned in AB 377 (Solorio, Chapter 687, Statutes of 2012).

Support: 8 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			

VI. Consideration of Comments on the FDA’s Draft Guidance Document #230 On Compounding Animal Drugs from Bulk Substances

President Gutierrez explained that this matter was discussed by the Enforcement Committee at its September 9 meeting and subsequently was made an action item for this board meeting.

President Gutierrez stated that the board previously expressed interest in submitting comments on the FDA’s Guidance Document 230, “Compounding Animal Drugs from Bulk Substances.”

President Gutierrez reported that after discussion at the September 9 meeting the Enforcement Committee made the following recommendation: Submit comments to the FDA in support of the policy articulated in the draft Guidance Document entitled “FDA Compounding Animal Drugs from Bulk Substances.”

Note: the FDA Guidance Document can be found in the board meeting materials on the board’s website using the following link:

http://www.pharmacy.ca.gov/meetings/agendas/2015/15_sep_bd_vi_mat.pdf

There were no comments from the board or from the public.

Committee Recommendation (Motion): Submit comments to the FDA in support of the policy articulated in the FDA Compounding Animal Drugs from Bulk Substances Guidance Document.

Support: 8 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			

VII. Regulation Report

a. Recommendation to Add Title 16 CCR section 1730 related to Advanced Practice Pharmacist (APP)

Ms. Herold reported that at the June 2015 Board Meeting, the board approved proposed text to add Section 1730 to Title 16 of the California Code of Regulations

related to Advanced Practice Pharmacist (APP). She noted that the 45-day comment period began on July 31, 2015 and ended on September 14, 2015.

Ms. Herold highlighted the comments received during the comment period, many of which asked the board to remove the requirement for the clinical experience to be earned within ten years from the time of application for APP licensure and require the experience to be earned during four consecutive years. President Gutierrez and Mr. Law explained that these requirements were included to ensure that advanced practice pharmacists have current education and experience.

Kathy Besinque, Pharm.D, asked the board to remove the time frame during which the pharmacists must gain the practice experience to qualify for APP licensure.

Steve Gray, representing Kaiser also asked the board to remove the requirement and recommended that the board consider creating an examination that would determine if the applicant has the necessary skills to be licensed as an APP.

Brian Warren, representing the California Pharmacist Association (CPhA), stated that the time frame limit creates an undue barrier to licensure and asked the board to remove the requirement.

Jonathan Nelson stated that CSHP agrees with the statements made by the previous commenters.

Doug Barcon, pharmacist, stated that many experienced and well qualified pharmacists would not be able to apply for APP licensure due to the time frame requirement the board is proposing.

The board did not take action to remove the requirement in 1730.1(c) that the one year of experience be completed within ten years of the time of application for APP licensure. The board also did not take action to remove the requirement in 1730.1(c) that the one year of experience be completed within four consecutive years.

President Gutierrez stated that during previous discussions on the experience requirement, many commenters asked the board to consider allowing an APP applicant's supervision of others (who provide direct care to patients) to fulfill the direct patient care experience required in the regulation. President Gutierrez asked the board if they felt experience supervising others would adequately qualify a pharmacist to apply for APP licensure. Board member Allen Schaad responded that as a pharmacist's administrative responsibilities increase, their experience with direct patient care decreases.

Ms. Herold reviewed a written comment submitted by Sara McBane, Pharm.D, of UCSD, which asked the board to remove the requirement for the pharmacist's supervisor to attest to his or her experience, and suggested that the board allow the

pharmacist to attest to their own experience. Dr. Besinque and Mr. Warren agreed with Dr. McBane’s written comment.

Board member Ramon Castellblanch stated that supervisor attestation is not an onerous requirement.

Mr. Law suggested that the board include language in the regulation that would allow someone who could not obtain their supervisor’s attestation to request a waiver from the board. The board asked Ms. Freedman, DCA legal counsel, to draft language stating that someone with good cause could submit a request to the board to waive this requirement.

Dr. Gray, representing Kaiser Permanente, expressed his support for creating a waiver provision for the supervisor attestation. Jonathan Nelson stated the CSHP would also support creating a waiver provision.

The board reviewed the comments submitted by Brian Warren on section 1730.1(c). Mr. Warren clarified that he would request the section to be modified to read: “...initiating, adjusting, ~~and~~ or discontinuing...”

President Gutierrez stated that previously the board had decided that an advanced practice pharmacist should have experience providing all three services. However, she stated that as there are additional requirements that must be fulfilled prior to licensure, the language could be changed as Mr. Warren suggests. Board member Stanley Weisser agreed with President Gutierrez.

Motion: Amend section 1730.1 as follows: “The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, ~~and~~ or discontinuing drug therapy of patients as authorized by law.”

M/S: Law/Weisser

Support: 7 Oppose: 0 Abstain: 1

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			

Ms. Freedman read the attestation waiver statement that the board previously asked her to draft. Ms. Freedman recommended that board add the following waiver language to the end of 1730.1 (c)(2): “For an applicant that cannot satisfy this documentation requirement, the board may grant a waiver of this subsection (1703.1(c)(2)).”

Motion: Add the following sentence to the end of 1730.1(c)(2): For an applicant that cannot satisfy this documentation requirement, the board may grant a waiver of this subsection.

M/S: Weisser/Law

Support: 8 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			

After additional discussion the board decided to add similar waiver language to section 1730.1 (d) which requires documentation of completion of residency.

Motion: Direct staff to add language to 1730.1 (b) that would allow applicants who cannot fulfil the documentation requirements for completion of residency to submit a waiver to the board.

M/S: Law/Weisser

Support: 5 Oppose: 3 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			

Ms. Herold explained that if there were no further amendments to the language, the next step in the regulation process would be for the board to approve the text as modified today for 15-day comment period.

Jon Roth, representing CPhA, stated that the proposed regulations are onerous and create artificial barriers to licensure. Mr. Roth added that CPhA would oppose moving forward in the regulation process with language, as modified at today's meeting.

Motion: Approve the text as modified today for 15-day comment period. Delegate to the executive officer the authority to adopt the proposed regulatory changes as modified if there are no adverse comments received during the public comment period. Delegate to the executive officer the authority to make any non-substantive changes that may be required and complete the rulemaking file.

M/S: Law/Weisser

Support: 6 Oppose: 1 Abstain: 1

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 recessed for a break at 12:55 a.m. and resumed at 1:28 p.m.

VIII. Petitions for Early Termination of Probation

The board heard petitions for early termination of probation from the following licensees.

- a. Ad-Rx Pharmacy, PHY 50996
- b. Fadi W. Atiya, RPH 45978
- c. Marvin Yuk-Kwan Fong, RPH 46421

The board recessed to closed session at 4:45 p.m. to discuss disciplinary matters.

The board returned to open session at 6:05 p.m.

Note: Dr. Castellblanch left the meeting at 6:05 p.m.

President Gutierrez announced that due to time constraints the board would not be discussing all of the remaining items on the agenda. She explained that any items not discussed at today's meeting would be agendized for the October Board Meeting.

VII. Regulation Report (continued)

a. Recommendation to Add Title 16 CCR section 1746.3 related to Naloxone Hydrochloride

Ms. Herold explained that at the April 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the emergency regulation text of 16 CCR section 1746.3. The 45-day comment period began on May 22, 2015 and ended on July 13, 2015. Ms. Herold stated that a 15-day comment period was required due to an error made with the incorrect proposed text being noticed in May 2012. The 15-day comment period began on September 4, 2015 and ended September 19, 2015.

Ms. Herold reported that only one comment had been received during the comment period. The commenter had asked the board to change the term "rubber gloves" to "protective gloves" to clarify that the pharmacists are not to use rubber dishwashing gloves.

The board determined that pharmacists would recognize that "rubber gloves" do not refer to rubber dishwashing gloves, and consequently did not make any changes to the proposed language in 1746.3.

There were no comments from the public.

Motion: Approve the proposed modified text. Delegate to the executive officer the authority to adopt the proposed regulatory changes as modified. Delegate to the executive officer the authority to make any non-substantive changes that may be required to complete the rulemaking file.

M/S: Weisser/Law

Support: 7 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. Recommendation to Add Title 16 CCR section 1746.1 related to Self-Administered Hormonal Contraception

Ms. Herold reported that at the March 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 CCR section 1746.1 for Self-Administered Hormonal Contraception. The 45-day comment period began on May 8, 2015 and ended on June 22, 2015.

Ms. Herold explained that based on testimony received at the July 2015 Board Meeting, the board voted to amend the protocol to remove the requirement for pharmacists to take a patient’s seated blood pressure. Ms. Herold noted that because the board amended the protocol, it must be returned to the Medical Board of review and approval.

President Gutierrez stated that she had asked this item to be brought back to the full board for reconsideration because at the July Board Meeting when the language was amended many members were not present for the discussion. Mr. Weisser added that he was not in attendance for the discussion, and was disappointed to learn that the board removed the seated blood pressure requirement. He added that taking a patient’s blood pressure should be the standard of care for pharmacists providing hormonal contraception.

Ms. Freedman explained that if the board would like to discuss the item again before moving it forward in the regulation process, the board would need to motion for reconsideration.

Jonathan Nelson, representing Icebreaker Health and Planned Parenthood, stated that he was surprised by the board’s desire to reconsider the decision made by the board at the July 2015 Board Meeting. He added that the experts who testified at the July meeting stating it was not necessary for a pharmacist to take a patient’s blood pressure.

President Gutierrez explained that at the July Board Meeting one of the doctors who testified in support of removing the requirement for seated blood pressure had represented himself as an employee of UC Davis. President Gutierrez asked Mr. Nelson if that doctor was an employee of Icebreaker Health (which was not disclosed to the board). Mr. Nelson responded that the doctor was an expert in the field of contraception and serves as a technical advisor for Icebreaker Health. Mr. Nelson stated that failure to disclose the doctor’s relationship with Icebreaker Health had been an accidental omission.

Brain Warren, with the California Pharmacist Association, stated that CPhA supports the boards desire to reconsider the removal of the seated blood pressure requirement.

Dr. Kathy Besinque spoke in support of the board’s consideration to add back the requirement for a pharmacist to take a patient’s blood pressure.

Dr. Steve Gray asked if the board would consider this discussion as part of the October Board Meeting. Ms. Freedman explained that the board did not have to take the item back to the board in October, as the item had been properly agendized to allow the board to reconsider the requirement and move forward with the regulation process with amended language.

Motion: Reconsider the July 2015 board vote to remove the seated blood pressure requirement from Title 16 CCR section 1746.1.

M/S: Weisser/Butler

Support: 7 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			

President Gutierrez and Mr. Weisser explained that the requirement for taking a patient’s seated blood pressure had been discussed at numerous SB 493 Committee meetings. President Gutierrez added that experts both in support and opposition to taking blood pressure had testified at the committee meetings and after much consideration the committee had decided that taking a patient’s blood pressure prior to dispensing hormonal contraception should be a standard of care for pharmacists.

Ms. Herold noted that the language including the blood pressure requirement had been reviewed and approved by the Medical Board.

Dr. Kathy Besinque, pharmacist, spoke in support of requiring a pharmacist to take a patients’ seated blood pressure. She noted that women are often unable to self-diagnose elevated blood pressure.

Leona Dembronski, pharmacist, spoke in opposition of requiring a pharmacist to take a patient’s blood pressure, as it would make it more difficult for patients to access hormonal contraception.

Jonathan Nelson, representing Icebreaker Health and Planned Parenthood, apologized for not being more involved during the committee meetings. He asked the board to not require a pharmacist to take a patient’s seated blood pressure.

Brian Warren, representing CPhA, expressed his support of requiring a pharmacist to take each patient’s seated blood pressure.

Dr. Kathy Besinque, pharmacist, explained to the board that a woman who does not want her blood pressure taken or has elevated blood pressure, could still receive hormonal contraception from the pharmacist. The pharmacist would simply need to provide the patient with progesterone *only* hormonal contraception, as estrogen containing hormonal contraception is contraindicated for women with high blood pressure.

Mr. Law reminded the board and the public that the Medical Board had approved the protocol with the inclusion of the seated blood pressure requirement.

Motion: Move forward in the regulation process to add Title 16 CCR section 1746.1 related to self-administered hormonal contraception, using the language that had been previously approved by both the Board of Pharmacy and the Medical Board (including the requirement for a pharmacist to take a patient’s seated blood pressure).

M/S: Law/Weisser

Support: 7 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			

Motion: Delegate to the executive officer the authority to adopt the proposed regulatory changes as modified. Delegate to the executive officer the authority to

make any non-substantive changes that may be required to complete the rulemaking file.

M/S: Law/Weisser

Support: 7 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			

c. Recommendation to Add Title 16 CCR section 1746.4 related to Vaccinations

Ms. Herold reported that at the June 2015 Board Meeting, the board approved proposed text to add section 1746.4 to Title 16 of the CCR related to vaccinations. The 45-day comment period began on July 24, 2015 and ended on September 7, 2015.

Ms. Herold stated that during the comment period the California Department of Public Health (CDPH) asked the board to add a requirement for pharmacists to report any immunization administered to a pregnant patient to the patient’s prenatal care provider within 14-days of administration. The board agreed with this recommendation.

Ms. Herold stated that CDPH submitted a comment requesting the board change the reporting to the primary care provider for all patients from 30 days to 15 days. The board agreed to this recommendation; however, they decided to change the reporting timeframe from 30 days to 14 days to be consistent with the prenatal care provider reporting time frame.

Ms. Herold stated that CDPH also requested the board change the time frame for reporting into the immunization registry from 30 days to 15 days. The board agreed to this recommendation; however, they decided to change the reporting timeframe from 30 days to 14 days to be consistent with the other reporting time frames.

Ms. Herold reported that the San Diego Pharmacist Association submitted comments requesting the board completely remove the requirement to report immunizations into the immunization databank. A member of the public also stated that the board

should not mandate the reporting into the immunization databank. The board did not amend the language in response to either the written or oral comments.

Motion: Approve the modified text (below) for the 15-day comment period.

M/S: Weisser/Schaad

(d) Notifications: The pharmacist shall notify the patient’s primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within ~~30~~ 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient’s choice. Notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within ~~30~~ 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient’s guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

Support: 7 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			

Motion: Delegate to the executive officer the authority to adopt the proposed regulatory changes as modified if there are no adverse comments received during the public comment period. Delegate to the executive officer the authority to make any non-substantive changes that may be required and complete the rulemaking file.

M/S: Weisser/Schaad

Support: 7 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			

IX. SB 493 Committee

President Gutierrez reported that the SB 493 Committee would be reestablished (with the same members) with the purpose of defining certification and consideration of developing additional routes for licensure as an Advanced Practice Pharmacist. She added that the first meeting would occur on October 30, 2015.

Brian Warren, representing CPHA, supported the reestablishment of the committee.

X. Discussion and Possible Revisions to Mail Ballot and Hold Policies for Disciplinary Matters

President Gutierrez announced that the board staff and legal counsel recently reviewed the board's current mail ballot and made modifications to provide clarity for board members when voting.

President Gutierrez noted that at the bottom of the new mail ballot form appropriate contacts are listed should board members have questions about a decision and/or settlement.

A copy of the new mail ballot form is provided immediately following these minutes.

There were no comments from the board or from the public.

President Gutierrez adjourned the meeting at 7:05 p.m.