

**BOARD OF PHARMACY**  
Professional & Vocational Licensing Division  
Department of Commerce and Consumer Affairs  
State of Hawaii

**MINUTES OF MEETING**

Date: Thursday, November 19, 2015

Time: 9:00 a.m.

Place: Queen Liliuokalani Conference Room  
335 Merchant Street, First Floor  
King Kalakaua Building  
Honolulu, HI. 96813

Members Present: Garrett Lau, RPh, Vice Chair, Pharmacist  
Mary Jo Keefe, RPh, Pharmacist  
Marcella Chock, PharmD., Pharmacist  
Carolyn Ma, PharmD., BCOP, Pharmacist

Members Excused: Kerri Okamura, RPh, Chair, Pharmacist

Staff Present: Lee Ann Teshima, Executive Officer ("EO")  
Shari Wong, Deputy Attorney General ("DAG")  
Lisa Kalani, Secretary

Guests: Paul Smith, Walgreens  
Albert Lau, Kaiser Permanente  
Greg Edwards, Department of Health, Food and Drug Branch  
Mike Kido, Ashford & Wriston LLP  
Fred Cruz, CVS Caremark  
Zach Bowser, Times  
Amie Livit, Times  
Richard S. Mejia, Times  
Mark Gregory, Medical Center Pharmacy  
Rebecca Skowvonsia, Medical Center Pharmacy

Call to Order: The agenda for this meeting was filed with the Office of the Lieutenant Governor, as required by section 92-7(b), Hawaii Revised Statutes ("HRS").

There being a quorum present, the Vice Chair called the meeting to order at 9:02 a.m. and excused the Chair from today's meeting.

Chair's Report: **Announcements and Introductions**

The Vice Chair asked the audience to introduce themselves.

### **Additions/Additional Distribution to Agenda**

None.

### **Approval of the Previous Minutes – October 22, 2015**

The Vice Chair called for a motion in regards to the minutes of the October 22, 2015 meeting.

There being no discussion, upon a motion by Ms. Keefe, seconded by Dr. Ma, it was voted on and unanimously carried to approve the minutes for the October 22, 2015 meeting as circulated.

### Executive Officer's Report:

#### **HAR Title 16, Chapter 95 – Status Report**

The EO reported the rules will be mailed to the Small Business Regulatory Review Board ("SBRRB") for their consideration and that she's hoping to get on their December 10, 2015 agenda. She stated that once SBRRB gives their approval, it goes to the Governor's Office for approval to hold a public hearing. She's hoping to have the public hearing for the February meeting, when the Board is scheduled to have their meeting off-site with a live video feed with the UH College of Pharmacy.

#### **Conferences/Seminars/Meetings**

The EO reported that she will be attending the NABP Interactive Compliance Officer and Legal Counsel Forum, December 1-2, 2015, Illinois with RICO Investigator Kristen Kimoto.

#### **RICO Pharmacy Advisory Committee – Deferred from October 22, 2015 meeting**

This discussion was deferred to the end of the meeting.

#### **Emergency Preparedness/State of Emergency – Deferred from August 13, 2015, September 17, 2015 and October 22, 2015 Meetings**

The EO stated that she has not had an opportunity to discuss with the DAG and asked if this could be deferred indefinitely.

There were no objections by the Board.

#### **2016 Legislature**

##### Bill Relating to Opioid Related Drug Overdose Prevention

- Copy of Draft of Bill

The EO asked the Board if they had any comments. Would they support, oppose or change the bill.

Ms. Keefe stated that she had concerns that “standing order” was not defined in the bill nor is it defined in the pharmacy practice act.

Dr. Ma stated that a “standing order” in an institution is different from a “standing order” between a pharmacist and a licensed physician, which is more like a collaborative agreement.

Dr. Chock stated that it appears that the “standing order” in the bill is similar to the collaborative agreement pertaining to emergency contraception, which is already in the pharmacy practice act. She also stated that perhaps the National Association of Boards of Pharmacy (“NABP”) may have more information on this as other states are adopting similar measures.

Ms. Keefe stated that she is also concerned with how pharmacies will be reimbursed.

The EO stated that normally, the Board does not get involved or address reimbursement issues.

Mr. Edwards stated that the proposed bill appears to refer to the Department of Human Services’ Medicaid program for coverage of the drug.

Ms. Keefe also had concerns with the liability for the pharmacists/pharmacies.

The EO pointed out that the proposed measure appears to address that as well.

After further discussion, it was the consensus of the Board to submit a request to the UH College of Pharmacy’s law class to assist the Board in researching other state regulations on Naloxone, including the term “standing order”, and protocols/procedures for dispensing/administering by pharmacists.

The EO also stated that she will see if she can find additional information from the NABP as she will be attending the forum in a couple of weeks.

- Copy of Virginia Protocol for the Prescribing and Dispensing of Naloxone

The Board reviewed a copy of Virginia’s Protocols for Prescribing and Dispensing of Naloxone.

The EO stated she will review Virginia’s laws/rules as it pertains to the prescribing and dispensing of Naloxone.

Bill Relating to Advanced Practice Registered Nurses

The EO explained that this bill amends various state laws to include the recognition of an advance practice registered nurse ("APRN") where applicable. Due to the physician shortage, APRNs are able to practice independently therefore, attempting to alleviate some of the shortage issues, especially in rural areas. She asked the Board if they had any comments or recommendations on the amendments to HRS Chapters 461 and 328.

She explained that under HRS Chapter 461, section 461-1, definition of "Practice of pharmacy" to include a licensed APRN with prescriptive authority that a pharmacist may enter into a collaborative agreement with to initiate emergency contraception, administer drugs, and initiate or adjust the drug regimen of a patient.

The other amendment was to HRS Chapter 328, section 328-1, definition of "Out-of-state practitioner" delete "physician, surgeon, osteopathic physician and surgeon, dentist, podiatrist, or veterinarians and include "practitioner". This would allow changes for prescriptive authority to a health professional's practice act to be automatically included in this definition.

Mr. Edwards stated an in-state practitioner versus an out-of-state practitioner are different right now in 328, so this is proposing to not delineate between an out-of-state or in-state practitioner? It might not be even, for example a naturopath licensed in another state might have a much broader range of drugs he can prescribe than a naturopath licensed in Hawaii.

The EO stated that is correct, so the pharmacist would have to do their due diligence.

Ms. Keefe asked how would a pharmacist know if an out-of-state APRN has prescriptive authority?

The EO stated that pharmacists would have to check or ask the out-of-state APRN to provide proof that they are authorized to prescribe the drug(s).

Dr. Chock stated that appears to be burdensome for the pharmacist.

The EO stated it appears that pharmacists assume that all MDs have the authority to prescribe, however, what if you receive a prescription from an MD, whether in-state or out-of-state, that has had his/her prescriptive authority revoked for some reason?

Mr. Edwards stated currently HRS 328 requires out-of-state prescriptions from an out-of-state practitioner to be verified by the pharmacists. They are responsible for validating and verifying the practitioner's prescriptive authority by virtue of a valid out-of-state license, a DEA registration number, or other appropriate measures.

After further discussion, it was the consensus of the Board to support amending the definition of "Out-of-state practitioner" under HRS 328-1 and adding "advanced practice registered nurses with prescriptive authority".

### **Renewals**

The EO reported that the renewals went "live" on November 9, 2015

The EO also announced that the Formulary Accessibility Working Group held their last meeting on November 16, 2015 and that the Group agreed to recommend in a report to the Legislature to require all health plans to contain a statement to assist consumers in making informed decisions in regards to drug costs; not mandate that health plans use a standard formulary; and that health plans be allowed to meet the requirements of Act 197, SLH 2015 without using a standard formulary template.

### Correspondence:

#### **Prescription Drop Ship Request**

The Vice Chair lead the discussion on the following email inquiry from Henry Schein Animal Health requesting "validation" of the following practice:

"Henry Schein Animal Health sells products to licensed veterinarians in your state. It is very common for practitioners to visit a customer's farm to take care of animals. We have had a request from a DVM to send prescription products directly to the farm or location for them to administer upon their arrival. We would like to know if this is an acceptable practice compliant with your states rules and regulations. At no time will we send a controlled substance to an alternate location, but we would like to send prescription and non-prescription items directly to the end-user, at the DVM's direction, for the DVM to administer on a regular basis. We would put our expectations into writing for the DVM to sign off on prior to shipping any items. We would like validation that we could do this. Our expectations to the DVM would be as follows:

- The product must be shipped to your attention at the secondary location
- The product must be secured upon arrival in your "office" at the location. The office may be any secure (locked) area at the shipping location, including a locked storage closet; and
- You must pursuant to a valid veterinarian-client relationship, either dispense the medication to personnel at the location for administration to the animals (as you would to an animal's owner at your office) or personally administer the medication to the animals.
- You may not order product on behalf of a client if product is not secured at the location and you do not dispense for administration or administer the product.
- HSAH will only ship controlled substances to the address on your Drug Enforcement Administration registration.

Would a letter with the above expectations suffice as proof of our due diligence?

The Vice Chair stated that although it is not clear, as an out-of-state wholesale distributor, no license is required.

Mr. Edwards stated that HRS 328, Part VII pertaining to wholesale prescription drug distributors, only applies to wholesalers of human drugs, however, if the veterinarian is prescribing a "human" drug for an animal then the wholesale distributor section applies if the wholesaler has a facility located in this State.

The EO stated so although it is not clear if Henry Schein Animal Health is "dispensing" or "distributing", we know that a pharmacy license/permit is required to "dispense" any prescription drug, whether it be for a human or animal but as Mr. Edwards previously indicated, distributing a veterinary product does not require wholesale distributor's license and distributing any human drug from an out-of-state wholesale distributor does not require a Hawaii wholesale distributor's license, only in-state wholesale distributor's require a wholesale distributor's license to distribute human prescription drugs.

After further discussion, it was the consensus of the Board to inform Henry Schein Animal Health of the requirements of "dispensing" veterinary products and also provide information on the distribution of veterinary products. Furthermore, the inquirer should be notified that this only applies to non-controlled substances and that he may contact the Department of Public Safety, Narcotics Enforcement Division for requirements of the delivery/dispensing/distribution of a controlled substance.

### **Requirements for Voluntary Recall of Sterile Products**

The Vice Chair lead the discussion on an email inquiry regarding requirements for voluntary recall of sterile products. He stated that the pharmacy laws and rules does not address this and asked Mr. Edwards if HRS Chapter 328 addressed?

Mr. Edwards stated that §328-17.5 states:

**§328-17.5 Principal labeler responsibility under recall of drug.** Whenever the manufacturer of a drug voluntarily recalls the drug or the Federal Food and Drug Administration or a court orders the recall of a drug, the principal labeler of the drug shall remove the drug from all pharmacies, prescriber offices, medical oxygen distributors, distributors of nonprescription drugs, and health care facilities.

He stated it does not specify any notice to the Board.

After further discussion, it was the consensus of the Board that although not required, as a consumer protection issue, it would be prudent for the manufacturer or distributor, who has records of who received the drugs, to notify them of the recall. Furthermore, this consensus does not apply to the recall of controlled substances and the inquirer should be referred to the Department of Public Safety, Narcotics Enforcement Division for the requirements of any recall of a controlled substance.

### **Accreditation Commission for Health Care – Pharmacy Compounding Accreditation Board**

The Vice Chair summarized a letter from the Accreditation Commission for Health Care (“ACHC”) explaining their accreditation program, for sterile and non-sterile compounding pharmacies.

The EO asked Mr. Gregory if his pharmacy was accredited by this organization.

Mr. Gregory said yes.

The Vice Chair asked if the ACHC does inspections annually?

Mr. Gregory said every three years.

The Vice Chair recommended that this correspondence be referred to the Laws and Rules Committee for information to consider when discussing requirements for compounding pharmacies/facilities.

### **Compounding for Clinical Study**

The Vice Chair lead the discussion of an inquiry regarding any restrictions for compounding a product that has a commercial product available. He stated that this is not addressed in the pharmacy laws and rules.

Mr. Edwards stated that Chapter 328 doesn’t specifically address this. He also checked the federal regulations, and if a pharmacy is compounding, they need to comply with the 503A and 503B for outsourcing facilities.

After further discussion, it was the consensus of the Board to refer the inquirer to the federal regulations as the State laws/rules do not specifically address and to refer to the Department of Public Safety, Narcotics Enforcement Division if compounding a controlled substance.

### **Applications:**

#### **Ratification List**

Upon a motion by Ms. Keefe, seconded by Dr. Chock, it was voted on and unanimously carried to approve the attached ratification lists.

### **Executive Session:**

At 9:56 a.m. upon a motion by Ms. Keefe, seconded by Dr. Chock it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-5(a)(4), “To consult with the board’s attorney on questions and issues pertaining to the board’s powers, duties, privileges, immunities, and liabilities”.

At 10:15 a.m. upon a motion by Ms. Keefe, seconded by Dr. Ma it was voted on and unanimously carried to move out of executive session.

Chapter 91, HRS,  
Adjudicatory Matters:

The Vice Chair called for a recess from the meeting at 10:15 a.m. to discuss and deliberate on the following adjudicatory matter(s) pursuant to Chapter 91, HRS:

In the Matter of the Pharmacist's License of **Valerie N. Henckel; PHA 2012-13-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1"-"2"

Upon a motion by the Vice Chair, seconded by Ms. Keefe it was voted on and unanimously carried to approve the Board's Final Order.

In the Matter of the Miscellaneous Permit of **Stroheckers Pharmacy Inc.; PHA 2015-43-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

Upon a motion by Dr. Chock seconded by the Vice Chair it was voted on and unanimously carried to approve the Board's Final Order.

In the Matter of the Miscellaneous Permit of **Wellpartner, Inc.; PHA 2015-107-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

Upon a motion by Dr. Chock, seconded by Ms. Keefe it was voted on and unanimously carried to approve the Board's Final Order.

Following the Board's review, deliberation, and decisions in this matter, pursuant to Chapter 91, HRS, the Vice Chair announced that the Board was reconvening its scheduled meeting at 10:17 a.m.

Executive Officer's  
Report

**RICO Pharmacy Advisory Committee – Deferred from October 22, 2015 meeting**

Upon a motion by Dr. Chock, seconded by Ms. Keefe it was voted on and unanimously carried to accept the list as amended.

Next Meeting:

The Vice Chair announced the next Board meeting as January 28, 2016 and asked if everyone was available.

Dr. Ma and Dr. Chock stated they cannot make the 28<sup>th</sup> and that the third Thursday is January 21<sup>st</sup>.

The EO stated she will try to switch the meeting back to the third Thursday, January 21<sup>st</sup>.



January 28, 2016 - Tentative  
9:00 a.m.  
Queen Liliuokalani Conference Room - Tentative  
King Kalakaua Building  
335 Merchant Street, First Floor  
Honolulu, Hawaii 96813

Adjournment: With no further business to discuss, the Vice Chair adjourned the meeting at 10:20 a.m.

Taken and recorded by:

Reviewed and approved by:

/s/ Lisa Kalani  
Lisa Kalani, Secretary

/s/ Lee Ann Teshima  
Lee Ann Teshima, Executive Officer

11/30/15

Minutes approved as is.  
 Minutes approved with changes; see minutes of \_\_\_\_\_

## BOARD OF PHARMACY

November 19, 2015 Ratification List

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### **Miscellaneous Permits (PMP)**

#### Change of PIC

#### **Vicksburg Special Care Pharmacy and Compounding LLC (PMP-880) dba Aspire Rx**

4079 Pemberton Blvd.

Vicksburg, MS. 39180

New PIC: Dennis Reves

Effective: 10/28/15

#### **HMX Services LLC dba HM Compounding (PMP-904)**

558 Kennedy Blvd.

Bayonne, NJ. 07002

New PIC: Matthew Bernstein

Effective: 9/28/15

#### **Preferred Rx LLC (PMP-698)**

1221 Corporate Dr. E

Arlington, TX. 76006

New PIC: John Helfrich

Effective: 7/23/15

#### **Quick Care Pharmacy Inc. (PMP-1115)**

9397 Haven Ave.

Rancho Cucamonga, CA. 91730

New PIC: Huy Dang Tuong Hoang

Effective: 10/1/15

#### **Express Scripts Specialty Distribution Services Inc. (PMP-1068)**

4700 N Hanley Rd. #A

St. Louis, MO. 63134

New PIC: Tara Wesselmann

Effective: 10/5/15

#### **Pharmalabs LLC (PMP-859)**

10901 Roosevelt Blvd. Ste. 200

St. Petersburg, FL. 33716

New PIC: David Putney

Effective: 10/7/15

#### **Village & Compounding Inc. dba Science Pharmaceutical (PMP-1088)**

7225 Fulton Ave. Ste. H

North Hollywood, CA. 91605

New PIC: Kathy Truong

Effective: 10/5/15

**PCPLV LLC dba Pinnacle Compounding Pharmacy (PMP-1135)**

4445 S Eastern Ave. Ste. B  
Las Vegas, NV. 89119  
New PIC: Jung Kook  
Effective: 9/17/15

**Rx Pros Inc. dba Sterlington Village Pharmacy/Aspire Rx (PMP-924)**

10374 Hwy. 165 N Ste. C  
Sterlington, LA. 71280  
New PIC: Sara Barham  
Effective: 10/6/15

**Cardinal Health 128 LLC dba MMS Solutions (PMP-1191)**

202 Cumberland Bend  
Nashville, TN. 37228  
New PIC: Kimberly Epps  
Effective: 10/6/15

**Zynex Medical Inc., dba Pharmazy (PMP-927)**

9990 Park Meadows Drive  
Lone Tree, Colorado 80124  
New PIC: Vakindi Unvu  
Effective: 10/1/15

**Salveo Specialty Pharmacy Inc., dba Mission Road Pharmacy (PMP 856)**

1155 N. Mission Road  
Los Angeles, California 90033  
New PIC: Carlos Alan Martinez  
Effective: November 1, 2015

Closure

**Good Health Inc. dba Premier Pharmacy #4 (PMP-955)**

2657 Saturn St.  
Brea, CA. 92821  
Effective: 8/3/15

**Rx To You Pharmacy Inc. (PMP-911)**

3202 SE Federal Hwy.  
Stuart, FL. 34997  
Effective: 10/18/15

**Cardinal Health Pharmacy Services LLC dba Rx E-Fill Solutions (PMP-960)**

28341 Constellation Rd.  
Santa Clarita, CA. 91355  
Effective: 10/22/15

**Southwestern Regional Medical Center Inc Cityplex Pharmacy dba  
Pharmacy and Nutrition Shoppe (PMP-1151)**

10109 E 79<sup>th</sup> St.  
Tulsa, OK. 74133  
Effective: 10/17/15

**Cornerstone Compounding Pharmacy (PMP-937)**

1131 N Pacific Ave.  
Glendale, CA. 91202  
Effective: 11/13/15

Relocation

**Coastal Express Pharmacy Inc. (PMP-702)**

3198 F Suite 102  
Airport Loop Drive  
Costa Mesa, CA. 92626  
Effective: 10/7/15

**Transition Pharmacy LLC (PMP-867)**

2450 Metropolitan Drive, Ste. 2546  
Trevose, PA. 19053  
Effective: 10/2/15

**Matrix Pharmacy LLC dba MyMatrix Pharmacy (PMP-571)**

311 W Martin Luther King Jr. Blvd. Ste. 800  
Tampa, FL. 33607  
Effective: 10/1/15

**Goodhealth Inc. dba Premier Pharmacy Services (PMP-990)**

410 Cloverleaf Drive  
Baldwin Park, CA. 91706  
Effective: 8/3/15

**Apogee Bio-Pharm LLC (PMP-1159)**

180 Raritan Center Parkway, Ste. 101  
Edison, NJ. 08837  
Effective: 10/2/15

**Correct Rx Pharmacy Services Inc. (PMP-582)**

1352 Charwood Rd. Ste. C  
Hanover, MD. 21076  
Effective: 10/19/15

**Pharmacy (PHY)**

Change of PIC

**Longs Drug Stores California LLC dba Longs Drugs #10621 (PHY-894)**

2155 Kalakaua Ave. Ste. 102  
Honolulu, HI. 96815  
New PIC: Yuri Miura  
Effective: 10/11/15

**University of Hawaii at Hilo Student Health Services (PHY-832)**

200 W Kawili

Hilo, HI. 96720

New PIC: George Karvas

Effective: 10/26/15

Closure

**Mina Corporation dba Mina Compounding Pharmacy #4 (PHY-888)**

1620 N School St. #107

Honolulu, HI. 96817

Effective: 10/5/15

LTYPE	LIC NUM	BP NAME PART 1
PH	3941	PHYLLIS T G L <ARAKAKI<
PH	3942	RON A <TAMAYO<
PH	3943	DIAA E <ZAED<
PH	3944	AMANDA K <RAMSEY<
PH	3945	LINH HONG <TRAN<

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN		
				ST	BUSN ZIP	BP NAME PART 1
PHY	896	5156 KALANIANAOLE HWY	HONOLULU	HI	96821	LONGS DRUG STORES CALIFORNIA LLC

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN		
				ST	BUSN ZIP	BP NAME PART 1
PMP	1201	9045 E PIMA CENTER PKY	SCOTTSDALE	AZ	85258	BIORX LLC
PMP	1202	2700 WEST FRYE RD STE 200	CHANDLER	AZ	85224	CAREMARK ARIZONA SPECIALTY PHARMACY LLC
PMP	1203	8030 FM 1765 STE A104	TEXAS CITY	TX	77591	AFFORDABLE PHARMACY INC
PMP	1204	432 CEDARVILLE RD	EASTON	PA	18042	KEYSTONE CHOICE PHARMACY LLC
PMP	1205	1911 CHURCH ST STE 204	NASHVILLE	TN	37203	USRC PHARMACY LLC
PMP	1206	255 MAIN ST	ARCADE	NY	14009	COTTRILL'S PHARMACY INC
PMP	1207	255 VALLEY BLVD	WOOD-RIDGE	NJ	07075	DGN PHARMACY INC
PMP	1208	99 N LA CIENEGA BLVD #104	BEVERLY HILLS	CA	90211	YASMIN'S PHAMRACY INC
PMP	1209	617 E COLORADO ST	GLENDALE	CA	91205	GLEN RX DRUGS INC
PMP	1210	540 ROUTE 10 WEST	RANDOLPH	NJ	07869	PHARMACY CREATIONS LLC



LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN		
				ST	BUSN ZIP	BP NAME PART 1
PWD	176	99-045 KOAHA WAY	AIEA	HI	96701	HAWAII MEGA-COR INC
PWD	177	64-1021 MAMALAOA HWY	KAMUELA	HI	96743	ANIMAL HEALTH INTERNATIONAL INC