#### **BOARD OF PHARMACY**

Professional & Vocational Licensing Division
Department of Commerce and Consumer Affairs
State of Hawaii

#### **MINUTES OF MEETING**

Date: Thursday, September 17, 2015

<u>Time</u>: 9:00 a.m.

Place: Queen Liliuokalani Conference Room

335 Merchant Street, First Floor

King Kalakaua Building Honolulu, HI. 96813

Members Present: Kerri Okamura, RPh, Chair

Garrett Lau, RPh, Vice Chair

Marcella Chock, PharmD., Pharmacist Carolyn Ma, PharmD., BCOP, Pharmacist

Members Excused: Mary Jo Keefe, RPh, Pharmacist

<u>Staff Present</u>: Lee Ann Teshima, Executive Officer ("EO")

Shari Wong, Deputy Attorney General ("DAG")

Lisa Kalani, Secretary

Guests: Kellie Noguchi, Times

Paul Smith, Walgreens Tina Liu, Walgreens Catalina Cross, Times Fred Cruz, CVS/Caremark

Tifanny Yajima, Ashford & Wriston Stacy Pi, Kaiser Permanente Albert Lam, Kaiser Permanente

Amy Este, Walmart Keiko Hiraoka, Lilly

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 Chair called the meeting to order at 9:00 a.m.

Chair's Report: Announcements and Introductions

The Chair asked the audience to introduce themselves.

## Additions/Additional Distribution to Agenda

None.

## Approval of the Previous Minutes – August 13, 2015

The Chair called for a motion in regards to the minutes of the August 13, 2015 meeting.

Dr. Ma stated on page 7, under **Theft Reporting**, second sentence, the word "ask" should be "ask's".

There being no further amendments, upon a motion by Dr. Chock, seconded by the Vice Chair, it was voted on and unanimously carried to approve the minutes for the August 13, 2015 meeting as amended.

### Vice Chair's Report:

None.

# Executive Officer's Report:

## HAR Title 16, Chapter 95 – Status Report

The EO reported the rules are currently on step three (3) of the rule making process. Once the DCCA Director signs off on the letters, they will be sent to the Attorney General's office, Legislative Reference Bureau, and Regulated Industries Complaints office for review and recommendations. We are hoping for a quick turn around since we are only amending two (2) sections.

## Conferences/Seminars/Meetings

# <u>2015 MPJE State Item Pool Review – September 10-11, 2015, Chicago, Illinois – Marcella Chock</u>

Dr. Chock reported at this meeting they reviewed all the questions that they had previously wrote and vetted with NABP. They reviewed over 1700 items.

At the Standard Setting Meeting that was held two (2) weeks prior to this meeting, what they did at that meeting was look at what the cut points are for passing. They gave everyone a pool of questions and the goal was for that one pharmacist that is teetering on passing, try to decide what that cut point would be. So as a competent pharmacist once they are licensed, what should they know.

# NABP/AACP District 6,7 & 8 Meeting – September 14-17, 2015 Lake Tahoe, Nevada – Mary Jo Keefe

The EO reported Ms. Keefe is not present at today's meeting because she is attending the NABP/AACP District 6, 7, & 8 Meeting in Lake Tahoe, Nevada.

### 2016 Legislature

Advanced Practice Registered Nurses Bill (Amendments to various HRS' including HRS 461

The EO reported there is going to be a bill introduced relating to Advanced Practice Registered Nurses ("APRNs"), probably by the Hawaii State Center for Nursing that will amend various HRS', including your pharmacy HRS 461. Basically wherever it refers to physician, we included Advanced Practice Registered Nurse with Prescriptive Authority.

The EO asked if anyone has corrections or recommendations to the bill? Would the Board support or oppose the section pertaining to amendments to HRS 461? She asked that the members please email any concerns/corrections and we can discuss at the next meeting.

## \$71 Million Settlement with Biologics Manufacturer Amgen, Inc.

The Board was provided with a copy of a news release for their information stating "Hawaii Reaches \$71 Million Settlement with Biologics Manufacturer Amgen Inc". The State Office of Consumer Protection cites improper drug promotion and labeling for biologic medications. The state Department of Commerce and Consumer Affairs' Office of Consumer Protection along with 48 state law enforcement agencies, and the District of Columbia, announced a major settlement with Amgen Inc. for the promotion of Aranesp and Enbrel. Hawaii's share of the settlement is approximately \$800,000.

## **Emergency Preparedness/State of Emergency**

The EO stated she was not able to meet with the DAG regarding this issue, however we may want to consider changing the title "State of Emergency", since the emergency could be specific to only one county.

Dr. Ma stated in the title you are referring to state as geographical, versus a level of emergency?

The DAG stated it is not state versus county, this refers to a level or condition of emergency.

The EO stated right now it says State of Emergency as declared by the Governor. On Hawaii island during the recent lava flow, it was specific to that county so there was no State of Emergency as declared by the Governor, so none of this would have applied, but we want it to.

The DAG stated we would have to find the correct term that a county Mayor has authority to declare.

The EO stated that's why we should change the title because it may not necessarily be the entire state.

The DAG asked if you are anticipating an HRS statute on this? Otherwise it has no force and effect of law.

The EO stated it's a policy.

The DAG reiterated that it would have no force and effect of law.

The EO stated in an emergency, does it matter? The purpose of this is so that patients can get their medications during an emergency.

The DAG stated you can't exempt license requirements in a board minutes.

The EO stated it's not exempting license requirements.

Dr. Ma stated because it's not law you can't enforce it.

The EO stated it would allow certain policies and procedures to kick in; it does not mandate that you have to follow them, but it would allow you to.

The Chair stated it would give you the flexibility to provide services for the welfare of that community during an emergency.

The EO stated this document that was previously adopted by the Board back in February 2013 allows pharmacies in a State of Emergency to get drugs to the patients who need them. It does not waive any licensing requirements and only applies to non-controlled substances.

Further discussion on this issue was deferred.

# Are Out-of-State Pharmacies Permitted by the Board Required to Comply with Hawaii Pharmacy Laws/Rules? – Deferred from August 13, 2015 meeting

The EO stated she spoke to Greg Edwards from the Department of Health, Food and Drug Branch and he said that Chapter 328 says specifically "in this state" and he would interpret that as Chapter 328 does not apply. She also spoke with Mr. Keith Kamita from the Department of Public Safety, Narcotics Enforcement Division and he said that Chapter 329-32 and 329-38 would apply if they are shipping controlled substances directly into Hawaii without having an entity here.

The Chair stated the application requirements addresses the laws and rules of Hawaii.

The DAG stated if they hold a license or permit in Hawaii, then they are subject Hawaii laws and rules.

Dr. Chock stated in section 461-15(a)(7)9C) Miscellaneous permits, refers to compliance with the laws of the home state.

The DAG stated that is how they qualify for license or permit, but it does not say once you're a licensee you don't have to follow Hawaii's laws.

Dr. Ma stated, so the answer is they must comply with Hawaii laws and rules.

The DAG stated as a licensee or permitee allowed to dispense prescription drugs and devices into the State of Hawaii you must comply with HRS 461 and HAR 16-95. If you are licensed under these chapters you must comply with these chapters.

By consensus the Board determined that as a holder of a Hawaii miscellaneous permit as an out-of-state pharmacy, the out-of-state pharmacy is permitted to dispense prescription drugs or devices directly to the patient residing in this State, in compliance with the Hawaii pharmacy laws/rules, HRS Chapter 461 and HAR Chapter 95

#### Correspondence:

The following correspondence was distributed to the Board members for their information.

#### **NABP**

## NABP e-News – Coming Soon to the Board of Pharmacy Web Page!

The EO reported she received permission from NABP to post a "link" on the Board's webpage to the NABP e-News.

#### NABP News Roundup – August 2015

The Board was provided with a copy of the NABP News Roundup for their information.

#### NABP Newsletter

The Board was provided with a copy of the NABP Newsletter highlighting the following articles.

- Updated Model Act; Amended Language Addresses Timely Pharmacy Practice Topics
- Upcoming Interactive Forums; EO, Pharmacy Compliance Officers and Legal Counsel
- Defamation Case SLAPPED on Pharmacies
- Survey Results Give Insights Into State Board Responsibilities and Resources Including Support Staff and Fiscal Data

# Two Separate Inquiries Pertaining to License/Permit Requirements for FDA-Registered 503 Outsourcing Facility

The Board reviewed two (2) separate inquiries pertaining to license/permit requirements for FDA Registered 503 Outsourcing Facility.

Dr. Ma asked what is an outsourcing facility?

The Chair stated they are sterile compounders.

The first inquiry with the Board's responses are as follows:

- 1. Is a pharmacy license required? Yes, if dispensing a prescription drug directly to the patient.
- 2. Is a wholesale distributor license required? The Board deferred this question to Greg Edwards, Department of Health, Food and Drug Branch as they are the authority over wholesale distributors.
- 3. Is there a license specific to outsourcing facilities? No.
- 4. In the event that the outsourcing facility plans to ship controlled substances, is a separate controlled substance license/permit required? The Board deferred this question to the Department of Public Safety, Narcotics Enforcement Division as they are the authority over the dispensing and prescribing of controlled substances.

The second inquiry with the Board's responses are as follows:

- Does Hawaii require that 503B facilities register as a non-resident pharmacy to be able to ship compounded products into and/or out of the state? The Hawaii pharmacy laws/rules require that only a pharmacy can "dispense" a prescription drug pursuant to a valid and patient specific prescription directly to the patient. Currently, the pharmacy laws/rules do not require registration as a 503B outsourcing facility.
- Are 503B facilities in Hawaii allowed to fill patient-specific prescription? Same as above response.
- Are there any other special state requirements/permits required for a 503B to operate? The Board deferred this question to Greg Edwards, Department of Health, Food and Drug Branch to inquire if a wholesale distributor's license would be required.

## Rx Ipsa Loquitur – July/August 2015

The Board was provided with a copy of the Rx Ipsa Loquitur – July/August 2015 publication for their information. The featured article is "PharMerica Settlements Highlight Potential for Dual False Claims Act and Controlled Substances Act Liability for Invalid Prescriptions".

## ACPE - Continuing Pharmacy Education Provider eUpdate

The Board was provided with a copy of the ACPE – Continuing Pharmacy Education Provider eUpdate for their information.

# <u>Can Patient Pick Up Prescription Medication, Dispensed by a Pharmacy, From the Patient's Doctors Office?</u>

The Board reviewed an email inquiry asking, "If a pharmacy receives a valid prescription from a physician and fills that prescription, is it permissible for the pharmacy to send the filled prescription to the physician's office for pick up by the patient?"

The Vice Chair asked if he should recuse himself from this discussion because he was one of the pharmacist initially asked this question a few years back.

The DAG asked the Vice Chair if he is able to vote fairly and objectively today?

The Vice Chair replied yes.

The Chair stated once the medication leaves the pharmacy, it is dispensed and cannot be returned.

Dr. Chock stated as a patient, you can designate anyone you want to receive your medication.

After some discussion and a review of the pharmacy laws and rules, the Board by consensus determined that it was permissible for a patient to designate to the pharmacy to have their prescription drugs delivered to the physician's office so that the patient may pick up his/her medication from the physician's office. The Board determined that once the drugs have left the pharmacy, it is considered "dispensed" and may not be returned to the pharmacy. This interpretation does not apply to the dispensing or delivery of controlled substances.

#### "Delivery" of Prescriptions to Clinics

The Board reviewed an email inquiry describing a plan of action that was put into place to accommodate patients affected by the June 27 Pahoa lava flow. A health organization partnered with retail pharmacies to carry out delivery pharmaceutical service to a clinic located in Pahoa. A pharmacy technician of one of the partnered retail pharmacies delivers/dispenses medications to the Pahoa clinic twice a week, but, a position within the health organization has become available to take over the delivery for the Pahoa clinic and eventually for other clinics.

The following questions were asked in the email:

- 1. Does the appointed individual within our organization need to be a certified pharmacy technician to dispense medication?
- 2. Does a pharmacist have to be present inside the clinic when medications are being dispensed?

The Chair stated it appears she is using the wrong terms, because it sounds like they want someone to pick-up and "deliver" patients medications.

The EO stated so it appears they just want to know what the qualifications are for that individual that is delivering the medications.

Dr. Chock stated that she does not think they mean "dispense" as defined in the rules.

The EO asked does someone have to be a pharmacy technician to "deliver" medications?

Dr. Ma stated no.

After some discussion and a review of the pharmacy laws and rules, the Board by consensus responds as follows:

Pursuant to Hawaii Administrative Rules §16-95-86, Scope of pharmacy technician, does not include "dispensing" of drugs. Therefore, a pharmacy technician may not "dispense" drugs. Furthermore, a pharmacy technician must be supervised by a registered pharmacist. If the question is if a pharmacy technician is allowed to "deliver" the drugs to the clinic, the Board considers the drug dispensed once it has left the pharmacy premises (HAR §16-95-87), the pharmacy laws/rules do not address the "delivery" of drugs.

## STAT Dispense – Emergency Medication Management System

The Board reviewed an email introducing them to STATdispense. STATdispense is a pharmacy-integrated electronic stat/emergency-medication storage solution which securely controls such inventory onsite within authorized institutional facilities, and provides real-time notification when any such inventory is withdrawn. STATdispense utilizes a laptop that is securely connected to an electronically-locked medication cabinet/cart, and only allows authorized facility personnel access based on secure user login credentials.

#### Applications:

The Board moved into Executive Session.

# **Executive Session**:

At 10:09 a.m. upon a motion by Dr. Chock, seconded by the Vice Chair it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-5(a) (1) and (4), "To consider and evaluate personal information relating to individuals applying for professional or vocational licenses cited in section 26-9 or both;" and "To consult with the board's attorney on questions and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities".

At 10:38 a.m. upon a motion by Dr. Chock, seconded by Dr. Ma it was voted on and unanimously carried to move out of executive session.

# Applications: Ratification List

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

## **Applications**

#### Pharmacist

Upon a motion by the Chair, seconded by Dr. Chock, it was voted on and unanimously carried to approve the following application:

Wayne A. Hudson

## Miscellaneous Permit

Upon a motion by the Chair, seconded by Dr. Chock, it was voted on and unanimously carried to approve the following request, subject to receipt of a current license verification for Christopher Thomas Ball.

BIORX, LLC (PMP 697) – Christopher Thomas Ball, Staff Pharmacist

Upon a motion by the Chair, seconded by Dr. Ma, it was voted on and unanimously carried to approve the following applications:

Maxor National Pharmacy Services, LLC, dba IV Solutions of Lubbock Jay Pharmacy of Jay Florida Inc.

Upon a motion by the Chair, seconded by the Vice Chair, it was voted on and unanimously carried to deny the following application pursuant to HRS §§436B-19(13) Revocation, suspension, or other disciplinary action by another state or federal agency against a licensee or applicant for any reason provided by the licensing laws or this section; 461-21(a)(2) Professional misconduct, gross carelessness, or manifest incapacity; and 461-21(a)(5) Violation of any state or federal drug, controlled substance, or poison law:

Trilogy Pharmacy Inc.

Upon a motion by the Chair, seconded by the Vice Chair, it was voted on and unanimously carried to approve the following application, subject to receipt of a current license verification:

Main Avenue Corp.

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Next Meeting:	The Chair announced the next Board meeting as October 22, 2015 and asked if everyone was available.						
	The Vice Chair stated he may not be able to attend the October meeting. He will check his schedule and let the EO know.						
	October 22, 2015 – New Date 9:00 a.m. King Kalakaua Conference Room – New R King Kalakaua Building 335 Merchant Street, First Floor Honolulu, Hawaii 96813	oom					
Adjournment:	With no further business to discuss, the Chair	adjourned the meeting at 10:42 a.m.					
Taken and recorded by:	Reviewed and appro	ved by:					
<u>/s/ Lisa Kalani</u> Lisa Kalani, Secretary	_ <u>/s/ Lee Ann Teshin</u> Lee Ann Teshima, E						
9/28/15							
[ X] Minutes approved as is. [ ] Minutes approved with changes; see minutes of							

#### **BOARD OF PHARMACY**

## September 17, 2015 Ratification List

## **Miscellaneous Permits (PMP)**

#### Closure

# National Compounding Pharmacy Inc. (PMP-985) dba Soothe Compounding Pharmacy

1824 59<sup>th</sup> St. West Bradenton, FL. 34209 Effective: 9/1/15

# Alicea Enterprises LLC dba

# Physician Specialty Compounding by Sunlake Pharmacy (PMP-1011)

18964 N Dale Mabry Hwy. #103

Lutz, FL. 33548

Effective: 7/31/15

# **ASL Pharmacy (PMP-737)**

900 Calle Plano Ste. M Camarillo, CA. 93012 Effective: 8/7/15

# Sinutopic Inc. dba Sinus Dynamics Pharmacy (PMP-805)

755 Lakefield Rd. Unit D Westlake Village, CA. 91361

Effective: 8/7/15

## **Specialty Compounding LLC (PMP-642)**

211 S Bell Blvd.

Cedar Park, TX. 78613 Effective: 7/28/15

# National Compounding Pharmacy Inc. dba Soothe Compounding Pharmacy (PMP-985)

1824 59<sup>th</sup> St. West Bradenton, FL. 34209 Effective: 9/1/15

#### Relocation

# Briovarx of Nevada LLC dba Briovarx (PMP-826)

8350 Briova Drive Las Vegas, NV. 89113 Effective: 7/13/15

## Name Change

# **Liberty Medical LLC (PMP-137)**

8881 Liberty Lane

Port St. Lucie, FL. 34952

Effective: 7/1/15

# **Sterlington Village Pharmacy/Aspire Rx (PMP-924)**

10374 Hwy. 165 North, Suite C

Sterlington, LA. 71280 Effective: 8/6/15

# Monroe Clinic Drugs/Aspire Rx (PMP-851)

1470 Garrett Road, Suite A

Monroe, LA. 71202 Effective: 8/6/15

# US Med LLC (PMP-747

1480 NW 79<sup>th</sup> Ave. Miami, FL. 33126

Effective: 9/2/15

## Trade Name Change

## World Health Industries Inc. dba Aspire Rx (PMP-885)

1485 Livingston Ln. Jackson, MS. 39213

Effective: 7/23/15

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

4079 Pemberton Blvd. Vicksburg, MS. 39180 Effective: 7/6/15

## Pharmacy (PHY)

### Change of PIC

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

1620 N School St. #107 Honolulu, HI. 96817

New PIC: Hany Adeeb Guirguis

Effective: 8/1/15

## Longs Drug Stores California LLC dba Longs Drugs #7356 (PHY-794)

91-919 Fort Weaver Rd. #106

Ewa Beach, HI. 96706 New PIC: Kim Nguyen

Effective: 8/16/15

# Walgreen of Hawaii LLC dba Walgreens #16100 (PHY-850)

1250 Liliha St. Ste. 201 Honolulu, HI. 96817

New PIC: Alice Hwang

Effective: 8/13/15

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3915 CHI CHIU <AU YEUNG<

3916 CHERYL L <JEZWINSKI<

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BUSN

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PHY	891	2436 KAUMUALII HWY	KALAHEO	HI	96741	BRIAN A CARTER INC
PHY	892	2829 ALA KALANIKAUMAUKA ST	KOLOA	HI	96756	LONGS DRUG STORES CALIFORNIA LLC
PHY	893	4454 NUHOU ST	LIHUE	HI	96766	SAFEWAY INC

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BUSN

LTYPE L	IC NUM	BUSN ADDR 1	BUSN CITY	ST	BUSN ZIP	BP NAME PART 1
		0101 1000 100				
PMP	1177	8121 10TH AVE N	GOLDEN VALLEY	MN	55427	MCKESSON MEDICAL-SURGICAL MEDIMART INC
PMP	1178	1052 S POWERLINE RD STE B	DEERFIELD BEACH	FL	33442	Alability inc
PMP	1179	3218 BELTLINE RD STE 510	FARMERS BRANCH	TX	75234	JPX2 LLC
PMP	1180	2441 WARRENVILLE RD 5TH FLOOR	LISLE	IL	60532	CATAMARAN HOME DELIVERY OF ILLINOIS LLC
PMP	1181	6388 FOLSOM DR	BEAUMONT	TX	77706	RPH PARTNERS LLC
PMP	1182	290 PLANDOME RD	MANHASSET	NY	11030	MANHASSET PARK DRUG CORP
PMP	1183	3007 OCEAN HEIGHTS AVE	EGG HARBOR TOWNSHIP	NJ	08234	EHT PHARMACY LLC
PMP	1184	8881 LIBERTY LANE	PORT SAINT LUCIE	FL	34952	LIBERTY MEDICAL LLC
PMP	1185	1704 E GREENVILLE ST STE 1D	ANDERSON	SC	29621	ALL ABOUT YOUR HEALTH INC
PMP	1186	1829 WEST DRAKE DR STE 102	TEMPE	AZ	85283	LLC PATIENT SERVICES INC
PMP	1187	4611 E SHEA BLVD BLDG 3 #180	PHOENIX	AZ	85028	CUSTOMCEUTICAL COMPOUNDING LLC
PMP	1188	5204 JACKSON RD STE C	ANN ARBOR	MI	48103	PHARMACEUTICAL CARE SOLUTIONS INC
PMP	1189	451 UNIVERSITY BLVD STE 103	JUPITER	FL	33458	TIME SQUARE DRUGS INC
PMP	1190	1757 SAN MARCO RD #B	MARCO ISLAND	FL	34145	RELIABLE PHARMACY LLC
PMP	1191	202 CUMBERLAND BEND	NASHVILLE	TN	37228	CARDINAL HEALTH 128 LLC DBA MMS SOLUTIONS
PMP	1192	730 W HALLANDALE BCH BLVD	HALLANDALE BEACH	FL	33009	HEALTHY MEDS PHARMACY CORP
PMP	1193	2450 N LAKE AVE	ALTADENA	CA	91001	2 M PHARMACY INC
PMP	1194	7840 GRAPHICS WAY	LEWIS CENTER	OH	43035	MODERN MEDICAL INC
PMP	1195	500 KIRTS BLVD STE 300	TROY	MΙ	48084	HOMESCRIPTS.COM LLC

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BUSN

LTYPE LIC NUM BUSN ADDR 1 BUSN CITY ST BUSN ZIP BP NAME PART 1 \_\_\_\_\_

175 91-163 HANUA ST KAPOLEI HI 96707 MATHESON TRI-GAS INC