

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

**MINUTES OF MEETING**

Date: Thursday, September 18, 2014

Time: 9:00 a.m.

Place: King Kalakaua Conference Room  
King Kalakaua Building  
335 Merchant Street, First Floor  
Honolulu, Hawaii 96813

Members Present: Kerri Okamura, Chair  
Garrett Lau, Vice Chair  
Marcella Chock, Pharmacist  
Lydia Kumasaka, Public Member

Members Absent: Carolyn Ma, Pharmacist  
Mary Jo Keefe, Pharmacist

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

Guests: Victor Ung, The Honolulu Pharmacy  
Catalina Cross, Times Supermarket  
Kellie Noguchi, Times Pharmacy  
Stacy Pi, Kaiser Permanente  
Paul Smith, Walgreens  
Abigail Wong, Walgreens  
Jaclyn L. Moore, Foodland  
Pat Adams, Foodland  
Tiffany Yajima, Ashford & Winston  
Fred Cruz, CVS Caremark

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.

The Chair excused Ms. Keefe and Dr. Ma from today's meeting.

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

None

### **Approval of the Previous Minutes – August 21, 2014**

The Chair called for a motion in regards to the minutes of the August 21, 2014 meeting.

The Chair had the following amendments:

- Page 3, second paragraph, in the last sentence, correct the word “apportion” to “position”
- Page 3, under the heading “Scheduling of Tramado into Schedule IV”, correct “Tramado” to “Tramadol”.

There being no further discussion or amendments, upon a motion by Ms. Kumasaka, seconded by Dr. Chock, it was voted on and unanimously carried to approve the minutes for the August 21, 2014 meeting as amended.

### Vice Chair’s Report:

None.

### Laws and Rules Committee Report

The Chair reported that at the August 21, 2014 meeting, the Committee discussed a draft of language pertaining to collaborative agreements. She stated that the Committee was not ready to submit any recommendations to the Board and will continue their discussions and research on the matter.

### Executive Officer’s Report:

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

The EO stated she just received the final draft and will begin moving forward with Chapter 95 rules adoption process.

#### **Follow-up of CLIA Waived Tests**

The EO stated that she contacted the Department of Health, Office of Health Care Assurance – CLIA Program and received information regarding clinical laboratory permits, which was distributed to the Board members for their information.

The Chair clarified that if a pharmacy wants to do CLIA waive testing; it appears they have to be a lab and that the pharmacy license/permit does not permit a pharmacy to conduct any laboratory tests.

### Correspondence:

#### **National Association of Boards of Pharmacy (“NABP”)**

##### NABP Newsletter – Article, “The Drug Quality and Security Act: What Does it Mean for Compounding Pharmacies”?

The Chair reported that section 503A of the FD&C Act states that compounding must be performed by a licensed pharmacist in a state licensed pharmacy or federal facility, or by a licensed physician. It does not exempt so-called office use compounded products. For example, those provided to a practitioners office or a healthcare facility for administration to a patient

without receipt of a prescription order for an identified individual patient. Other conditions of exemption from the requirements are as follows:

- The compounder must use ingredients meeting United States Pharmacopeia (USP) standards or contained in an FDA-approved drug;
- The drug must not appear on an FDA-established list of products removed or withdrawn from the market for safety or efficacy reasons;
- The compounded product must not be “essentially a copy of a commercially available drug product”; and
- The drug must not be identified by FDA as “presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product”.

The article also states that although individual states vary in their approaches to enforcement of USP standards for compounding by statute, prescribed by rule, enforced as a standard of care, silence on issue, Section 503A appears to resolve any question of these standards; application to compounded drug products as a matter of federal law.

The DAG stated it appears the most important point they are making in context of what the Board has been considering, is that you need a patient specific prescription for compounding or they consider it to be manufacturing.

The EO asked if other states that have compounding for office use in their practice act will be affected by the FDA’s determination?

The DAG stated it appears everyone will be affected.

The EO stated that even if the Board gives approval to do compounding, the pharmacy still has to comply with other state or federal regulations.

#### August 2014 State News Roundup

The Chair reported on the following articles:

“Delaware Board Licensing Outsourcing Facilities” – On June 18, 2014, the Delaware State Board of Pharmacy unanimously agreed to license “outsourcing pharmacies” as described under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

“Dispensing Naloxone in Delaware” - Also in Delaware, Naloxone for nasal administration can be dispensed by a pharmacist with a prescription for patients at risk of an opioid overdose.

“2014 Minnesota Legislation Concerning the Practice of Pharmacy” - Changes were made to the statutes that will have an impact on the practice of pharmacy. The statutes now allow the pharmacist to perform laboratory tests that are waived under the federal Clinical Laboratory improvement Act of 1988... provided that a pharmacist may interpret the results of laboratory tests but may modify drug therapy only pursuant to a protocol or collaborative practice agreement. They also made changes pertaining to immunizations. In order to provide immunizations, a pharmacist must have completed a program approved by the Accreditation Council for Pharmacy Education specifically for the administration of immunizations or a program approved by the Minnesota Board of Pharmacy. Pharmacists must comply with guidelines for vaccines and immunization practices, except that a pharmacist does not need to comply with

those portions of the guidelines that establish immunization schedules when administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under Chapter 147, a physician assistant authorized to prescribe drugs under Chapter 147A, or an advanced practice nurse authorized to prescribe drugs under Section 148.235, provided that the order is consistent with FDA-approved labeling of the vaccine. Also in Minnesota, the terms “protocol”, “collaborative practice”, and “collaborative practice agreement” are now defined in the statutes.

#### **License Requirements to Perform Medication Therapy Management – Deferred from August 21, 2014 meeting**

Dr. Chock led the discussion on an email asking the following questions regarding Medication Therapy Management (MTM):

1. Do we need to obtain a pharmacy license to either speak with patients’ resident to your state, OR have pharmacists residing in your state to take calls/cases?
2. Do pharmacists need a pharmacist license in YOUR state in order to (a) be located in your state while working on out-of-state patients, or (b) while working on patients residing in your state regardless of their physical location?

After some discussion, it was the consensus of the Board that based solely on the information provided in the email, if the pharmacist performing the MTM for a resident of this State would have to be licensed as a Hawaii pharmacist and if the pharmacist was performing the MTM from a pharmacy, a miscellaneous permit would be required.

This is an informal interpretation for informational and explanatory purposes only and is not an official opinion or decision and therefore is not to be viewed as binding on the Board.

#### **In-State Virtual Manufacturer License Requirements**

Ms. Kumasaka led the discussion on an email asking for clarification regarding the license requirements for in-state virtual manufacturers (VM). The email explains that a VM is an entity that does not touch drugs but instead owns the label/approval for the drug, contracts the manufacturing of the drug out to a registered manufacturer who then directly ships the drug to the third party logistics who then ships the drug to the practitioner/prescriber. The VM is only responsible for sales, marketing, invoicing, record keeping, and title passing.

The EO stated she does not know what a VM is.

The DAG stated more information is needed.

The EO stated she will check with NABP, and also ask the inquirer for clarification.

The Board deferred discussion on this matter.

#### **Filling Prescriptions of a Deceased Prescriber**

The Chair led the discussion on an email asking if a prescription that was written before a prescriber became deceased is valid and may be filled.

Mr. Lau stated this is not specifically addressed in the laws and rules.

Guest Mr. Cruz stated that the philosophy has always been if the doctor dies, the prescription dies.

Guest Mr. Adams stated they follow the same philosophy.

The EO stated it may have been valid at the time it was written, but it appears it would no longer be valid if the prescriber no longer exist.

Dr. Chock asked if the Hawaii Medical Board has something in its laws and rules regarding this.

The EO stated she doesn't know but she will check with the Medical Board, and she will also inform the inquirer that the Pharmacy laws and rules do not address this issue.

#### **“Centralized” Pharmacy Services – License/Permit Required?**

Dr. Chock led the discussion on an email inquiry asking if a miscellaneous permit or any other permit/pharmacy license is required for centralized functions (e.g. typing of prescriptions, handling of adjudication exceptions, communicating with customers about refill too soon rejections, initiating prior authorizations, etc.) that would occur in administrative offices. No drugs will be present, so the location would be considered non-dispensing. A pharmacist will always be on duty supervising these tasks, and in addition, the supervising pharmacist may be providing counseling services (e.g. Medication Therapy Management) to customers over the phone.

The Chair stated it sounds like the pharmacist is practicing pharmacy outside of a pharmacy.

Dr. Chock stated their question is if the “office” requires a miscellaneous permit.

The EO asked if what they are doing falls under the practice of pharmacy.

The Chair stated yes.

After further discussion, it was the consensus of the Board that based solely on the information contained in the email, the pharmacist is required to hold a Hawaii pharmacist license if practicing pharmacy in Hawaii or with Hawaii residents, however, the office may not be required to obtain a miscellaneous permit.

This is an informal interpretation for informational and explanatory purposes only and is not an official opinion or decision and therefore is not to be viewed as binding on the Board.

#### **CME Question**

The Chair led the discussion on an email asking if a Medical Management of Chemical and Biological Casualties CME course can count toward the continuing education requirement for the renewal of a Hawaii pharmacists' license.

The EO stated that previously the Board accepted CME courses, however pursuant to Act 24, effective January 1, 2014 the acceptance of CME courses was removed and only ACPE courses may be accepted.

### **Providing Drug Information to Patients in Electronic Format**

Ms. Kumasaka led the discussion on an email asking if there is anything in the laws and rules that would prevent sending the patient medication sheets to patients via e-mail or allowing patients to access the information on demand via website if they so choose. The patients would be given the choice of receiving this information electronically or via paper.

The EO asked if patient medication sheets contain personal information?

Guest Mr. Adams stated personal information is not on the sheets.

The EO stated that if someone intercepts the e-mail, then that person knows that the person the e-mail was intended is taking this particular drug.

The Chair stated our laws and rules do not address this, however FDA and HIPAA regulations need to be considered.

Ms. Kumasaka stated if the information is made available on their website then it's not addressed to anyone specific.

Guest Mr. Adams agreed and stated if you make them go to the website, you're not actually "giving" it to them.

Dr. Chock stated it appears this is not specifically addressed in our laws and rules.

Guest Mr. Smith stated if we're dealing with HIPAA, usually the standard is you have to give it to them personally or you have to mail it to their existing address on file. It appears an e-mail address would be the same scenario whereas it is their e-mail address, but if it is read by someone else that's the same as if someone intercepted their regular mail.

After further discussion, it was the consensus of the Board that the pharmacy laws and rules do not address this.

### **Executive Session:**

At 9:50 a.m., upon a motion by the Vice Chair, seconded by Dr. Chock, it was voted on and unanimously carried to move into executive session pursuant to §92-5(a)(1) and (4), HRS, "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 10:00 a.m. upon a motion by the Chair, seconded by the Vice Chair, it was voted on and unanimously carried to move out of executive session.

Chapter 91, HRS ,  
Adjudicatory Matters:

The Chair called for a recess from the meeting at 10:00a.m. to discuss and deliberate on the following adjudicatory matter(s) pursuant to Chapter 91, HRS:

In the Matter of the Miscellaneous Permit of **Acro Pharmaceutical Services LLC; PHA 2014-19-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final order; Exhibit "1"

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

Following the Board's review, deliberation, and decisions in this matter, pursuant to Chapter 91, HRS, the Chair announced that the Board was reconvening its scheduled meeting at 10:04 a.m.

Applications:

**Ratification List**

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

**Applications**

Pharmacist

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

Kelly Nguyen

Miscellaneous Permit

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

DMR Pharmacy Inc.  
The Medicine Store Pharmacy Inc., dba RXpress Pharmacy  
Woods Pharmacy, LLC  
Michael Lenczynski, PH for PMP

Next Meeting:

The Chair announced the next Board meeting and asked if everyone was available.

Thursday, October 23, 2014  
9:00 a.m.  
King Kalakaua Conference Room  
King Kalakaua Building  
335 Merchant Street, 1st Floor  
Honolulu, Hawaii 96813

Adjournment:

With no further business to discuss, the Chair adjourned the meeting at 10:06 a.m.

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Taken and recorded by:

Reviewed and approved by:

/s/ Lisa Kalani  
Lisa Kalani, Secretary

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

10/2/14

☒ Minutes approved as is.

☐ Minutes approved with changes; see minutes of \_\_\_\_\_



LTYPE	LIC NUM	BP NAME PART 1
PH	3696	JOSHUA K <WISE<
PH	3697	JACK CAMERON <GOLDSBERRY<
PH	3698	MARIKO <KATAGIRI<
PH	3699	ELIZABETH D <ACKERMAN<
PH	3700	JENNIFER E <OTA<
PH	3701	MICHELLE P Y <MATSUMOTO<
PH	3702	KESHIA K <MAHI-LEOPOLDINO<
PH	3703	EDEN Y H <CHIK<
PH	3704	MARISA ANNE A <NONAKA<
PH	3705	CHRISTOPHER N <TSUE<
PH	3706	MICHELLE S <KIM<
PH	3707	JACQULIN S <BRANER<
PH	3708	STEVEN M <NISHIMOTO<
PH	3709	DAYNA MICHELLE A <WONG<
PH	3710	TIFFANY C <MIZO<
PH	3711	IHILANI F T <HARU<
PH	3712	CARLIN M <VENTURA<
PH	3713	BRANDON Y <GO<
PH	3714	LAURYN M <KIM<
PH	3715	HEATHER K <TANAKA<
PH	3716	NICOLE K <TABANDERA<
PH	3717	MATTHEW P <GIBU<
PH	3718	ANNIE CHAO-AN <YUNG<
PH	3719	LANA K Y <YOUNG<
PH	3720	ESTHER S <YU<
PH	3721	SHARON C <VALDEZ<
PH	3722	JAYMIE S <KANDA<
PH	3723	DARREN K C <MOK<
PH	3724	ADAM S <CHESLER<
PH	3725	KIMBERLY <HOLDEN<

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN		BP NAME PART 1
				ST	BUSN ZIP	
PMP	1019	61 DOCTORS PARK	CAPE GIRARDEAU	MO	63703	AUREUS HEALTH SERVICES LLC
PMP	1020	6407 S COOPER ST STE 113B	ARLINGTON	TX	76001	AB PHARMACY INC
PMP	1021	15800 DOOLEY RD #185	ADDISON	TX	75001	AMERICARE INFUSION CENTERS LLC
PMP	1022	1860 OUTER LOOP STE 348	LOUISVILLE	KY	40219	AMERIPHARM INC
PMP	1023	5812 W PICO BLVD #A	LOS ANGELES	CA	90019	JI MEDICAL INC
PMP	1025	13933 17TH ST STE 300	DADE CITY	FL	33525	FLORIDA PHARMACY SOLUTIONS INC
PMP	1026	150 EILEEN WAY STE 1	SYOSSETT	NY	11791	SUNQUEST PHARMACEUTICALS INC
PMP	1027	5296 OLD HIGHWAY 11 STE 4	HATTIESBURG	MS	39402	ADVANTAGE MEDICAL INFUSION LLC
PMP	1029	6375 US HWY 98W	HATTIESBURG	MS	39402	ADVANTAGE PHARMACY LLC
PMP	1030	9257 RESEARCH DR	IRVINE	CA	92618	SOUTH COAST SPECIALTY COMPOUNDING INC
PMP	1031	780 PRIMOS AVE STE D	FOLCROFT	PA	19032	APRIA HEALTHCARE LLC DBA APRIA PHARMACY NETWORK
PMP	1032	2698N GALLOWAY AVE STE 108	MESQUITE	TX	75150	ACCORD PHARMACY INC
PMP	1033	2436 S I-35E STE 360	DENTON	TX	76205	AMERICAN SPECIALTY PHARMACY INC
PMP	1034	510 S 600 E	SALT LAKE CITY	UT	84102	ISOMERIC PHARMACY SOLUTIONS LLC
PMP	1035	1810 SUMMIT COMMERCE PARK	TWINSBURG	OH	44087	RGH ENTERPRISES INC
PMP	1036	1510 PENMAN RD	JACKSON BEACH	FL	32250	NORTH BEACHES PHARMACY INC
PMP	1037	32131 INDUSTRIAL RD	LIONIA	MI	48150	MEDCART LTC INC

## BOARD OF PHARMACY

September 18, 2014 Ratification List

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

#### Change of PIC:

**Alicea Enterprises LLC**

**dba Physician Specialty Compounding by Sunlake Pharmacy**

18964 N Dale Mabry Hwy. #103

Lutz, FL. 33548

New PIC: Sonia Mamus

Effective: 8/4/14

#### Closure:

**Unique Pharmaceuticals LTD (PMP 388)**

5920 S. General Bruce Dr.

Temple, TX. 76502

Effective: 8/6/14

### **Pharmacy (PHY)**

#### Change of PIC:

**Longs Drug Stores California LLC dba Longs Drugs #7669 (PHY 752)**

4469 Waialo Rd.

Eleele, HI. 96705

New PIC: Leland Ibara

Effective: 6/8/2014

**Longs Drug Stores California LLC dba Longs Drugs #9275 (PHY 719)**

850 Kamehameha Hwy. Ste. 107

Pearl City, HI. 96782

New PIC: Mayuko Hirota

Effective: 7/20/14

**Longs Drug Stores California LLC dba Longs Drugs #9813 (PHY 724)**

98-1005 Moanalua Rd. #408

Aiea, HI. 96701

New PIC: Christina Bain

Effective: 8/3/14

**Longs Drug Stores California LLC dba Longs Drugs #9209 (PHY 717)**

1450 Ala Moana Blvd. Ste. 2004

Honolulu, HI. 96814

New PIC: William Wong

Effective: 8/17/14

**William J. Farlander Inc. dba Westside Pharmacy**

1-3845 Kaumualii Hwy.

Hanapepe, HI. 96716

New PIC: Brian Carter

Effective: 9/5/14