

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

MINUTES OF MEETING

Date: Thursday, June 19, 2014

Time: 9:00 a.m.

Place: PVL Examination Room
King Kalakaua Building
335 Merchant Street, Third Floor
Honolulu, Hawaii 96813

Members Present: Todd Inafuku, Pharmacist
Garrett Lau, Pharmacist
Mary Jo Keefe, Pharmacist
Carolyn Ma, Pharmacist
Lydia Kumasaka, Public Member
Jill Oliveira Gray, Public Member

Members Absent: Kerri Okamura, Pharmacist

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

Guests: Greg Edwards, DOH, Food and Drug Branch
Wendy Taylor, Wal-Mart
Judy Ung, The Honolulu Pharmacy
Victor Ung, The Honolulu Pharmacy
Fred Cruz, CVS Caremark
Marcella Chock, HPha
Jaclyn Moore, Foodland
Catalina Cross, Times Supermarket
Paul Smith, Walgreens
Kim Skidgel, Ashford & Winston
Kevin Meno, UH Hilo College of Pharmacy
Jonathan Miura, UH Hilo College of Pharmacy
Brian Bautista, Creighton University
Stacy Pi, Kaiser Permanente
Cheryl Fujihara, Kaiser Permanente
Patrick Adams, Foodland
Sean Chu

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 Board members and audience to introduce themselves.

The Chair excused Kerri Okamura from today's meeting.

Additions/Additional Distribution to Agenda

ADDITIONS

- 7. Applications
 - b. Applications
 - 1) Miscellaneous Permit
 - iii. CAP Rx Inc., dba Central Avenue Pharmacy (PMP 943)
 - c. Pharmacist
 - i. Nancy Gallegos

Approval of the Previous Minutes – May 15, 2014

The Chair called for a motion in regards to the minutes of the May 15, 2014 meeting.

Upon a motion by the Chair, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the minutes for the May 15, 2014 meeting as circulated.

Laws and Rules
Committee Report:

The Chair reported on the Committee's May 15, 2014 meeting.

The Committee is still working on the collaborative agreement section. Ms. Keefe will be giving a report on her attendance at the NABP annual meeting and was asked to gather some information on the MOU between the NABP and the states in regards to the Drug Quality and Security Act.

Another section the Committee is working on is the miscellaneous permit section. The EO had stated there was a bill this past legislative session to regulate DME providers that did not pass. She will be doing research on the bill and provide that information to the Committee. The Chair stated although he is no longer on the Board he will continue to provide assistance to the Committee to work on language to make statutory changes to the miscellaneous permit section.

In closing the Committee would like to continue to ask for assistance from the Daniel K. Inouye College of Pharmacy University of Hawaii at Hilo students in regards to collaborative agreements and other changes that come up in the future.

Executive Officer's
Report:

Report on CE Audit for 2012 – 2013 Biennium

The EO reported out of 107 audited licensees, only 5 pharmacists did not respond or comply with the audit and will be referred to the Regulated Industries Complaints Office ("RICO").

NABP 110th Annual Meeting, May 17-20, 2014, Phoenix, Arizona – Report on Attendance by Mary Jo Keefe

Ms. Keefe reported there were members representing all the U.S. Boards of Pharmacy as well as from outside the U.S. such as Canada. Elections were held for the 2015-2015 officers and executive committee members. Some of the topics covered included, e-cigarettes, physician dispensing/pharmacist compounding, sterile compounding and interstate shipment, drug supply chain security, cannabis use, medication synchronization, regulating technicians, and prescribing pharmacists. NABP submitted 8 resolutions for approval by its members: illegal importation of prescriptions drugs; strategies for preventing and reacting to pharmacy robberies and thefts; pharmacies selling tobacco products; standards for use of PMP; veterinary pharmacy education; e-cigarettes and liquid nicotine products; and 2 resolutions recognizing contributions made by pharmacists. All resolutions were approved. There will be a sterile compounding training held this September and the next annual meeting will be held in New Orleans, May 16-19, 2015.

Ms. Keefe brought all her meeting materials and offered to share her materials with the Board if they wanted to see anything specific.

Correspondence:

Compounding for Office Use Out-of-State Pharmacies

The Board reviewed correspondence and continued their discussion from the May 15, 2014 meeting regarding compounding for office use.

The EO stated the Board needed to determine if the current laws and rules allow in state pharmacies to compound without a prescription for office use.

The Chair stated under Chapter §461-15(a)(6) it states for a miscellaneous permit for any person, as principal agent, to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug without first obtaining a permit from the board to do so. In our statutes we have language that recognizes a permit, but we don't have any rules regarding this section. The question is regarding the sale of the compounded product. There is no question if it is pursuant to a prescription; however the question is how you can compound for office use with an in-state pharmacy without a prescription. Based on this, it appears that a miscellaneous permit can be issued to in-state pharmacies so they can compound for office use for physicians in Hawaii. Something has to be defined in the rules, but until then, how can we move forward with this.

The EO agrees with the Chair. Under the definition of the practice of pharmacy it allows a pharmacy to compound. An in-state pharmacy already has a pharmacy license, the Board has jurisdiction over them, they then get a miscellaneous permit to compound, and under Chapter §461-15(a)(6) for office use. Out-of-state pharmacies, they get a miscellaneous permit they would come under Chapter §461-15(a)(6) and (7). Later, further requirements can be clarified in the rules. In regards to federal regulations, if they require any registration or MOU, etc., and you fail to do what is required, under Chapter §461-21(5) violation of any state or federal drug, controlled substance, or poison law is a violation of Hawaii laws. We need to really look at this closely and consult with the DAG first. However, if the DAG agrees with this interpretation then we can move forward.

Guest Pat Adams stated that Mr. Edwards states this is not manufacturing, however when the Board looks at the miscellaneous permit section, we say this is manufacturing. When we look at miscellaneous permits we say they are actually manufacturing and then we say by the definition of manufacturing in this state, it's not manufacturing. I see then, as a pharmacy, what's being issued is a permit to pharmacy, and once a permit is issued to a pharmacy, we're issuing it as a pharmacy permit and the reason we can issue it is because they are a pharmacy in another state and that's what they're telling us. Then at that point, even though we're saying we have no rules, as soon as we establish that somebody is a pharmacy and we are giving them a permit to do the practice of pharmacy as defined. Now they are subject to all the rules of a pharmacy in this state. I think the law says that you have to have a prescription for a person to compound and it has to be specific.

The EO clarified that under Chapter §461-15(a)(6) it says "engage in the business of preparing, manufacturing, *compounding*, packing, or repacking any drug"

Mr. Adams stated if we go by that then now they are subject to Chapter 328 that says they are a manufacturer.

The DAG stated it does not mean that a person or entity has to do all of the things listed.

Mr. Adams stated once they get a permit and they start practicing something outside of what a pharmacy can do in this state, the only way they can do it is because we said they're a manufacturer. Mr. Adams asked who in the state can do for office use products.

The Chair said right now we're only looking at in office use pertaining to compounding, not in office use of commercially prepared products. There are those that sell to physicians from a pharmacy with a wholesale license.

Mr. Adams said in the past, the Board has said if you are going to sell for in office use you have to get a wholesalers license.

The Chair stated this Board in the past has said no to compounding for office use, however, it needs to be looked at again because the Board may have been wrong.

The EO stated that Mr. Adams is correct in saying that in the past the Board has stated you need a wholesale distributor's license, because at that time based on the information received, the Board considered it manufacturing. However, now it's being looked at from a different angle. The EO asked the members and the audience, if they have any questions or concerns regarding this to send them to the Board's email so that it can be addressed at the next Board meeting.

Preprinted Prescription Pads, Keith Chamber, NuMedCare

The Board reviewed an email response from Mr. Chamber clarifying his correspondence from the May 15, 2014 meeting.

The questions asked by Mr. Chambers with the Board's responses are as follows:

1. Can a prescription pad contain multiple pre-printed multiple formulas of non-controlled substances? ***The pharmacy laws and rules do not specifically address this; therefore, it is not prohibited.***

2. Can we have pre-printed formulas if one or more of the formulas has a scheduled substance in it? ***In Hawaii, the prescribing and dispensing of any controlled substance falls under the purview of the Department of Public Safety, Narcotics Enforcement Division.***
3. Can there be more than one prescription be filled per prescription pad? ***See response to questions #1.***

Pharmacy Compounding Accreditation Board

The Board was provided with correspondence from the Pharmacy Compounding Accreditation Board ("PCAB") promoting a voluntary accreditation program that recognizes adherence to established principles, policies and standards. PCAB is an independent non-profit organization formed by several professional organizations in 2004. Currently, its Board of Directors includes representatives from the American College of Apothecaries, National Community Pharmacists Association, American Pharmacists Association, National Alliance of State Pharmacy Associations, International Academy of Compounding Pharmacists, National Home Infusion Association and the United States Pharmacopeia.

National Association of Boards of Pharmacy

PMP InterConnect Program

The Board reviewed a news release from the National Association of Boards of Pharmacy ("NABP") stating that twenty-five states' prescription data is now linked through NABP PMP InterConnect. The system enhances state efforts to combat prescription drug abuse.

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The Board reviewed a news release from NABP stating that the NABP and the Anti-Diversion Industry Working Group ("ADIWG"), a consortium of pharmaceutical manufacturers and distributors, has released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing controlled substance prescriptions. The video, entitled, "Red Flags", was released at the NABP 110th Annual Meeting.

NABP News Roundup

- Alabama Rule 680-X-2-.07, Mail Order Prescriptions, was amended on March 19, 2014, and is effective as of June 1, 2014. The two following conditions were added that non-resident pharmacies must comply with:
 - f. Designate a supervising pharmacist who shall be licensed by the Alabama State Board of Pharmacy. The supervising pharmacist shall be responsible for ensuring that the holder of the permit referenced herein complies with the requirements of this rule and all applicable statutory provision and rules;
 - g. If there is a change of the designated Supervising Pharmacist, the permit holder shall notify the Board by filing the "Notice of Change of Supervising Pharmacist" form provided by the Board. If the permit holder is unable to maintain a designated supervising pharmacist, the permit holder shall notify the Board within ten (10) days with an action

plan to designate another pharmacist as supervising pharmacist. A permit holder without a designated supervising pharmacist after the ninety (90) day action plan has expired may contact the Board for additional time.

- New Jersey's substantially modified N.J.A.C. 13:39-11 (Compounding Sterile and Non-Sterile Preparations in Retail and Institutional Pharmacies) is now in effect. The new regulation, N.J.A.C. 13:39-11.14 addresses the cleansing and garbing requirements for personnel who engage in compounding sterile preparations.
- On March 11, 2014, two pieces of legislation were signed into law in Ohio. **HB 44** provides pharmacists with a role in public health emergencies by requiring the director of health to develop one or more protocols regarding the availability of drugs during a public health emergency that authorize pharmacists and pharmacy interns to dispense limited quantities of certain dangerous drugs without a prescription or record of a prescription. **HB 170** aims to address Ohio's growing opioid drug overdose epidemic. This law permits doctors, advanced practice registered nurses, and physician assistants to prescribe, administer, dispense, or furnish naloxone to a person who is, or a person who is in a position to assist a person who is, apparently experiencing or who is likely to experience an opioid related overdose.

Walgreens – Response to Change to Win Correspondence

The Board reviewed a letter from Walgreens addressing their response to what they consider unsubstantiated claims made by a group called Change to Win (CtW). Walgreens is aware that last year, CtW sent a cover letter and report to every Board of Pharmacy expressing concerns about the Walgreens Well Experience pharmacy model.

Central Fill Compounding

The Board reviewed an email inquiry asking if Hawaii Board of Pharmacy allows compounding pharmacies to central fill.

After a brief discussion, it was determined that any pharmacy, regardless of the type of pharmacy, must be licensed/permitted in order to "dispense" any prescription drug directly to the patient/end user.

Where Can a Pharmacist Administer Immunizations?

The Board reviewed an email inquiry asking if the Board has a policy regarding the location of a pharmacist or intern who is administering immunizations.

After a brief discussion, it was the consensus of the Board that the pharmacy laws and rules do not specifically address this issue nor does the Board have any "policies" regarding this matter. It has been the Board's informal interpretation that based on the current laws and rules, since it is not addressed, a pharmacist who has received the appropriate training and is working collaboratively with another healthcare provider, may administer immunizations outside of the perimeters of a licensed/permitted pharmacy. In addition, other pharmacy and drug laws must be complied with such as the safe handling/maintenance of the drug and HIPAA or other federal

requirements.

Medication Monitoring of Controlled Substances and Prescription Questions

The Board reviewed an email inquiry asking questions regarding medication monitoring and state specific regulations on prescriptions. The following are specific questions asked with the Board's responses:

1. Is Tramadol a scheduled drug in your state? ***In Hawaii, the dispensing, prescribing and classifying of controlled substances fall under the purview of the Department of Public Safety, Narcotics Enforcement Division ("DPS-NED").***
2. Does your state require reporting of Tramadol? ***See response to question #1***
3. What drugs of concern require reporting in your state? (Scheduled and non-scheduled) ***Since the Board does not have a "reporting" requirement, they refer you to ask the DPS-NED.***
4. Other requirements that are state specific:
 - a. Serial number required on Rx? ***The Board refers you to HRS §328-16, which falls under the purview of the Department of Health, Food and Drug Branch ("DOH").***
 - b. Is there a 30 day limit for verbal Rx? ***No.***
 - c. Generic substitution allowed? ***The Board refers you to HRS §328-92, which falls under the purview of the Department of Health, Food and Drug Branch ("DOH").***

Old Business:

HAR Title 16, Chapter 95 – Status Report

The EO reported she is still working on getting the draft printed with the non-substantive changes.

Executive Session:

At 10:49 a.m., upon a motion by the Chair, seconded by Ms. Kumasaka, 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 11:08 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.

Applications:

Ratification List

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

Applications

Miscellaneous Permit

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

NuDak Ventures LLC. dba NuCara Pharmacy #1
JI Medical Inc.
CAP Rx Inc., dba Central Avenue Pharmacy (PMP 943)

Pharmacist

Upon a motion by the Chair, seconded by Dr. Ma, it was voted on and unanimously carried to defer the following application for further explanation:

Nancy Gallegos

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

The Vice Chair stated he will not be attending the July meeting.

Thursday, July 17, 2014
9:00 a.m.

Queen Liliuokalani Conference Room – New 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 11:12 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

7/3/14

[] Minutes approved as is.
[x] Minutes approved with changes; see minutes of 7/17/14

LTYPE	LIC NUM	BP NAME PART 1
PH	3662	ANDREW R <WILLIS<
PH	3663	MARK H <FRAZIER<
PH	3664	CARRIE D <LEWCHUK<
PH	3665	DAYU <KIM<
PH	3666	NICHOLAS A <PLUMER<
PH	3667	JOHN A <BRISSETTE<
PH	3668	LAREINA M E <CAJIGAL<
PH	3669	WHITMAN W <HUI<

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN		
				ST	BUSN ZIP	BP NAME PART 1
PHY	854	3-3420 KUHIO HWY	LIHUE	HI	96766	WILCOX MEMORIAL HOSPITAL

LTYPE	LIC NUM	BP NAME PART 1
PMP	988	SYNERGY PHARMACY SERVICES INC
PMP	989	CURANT HEALTH GEORGIA LLC
PMP	990	GOODHEALTH INC
PMP	991	CARDINAL HEALTH 414 LLC
PMP	992	THE <GREAT< ATLANTIC & PACIFIC TEA COMPANY INC
PMP	993	KAISER FOUNDATION HOSPITALS
PMP	994	AMERICAN CUSTOM COMPOUNDING PHARMACY LLC
PMP	995	TOTAL CARE RX INC
PMP	996	AUXILIUM SPECIALTY APOTHECARY PHARMACY
PMP	997	MAGNOLIA SPECIALTY PHARMACY INC

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN		
				ST	BUSN ZIP	BP NAME PART 1
PWD	167	300 OHUKAI RD STE C-315	KIHEI	HI	96753	VET MEDS N MORE INC

BOARD OF PHARMACY

June 19, 2014 Ratification List

Miscellaneous Permits (PMP)

Change of PIC:

Sina Drug LLC, dba Oncomed (PMP 526)

225 Community Drive, Ste. 100

Great Neck, New York 11021

New PIC: Frank Scimeca

Effective: 5/6/2014

Community Compounding Pharmacy Inc. (PMP 580)

11030 SW Capitol Hwy

Portland, Oregon 97219

New PIC: James Bui

Effective: 5/14/2014

Eagle Pharmacy LLC (PMP 815)

dba Eagle Pharmacy

500 Eagle Landing Drive, suite C

Lakeland, Florida 33810

New PIC: Arijit Aichbhaumik

Effective: 5/5/2014

WellDyneRx (PMP 263)

7472 S Tucson Way, Ste. 100-A

Centennial, Colorado 80112

New PIC: Irene Girgis

Effective: 5/5/2014

Oncology Rx Care Advantage (PMP 487)

13501 Park Vista Blvd., Suite 150

Fort Worth, Texas 76177

New PIC: Lowery J. Whisenant

Effective: 4/25/2014

Express Scripts (PMP 643)

5450 Riverside Drive

Fort Worth, Texas 76137

New PIC: Thomas Koontz

Effective: 5/1/2014

Express Scripts (PMP 962)

4865 Dixie Highway

Fairfield, Ohio 45014

New PIC: Eric Smither

Effective: 5/19/2014

Salveo Specialty Pharmacy Inc. (PMP 855)

9500 N Mission Road
Los Angeles, California 90033
New PIC: Carlos Gaston Martinez
Effective: 5/30/2014

Salveo Specialty Pharmacy Inc. (PMP 856)

1155 W Mission Road
Los Angeles, California 90033
New PIC: Salina Yip
Effective: 5/30/2014

Smart Pak Equine LLC (PMP 320)

40 Grissom Road, Ste. 500
Plymouth, Massachusetts 02360
New PIC: John A. Zaia
Effective: 5/21/2014

OK Compounding LLC (PMP 873)

102 N Broadway
Skiatook, Oklahoma 74070
New PIC: Jocelyn Leigh Anstine
Effective: 5/9/2014

Name Change/Conversion/Addition of TN or DBA:

Pharmacy Services, Inc., dba Bellevue Pharmacy (PMP 667)

212 Millwell Drive, Suite A
Maryland Heights, Missouri 63043
Effective: 4/24/2014

Envoy Health Management LLC (PMP 717)

325 West Atherton Road
Flint, Michigan 48507
Effective: 4/2/2014

Relocation:

Anazao Health (PMP 558)

7465 W. Sunset Road
Suite 1200
Las Vegas, Nevada 89113

Liberty Medical Supply, Inc. (PMP 137)

8881 Liberty Lane
Port St. Lucie, Florida 34952

Precise Compounding Pharmacy, Inc. (PMP 838)

10844-46 Washington Blvd.
Culver City, California 90232

Closure:

PMSI LLC (PMP 565)

4502 Woodland Corporate Boulevard, Suite 105

Tampa, Florida 33614-2443

Effective: 4/23/2014

Advantage Pharmacy LLC (PMP 824)

2175 Business Center Drive, Ste. 6

Memphis, Tennessee 38134

Effective: 5/5/2014

Express Scripts Pharmacy Inc. (PMP 338)

8800 Hidden River Parkway

Hidden River, Florida 33637

Effective: 3/21/2014

Pharmacy (PHY)

Change of PIC:

Pharmacy Corporation of America (PHY 578)

dba PharMerica/Hilo

688 Kinoole Street

Hilo, Hawaii 96720

New PIC: Matthew Sasaki

Effective 4/14/2014

R Weinstein Immunization & Prescription Services LLC (PHY 818)

dba R Weinstein 1010 S. King

1010 S. King Street, #704

Honolulu, Hawaii 96814

New PIC: Seul Ki Villoria

Effective: 4/16/2014

Longs Drug Stores of California LLC (PHY 747)

dba Longs drugs #6928

2070 N King Street, #5

Honolulu, Hawaii 96819

New PIC: Jenny Lee

Effective: 6/1/2014

Target Corporation (PHY 802)

dba Target Pharmacy

391 E Makaala Street

Hilo, Hawaii 96720

New PIC: Travis Young

Effective: 1/21/2013

Wal-Mart Stores Inc. (PHY 550)
dba Wal-Mart Pharmacy 10-2308
3-3300 Kuhio Highway
Lihue, Hawaii 96766
New PIC: Mitchell Andrews
Effective: 5/17/2014

Pharmacare International Inc. (PHY 661)
dba Pharmacare #5
98-1079 Moanalua Road, MOB Ste 150
Aiea, Hawaii 96701
New PIC: Christine Nucum
Effective 5/12/2014

R J B Corporation (PHY 271)
dba Aiea Medical Pharmacy
99-128 Aiea Hts Dr. #103
Aiea, Hawaii 96701
New PIC: Miles Nishizawa
Effective: 5/12/2014