

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

MINUTES OF MEETING

Date: Tuesday, January 24, 2017

Time: 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, Pharmacist
Carolyn Ma, PharmD., BCOP, Pharmacist
Mary Jo Keefe, RPh, Pharmacist
Garrett Lau, RPh, Vice Chair, Pharmacist
Ronald Weinberg, Public

Members Excused: Julie Takishima-Lacasa, PhD, Public
Marcella Chock, PharmD., Pharmacist

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

Guests: Kellie Noguchi, Times
Amy Este, Walmart
Courtney Neubert, Walgreens
Traci Eilers, Walgreens
Lily Fang, Walgreens
Paul Smith, Walgreens
Fred Cruz, CVS Caremark
Jacqueline Moore, Foodland
Tiffany Yajima, Ashford & Wriston LLP
Pat Adams, Foodland
Stacy Pi, Kaiser Permanente
Catalina Cross, Times

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 9:08 a.m. and excused Dr. Chock and Dr. Takishima-Lacasa from today's meeting.

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

The Chair asked the audience to introduce themselves

Approval of the Previous Minutes – December 15, 2016 Meeting

The Chair called for a motion in regards to the minutes of the December 15, 2016 meeting.

Ms. Keefe indicated that there were non-substantive typos on pages 3, 4, 7 & 8.

The Chair noted typos on pages 6 & 9.

Upon a motion by Mr. Weinberg, seconded by Dr. Ma, it was voted on and unanimously carried to approve the minutes for the December 15, 2016 meeting as amended.

Executive Officer's Report: **Conferences/Seminars/Meetings**

"Pharmacy Diversion Awareness Conference" – Hosted by the DEA, January 22 & 23, 2017, Honolulu, Hawaii – Report on Presentation

The EO reported that she did a joint presentation with the Hawaii State Narcotics Enforcement Division on Sunday and Monday on the corresponding responsibility statement. The first day there were approximately seventy plus attendees and Monday sixty plus attendees. Other presenters included William Winsley from the National Association of Boards of Pharmacy, Aziz Elkholy, DEA Diversion Control Division and Michael Cohen, Office of the Inspector General, U.S. Department of Health and Human Services. She reported that although all the presentations were very interesting, the presentation that the State NED did on pharmacy thefts and robberies in this State was most interesting as they provided information on local cases.

The Chair added that one of the presenters showed a video called "Chasing the Dragon" on addiction and the web sites erowid.org and bluelight.org. includes blogs on "recipes" on prescription and OTC drugs that can be combined with alcohol and other food items allowing the user to get "high".

Mr. Weinberg asked, "What is the bottom line?"

The Chair explained that basically the pharmacist is the "gatekeeper" between the prescriber and patient when it comes to dispensing drugs. The responsibility for the patient's safety lies with the pharmacist.

Mr. Weinberg asked, "What about the doctors?"

The Chair explained that doctors have a responsibility too, however, when a practitioner prescribes controlled substances for other than a legitimate medical purpose, the pharmacist has a corresponding responsibility to determine if they should fill or not fill the prescription if there is evidence that the prescription may not be for a legitimate medical purpose or raises "red" flags.

NABP's 113th Annual Meeting – May 20-23, 2017, Orlando, Florida – Ms. Keefe and Mr. Weinberg

The EO stated that although Mr. Weinberg is also interested in attending, since Ms. Keefe has attended before and is more familiar with the issues and indicated that she was interested in attending this year prior, she needs the Board to act on voting Ms. Keefe as Hawaii's delegate.

Upon a motion by Dr. Ma, seconded by Mr. Weinberg it was voted on and unanimously carried to delegate Ms. Keefe as the Board's voting representative.

The EO informed Mr. Weinberg if he was still interested in attending that he would have to pay for his travel and hotel accommodations but that we would try to pay for his registration and to let her know as soon as possible.

2017 Legislative Session

Pharmacist Provider Status Bill

NACDS, Stakeholders Urge Congress to Support Provider Status Bill

The Board reviewed the pharmacist provider status bill, HB 156 Relating to Reimbursement of Pharmacists. This bill would require insurers, mutual and fraternal benefit societies, and health maintenance organizations to recognize services provided by pharmacists.

The Chair stated that on page 3, line 11 as it refers to "services rendered by another health care provider", can the word "identical" be amended as it appears to be too restrictive.

The DAG recommended perhaps it should also include "or similar" and that amendment should also be on page 4, line 7, and page 5, line 2 as it also refers to "identical" in these sections.

Upon a motion by Mr. Weinberg, seconded by the Vice Chair, it was voted on and unanimously carried to support HB 156 by adding "or similar" as noted in the discussion.

The Board also reviewed an article by the NACDS in which NACDS is proactively urging support of H.R. 592/S. 314, Pharmacy and Medically Underserved Areas Enhancement Act which would increase access to state-approved pharmacy services for underserved Medicare patients.

Practice of Pharmacy Bill

The EO reported that she has not seen a bill similar to the draft that the Board previously reviewed.

Mr. Adams reported that he has not seen the final bill either.

Professional Development

The following issues were distributed to the members for their information:

- December 2016 Balanced Living;
- December 2016 Working Solutions;
- January 2017 The Wellness News

Latest Gallup Poll – Pharmacists Still Second to Nurses Who Rated Highest Among Professions for 15th Straight Year

The article was distributed to the members for their information.

Correspondence:

Rx Ipsa Loquitur, November/December 2016 – New England Compounding Center Pharmacists Dodge Criminal Charges

The Chair reported on the above mentioned article that stated a federal judge threw out criminal charges against pharmacists involved in the 2012 New England Compounding Center meningitis outbreak. The article stated that the court explained that the statute, as written, clearly punishes pharmacists who “fill or take part in the filling of invalid prescriptions placed into interstate commerce with the intent to defraud or mislead the government.” The court reasoned that the Federal Food, Drug and Cosmetic Act does not reach conduct “incidental to the distribution of a prescribed drug.” And that merely checking packages prior to being shipped, the pharmacists were not involved in the dispensing of the drugs. The court asked “Would a reasonable person, even a pharmacist, understand from the indictment that by matching orders to packages prior to their being shipped, she was criminally liable for participating in the filling of a prescription that she had never approved (or is even alleged to have seen), and as a result was guilty of dispensing (misbranding) the prescribed drug with the intent to defraud?” The court, in this instance determined that a reasonable person would not.

Board of Pharmacy Newsletters

North Dakota – Prescriptive Authority for Naloxone and Admin Rule

The Chair reported on the North Dakota administrative rule that grants prescriptive privileges for naloxone to pharmacists in North Dakota. According to the North Dakota Board of Pharmacy webpage, in order for a pharmacist to “prescribe” Naloxone, they must complete a training program and then sign up as a “trained” pharmacist, the Board then posts a list on their web page.

“Outsourcing Facilities Must Be Registered as Pharmacies in California to Compound or Dispense Within or Into California”

The Chair asked the Vice Chair to lead the discussion on the article that reported that California requires in-state and out-of-state outsourcing facilities to be registered as pharmacies in California.

Inquiry Regarding Pharmacy Technician Registration and Records Retention

The Chair asked Dr. Ma to lead the discussion on an email from an out-of-state pharmacy inquiry asking the following questions:

1. Do you require Pharmacy Technicians registered in NC to become registered in your state as well?
2. How long do you require Quality Assurance/Improvement records to be retained? Do you only want us to retain the records that pertain to medications shipped into your state for that period of time?

Dr. Ma stated that the answer to the first question is no, since Hawaii does not license/register/certify pharmacy technicians.

Dr. Ma stated that in response to the second question, she was not sure what they meant by “Quality Assurance/Improvement records” but that pursuant to HRS section 461-13 and HAR section 16-95-93, prescription records must be maintained for at least five years.

The EO asked as an out-of-state pharmacy, if their state requires that pharmacy records be kept for example, two years, can we require that pharmacies who fill prescriptions coming into this State maintain their prescription records for five years in compliance with Hawaii recordkeeping requirements?

It was the consensus of the Board that prescriptions filled by an out-of-state pharmacy for a patient residing in this State shall comply with the recordkeeping requirements of five years for those records pertaining to prescriptions for non-controlled substances dispensed into this State pursuant to Hawaii’s pharmacy laws and rules.

In accordance with HAR section 16-201-90, the above interpretation is for informational and explanatory purposes only. It is not an official opinion or decision and is thus, not binding on the Board.

Representative Cindy Evans – 503B Compounding Facilities

The Chair asked Ms. Keefe to lead the discussion on the inquiry from Representative Evans’ office regarding adding a definition to the pharmacy administrative rules.

Ms. Perez, Administrative Service Officer to Representative Evans stated they were contacted by a constituent to draft a bill to add a definition for "Outsourcing facility" however, upon further review and research, they believe the revision should be to HAR chapter 16-95 by adding a new definition to read as follows:

"Outsourcing Facility- means any person or entity in this state that engages in bulk compounded medications and "for in office use" medications that conform to FDA 503b laws and must be in state resident facilities to operate in the state of Hawaii."

The justification for the amendment was indicated as follows:

"In 2015 the FDA has recently revised its' law regarding compounded medications in sections 503a and 503b of the Federal code. The 503a section is very clear but the definition and oversight for the section pertaining to 503b has left each state to address the Outsourcing facilities and compounding for "in office use".

The FDA does not approve compounded medications for individual patient use. The FDA along with the USP approves and controls the medications and ingredients in all compounded prescriptions medications. The FDA has left the approval of compounded medications to each state through their Board of Pharmacy. Boards of pharmacy have laws in place concerning section 503a and compounded medications but 503b is a new area that would allow compounding pharmacies to provide bulk medications for in office use (non-patient specific medications). The result is a classification between manufacturing and pharmacy compounding. The FDA has told each state they are responsible for the control of these 503b compounded products. Since the inception of these new laws, out of state facilities (some that are not pharmacies) have asked for a pharmacy license through a broad category called Miscellaneous Permit to ship medications in bulk to health facilities to the state of Hawaii. The Hawaii Board of Pharmacy does not have out of state inspectors to control these operations and medications and need laws and guidelines to insure the safety of the medications and the Hawaiian residents. In order to address this issue the following definition should be added to the HAR Title 16, Department of Commerce and Consumer Affairs, Chapter 95 Pharmacists and Pharmacies should be made:

Hawaii Administrative Rules

Title 16

Department of Commerce and Consumer Affairs

Chapter 95

Pharmacists and Pharmacies

16-95-2 Definitions

Outsourcing Facility- means any person or entity in this state that engages in bulk compounded medications and "for in office use" medications that conform to FDA 503b laws and must be in state resident facilities to operate in the state of Hawaii."

Ms. Keefe stated that she had two concerns, the first being that this appears to only require only in-state outsourcing facilities, and, since Hawaii does not have pharmacy inspectors, compliance with any inspection requirement by the FDA will be virtually impossible since no one will be able to do the inspection.

Mr. Adams stated that Hawaii does require inspections but that there are self-inspections and that the State Narcotics Enforcement Division also does inspections.

After further discussion, it was the consensus of the Board to refer this matter to the Laws and Rules Committee for further research.

Executive Session: At 10:04 a.m. upon a motion by Mr. Weinberg, seconded by the Vice Chair, 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 10:16 a.m. upon a motion by Ms. Keefe, seconded by Mr. Weinberg, 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 10:16 a.m. to discuss and deliberate on the following adjudicatory matter(s) pursuant to Chapter 91, HRS:

In the Matter of the Pharmacy License of **William J. Farlander, Inc. dba Westside Pharmacy**, and Pharmacist licenses of **Brian A. Carter** and **William J. Farlander**; **PHA 2016-96-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order.

Upon a motion by Dr. Ma, seconded by Mr. Weinberg, 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 Chair announced that the Board was reconvening its scheduled meeting at 10:19 a.m.

Applications: **Ratification List**

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

Pharmacy Intern

Upon a motion by the Chair, seconded by Mr. Weinberg, with Dr. Ma recusing herself, it was voted on and carried to approve the following:

Robyn Rector

Miscellaneous Pharmacy Permits (PMPs)

Upon a motion by the Chair, seconded by the Vice Chair, it was voted on and unanimously carried to approve the following:

Ideal Specialty Apothecare, Inc., dba Ideal Pharmacy

Next Meeting: The Chair announced that the next Board meeting is scheduled for February 16, 2017.

February 16, 2017

9:00 a.m.

**The Daniel K. Inouye College of Pharmacy
677 Ala Moana Blvd., Suite 1025 – New Location
Honolulu, Hawaii 96813**

AND

**The Daniel K. Inouye College of Pharmacy
at the University of Hawaii at Hilo, Classroom I
722 South Aohoku Street
Hilo, Hawaii 96720**

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

Taken and recorded by:

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

2/3/17

[X] Minutes approved as is.

[] Minutes approved with changes; see minutes of _____

BOARD OF PHARMACY
January 24, 2017 Ratification List

Miscellaneous Permits (PMP)

Change of PIC

Tailor Made Compounding LLC (PMP-1281)

200 Moore Dr.

Nicholasville, KY. 40356

New PIC: Yara Banob

Effective: 12/28/16

Sina Drug LLC dba Onco360 (PMP-1222)

1901 Campus Place Ste. 100

Louisville, KY. 40299

New PIC: Julie Owen

Effective: 12/1/16

Ameripharm Inc. dba Medvantx Specialty Pharmacy (PMP-1022)

1860 Outer Loop Ste. 248

Louisville, KY. 40219

New PIC: Patrick Southall

Effective: 12/30/16

Soleo Health (PMP-524)

950 Calcon Hook Rd. Ste. 15

Sharon Hill, PA. 19079

New PIC: Christine Miller

Effective: 12/30/16

Closure/Cancellation

Family LTC Pharmacy Inc. (PMP-1120)

1049 Brookdale St. Ste. B

Martinsville, VA. 24112

Effective: 12/30/16

Central Rexall Drugs Inc. (PMP-930)

125 E Thomas St.

Hammond, LA. 70401

Effective: 12/31/16

Aureus Health Services LLC (PMP-1019)

61 Doctors Park

Cape Girardeau, MO. 63703

Effective: 1/6/17

Novixus LLC dba Novixus Pharmacy Services (PMP-825)

43159 W Nine Mile Rd.

Movi, MI. 49375

Effective: 3/31/17

Kaiser Foundation Health Plan Inc. dba Automated Refill Center (phy-613)

501 Alakawa St. Ste. 101

Honolulu, HI. 96817

Effective: 12/31/16

Auxilium Specialty Apothecary Pharmacy (PMP-996)

16 Keystone Dr. #B

Hattiesburg, MS. 39402

Effective: 1/20/17

Name/Trade Name Change

Abitacare LLC dba Vital Care Rx (PMP-627)

1501 23rd Ave, Ste. B

Meridan, MS. 39301

Effective: 1/1/17

Relocation/Address Change

ARJ Infusion Services Inc. (PMP-1139)

7930 Marshall Drive

Lenexa, KS. 66214

Effective: 12/19/16

Pharmacy (PHY)

Change of PIC

Longs Drug Stores California LLC dba Longs Drugs #9227 (PHY-731)

111 E Puainako St.

Hilo, HI. 96720

New PIC: Lynne Hirahara

Effective: 12/12/16

LTYPE	LIC NUM	BP NAME PART 1
PH	4123	EMILY Y <KIM<
PH	4124	VALERIE F <RENTFRO<
PH	4125	THERESA N <JAMES<
PH	4126	LISA P <FONSECA<
PH	4127	DAVID L <SNOW<
PH	4128	MELISSA M <GABRIEL<
PH	4129	REMY H <GUIRGUIS<
PH	4130	CATHERINE <FADROWSKY<
PH	4131	KAITLIN V <BERGER<
PH	4132	MATTHEW N <TANAID<

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN		BP NAME PART 1
				ST	BUSN ZIP	
PMP	1352	983 S 500 W	SANDY	UT	84070	NEW LIFE PHARMACY LLC
PMP	1353	331 TOM HUNTER RD	FORT LEE	NJ	07024	INCLINE HEALTH LLC
PMP	1354	11207 S LACIENEGA BLVD	LOS ANGELES	CA	90045	NUTRITION PLUS INC
PMP	1355	8350 S RIVERPARKWAY #101	TEMPE	AZ	85284	WALGREENS.COM INC
PMP	1356	24416 N 19TH AVE	PHOENIX	AZ	85085	AVELLA OF DEER VALLEY INC #38
PMP	1357	8610 S SEPULVEDA BLVD #108	LOS ANGELES	CA	90045	EMERSON PHARMACY INC
PMP	1358	2731 NATIONAL DR	ONALASKA	WI	54650	ALLERGYCHOICES INC
PMP	1359	141 IDAHO AVE	PLATTBURGH	NY	12903	STERX LLC
PMP	1360	960 E GREEN STREET #152	PASADENA	CA	91106	4M PHARMACY INC
PMP	1361	43159 W NINE MILE RD	NOVI	MI	48375	NPS GROUP LLC