

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

MINUTES OF MEETING

Date: Thursday, October 23, 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
Carolyn Ma, Pharmacist
Mary Jo Keefe, Pharmacist

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

Guests: Catalina Cross, Times Supermarket
Kellie Noguchi, Times Pharmacy
Paul Smith, Walgreens
Tiffany Yajima, Ashford & Winston
Fred Cruz, CVS Caremark
Greg Edwards, Dept. of Health, Food and Drug Branch
Kellie Noguchi, Times
Todd Inafuku, Retired

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

Upon a motion by the Vice Chair, seconded by Dr. Ma, it was voted and unanimously carried to add the following to the agenda:

ADDITIONS

- 5. Correspondence
 - e. “The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers” – Guidance for Industry from U.S. Department of Health and Human Services, Food and Drug Administration

- 6 Applications
 - b. Application
 - 1) Miscellaneous Permit
 - v. ExcelleRx
 - vi. Change of PIC for Express Plus Pharmacy LLC (PMP 913) – Dennis Soumoff

The Chair announced the following as additional distribution.

ADDITIONAL DISTRIBUTION

- 6. Applications
 - a. Ratification Lists

Approval of the Previous Minutes – September 18, 2014

The Chair called for a motion in regards to the minutes of the September 18, 2014 meeting.

Upon a motion by Ms. Kumasaka, seconded by Dr. Chock, it was voted on and unanimously carried to approve the minutes for the September 18, 2014 meeting as circulated.

Vice Chair's Report:

None.

Executive Officer's Report:

HAR Title 16, Chapter 95 – Status Report

The EO reported the rules are being prepared to be sent to the Small Business Regulatory Review Board for their consideration.

Conferences/Seminars/Meetings

NABP 2014 MPJE State Specific Review, September 4-5, 2014 – Report on Attendance from Kerri Okamura

The Chair reported that at this meeting they looked at questions to be added to the MPJE test pool and also reviewed approximately 2,000 existing questions to see if any needed to be deleted.

Sterile Compounding Inspection Training, September 16-17, 2014 – Report on Attendance from Mary Jo Keefe

Ms. Keefe reported that at this meeting there was an overview of USP Chapter 797 for surveyors and inspectors. The emphasis was on sterile compounding pharmacies. As of yet there is no Memorandum of Understanding that's been established and the FDA is still working on clarifications of outsourcing facility requirements. There are also online classes on sterile compounding that are available to Ms. Keefe for being a part of this group.

NABP Executive Officer's Forum, October 14-15, 2014 – Report on Attendance from Lee Ann Teshima, Executive Officer

The EO reported at this meeting the following topics were discussed:

- Collaborating on Compounding Safety;
- Outsourcing Facilities;
- FDA forum 483 – States Actions and Re-Actions;
- Medical Cannibus – Collaborating to Ensure Patient Safety – during this discussion the EO spoke with a gentleman from the Illinois Department of Financial and Professional Regulation and he said their department handles the licensing of the medical marijuana dispensaries, and the growers or cultivators come under their Department of Agriculture. Their Department of Health regulates the card holders;
- Durable Medical Equipment (DME) providers - Idaho DME's do not include medical gases. In North Dakota, a license practitioner oversees the product instead of a pharmacist;
- Disciplining – If a license is disciplined in one state, and they hold a license in another state, some states do not take action against them for having disciplinary action taken in another state;
- New Board Member Training;
- Drug Quality - Wholesale Distributors;
- Third Party Logistics Operators;
- Virtual Manufacturers and Wholesalers; and
- Unprofessional Conduct Assessment

New Board Member Orientation, December 5, 2014, 8:30 – 12:30 p.m., State Capitol Auditorium

The EO reported there will be a New Board Member orientation held on Oahu at the State Capitol Auditorium December 5, 2014. At this time the Chair, Ms. Keefe and Dr. Chock have requested to attend.

2015 Board Meeting Schedule

The EO reported the 2015 Board Meeting Schedule as follows:

January 22, 2015	King Kalakaua Conference Room, King Kalakaua Bldg
February 12, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg
March 19, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg
April 16, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg

May 14, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg
June 18, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg
July 16, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg
August 20, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg
September 17, 2015	King Kalakaua Conference Room, King Kalakaua Bldg
October 15, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg
November 19, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg
December 17, 2015	Queen Liliuokalani Conference Room, King Kalakaua Bldg

The only tentative change is the location of the February 12, 2015 meeting. The meeting may be held at the Daniel K. Inouye College of Pharmacy.

Correspondence:

In State Virtual Manufacturer License Requirements – Deferred from September 18, 2014 Meeting

The Chair led the discussion on an email inquiry deferred from the last meeting 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 Chair stated the Hawaii pharmacy laws and rules do not define a VM. Since they are not manufacturing or distributing it appears they do not require a license in Hawaii.

Ms. Keefe stated they say they do not touch drugs; however in the email they state that they would meet minimum requirements for license such as a locked room with a locked cabinet for the safe storage of samples and records, temperature and humidity controls, security systems, and a log book.

The EO stated that HAR §16-95-2 (7) Definitions, states “Wholesale distribution” means the distribution of prescription drugs to persons other than a consumer or patient, but does not include: The distribution of drug samples by manufacturers’ representatives or distributors’ representatives. For purposes of this section, “drug sample” means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

Guest Greg Edwards from the Dept. of Health, Food and Drug Branch stated it is the same for Chapter 328 that Virtual Manufacturers are not defined and it does not appear they are operating as a manufacturer. Mr. Edwards stated that what he is seeing is some companies will not do

business with you unless you have a wholesale distributor's license in a state, which is why they are probably asking if they will be allowed to be licensed if the minimum requirements are met.

The EO stated it appears a license is not required, but they cannot be prevented from applying for a license.

It is the consensus of the Board that Virtual Manufacturers are not defined; therefore a license or permit is not required. The consensus is based solely on the information provided.

The Chair deferred the topic to the Laws and Rules Committee for discussion.

Out-of-state Pharmacy Compounding for Office Use

Ms. Keefe led the discussion on an email inquiry asking if a Pharmacy Miscellaneous Permit (PMP) allows the permit holder to ship to Hawaii hospitals, surgery centers, and doctor office for office stock use. They are asking for confirmation that the patient names do not have to be on prescriptions that are being sent to hospitals and physicians.

It is the consensus of the Board that after careful consideration and a re-review of the Hawaii pharmacy laws and rules and the fact that the pharmacy may be registered with the FDA as an outsourcing facility, it was the Board's interpretation that pharmacies may only dispense a drug (compounded or not) directly to the patient pursuant to a patient specific prescription. Hawaii's pharmacy laws and rules do not allow for pharmacies to compound for office use.

Furthermore, although other state pharmacy laws may allow pharmacies to compound for office use, Hawaii does not, and if the drugs are being distributed into this State, Hawaii's pharmacy laws and rules apply.

The Board is attempting to amend their laws/rules to allow compounding for office use, but realizes this is a consumer protection issue and is taking everything into consideration to ensure patient safety.

FDA Data Dashboard

Dr. Ma reported on an email memo announcing the U.S. Food and Drug Administration's (FDA's) Office of Regulatory Affairs (ORA) launched a new online tool to provide insights into FDA compliance and enforcement data. The FDA Data Dashboard makes publicly available compliance information more readily accessible to the public. In its first phase, the Dashboard provides access to data on:

- Inspections;
- Compliance actions, with specific focus on warning letters, seizures, and injunctions; and
- Recall information.

The FDA Data Dashboard can be accessed from FDA's Transparency main webpage.

National Transportation Safety Board (NTSB) – Safety Recommendations to the Federal Aviation Administration and the States

Dr. Chock reported on a memo received from The National Transportation Safety Board (NTSB) on results of their safety study, Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment. As a result of the safety study NTSB issued six new recommendations, including four recommendations to the Federal Aviation Administration and the following two recommendations to the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico:

- Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation; and
- Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical condition or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.

The Chair stated they recommend using routine forms of communication; therefore should this be posted on our webpage.

The EO stated it will not be posted on the webpage, but she will inform NTSB that the Board will make an effort to inform the public. This will also be copied to the Department of Public Safety, Narcotics Enforcement Division.

“The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers” – Guidance for Industry from U.S. Department of Health and Human Services, Food and Drug Administration

The Chair led the discussion on a guidance document from the U.S. Department of Health and Human Services, Food and Drug Administration (FDA). The document is available on the FDA's website for review.

The EO asked the Board to review the guidance document and decide if this is something that they think should be posted on the Board's webpage.

Executive Session:

At 9:51 a.m., upon a motion by Ms. Keefe, 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 10:28 a.m. upon a motion by Ms. Kumasaka, seconded by Dr. Ma, 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 10:28 a.m. to discuss and deliberate on the following adjudicatory matter(s) pursuant to Chapter 91, HRS:

In the Matter of the Miscellaneous Permit of **America's Best Care Plus Inc.**, PHA 2014-15-L, First Amended Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1" – "3".

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

In the Matter of the Pharmacist's License of **William J. Mumbert, aka William James Mumbert**, PHA 2010-44-L, Settlement Agreement after Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1" – "3".

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

Applications:

Ratification List

Upon a motion by Ms. Keefe, seconded by Ms. Kumasaka, 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. Keefe, it was voted on and unanimously carried to delegate approval of the following applications to the EO upon receipt of an acceptable explanation of answer to question #3.:

RS Compounding LLC, dba Westchase Compounding Pharmacy
Medicine Shoppe Pharmacy of Reading, dba Reading Medicine Shoppe
Coast Quality Pharmacy, LLC, dba AnazaoHealth

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

Change of PIC for Walgreens Specialty Pharmacy LLC (PMP 547) – Clay Parkel
Change of PIC for Express Plus Pharmacy LLC (PMP 913) – Dennis Soumoff

Upon a motion by the Chair, seconded by Ms. Keefe, it was voted on and unanimously carried to defer the following application for further information from the State of Tennessee:

ExcelleRx

Next Meeting: The Chair announced the next Board meeting as November 20, 2014 and asked if everyone was available.

Ms. Keefe is excused from the November 20, 2014 meeting so she can attend a NABP VIPP's inspection at a veterinary pharmacy on Maui.

Thursday, November 20, 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 10:36 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

11/6/14

[] Minutes approved as is.

[X] Minutes approved with changes; see minutes of 11/20/14

LTYPE	LIC	NUM	BP NAME PART 1
PH		3726	CAROLYN A <SUNG<
PH		3727	JIZAN-ANNE E <BENAVENTE<
PH		3728	CAROLINE S <SOUSA<
PH		3729	LARA S <BERGER<
PH		3730	SEUNG Y <YEO<
PH		3731	JAMIE Y <HONG<
PH		3732	BRONSTON S <LALLIER<
PH		3733	KANDICE L <LATHROP<
PH		3734	KARIA J <WIGGINS<
PH		3735	SARA M <FUKUMURA<
PH		3736	BRIANNE A <GUSTILO<
PH		3737	CHAD T <KAJIWARA<
PH		3738	KERRY L <WILLIAMS<
PH		3739	STACIE T <TAKAHASHI<
PH		3740	SCOTT Y <SUMIDA<
PH		3741	TRACY M <NAKAMA<
PH		3742	BRYAN T <CHO<
PH		3743	KERI E <OYADOMARI<
PH		3744	JOHN JOSEPH <FUJITA<
PH		3745	DENISE D <KOBASHIKAWA<
PH		3746	HAI LIANG <HUANG<
PH		3747	VICTOR W <LIN<
PH		3748	BONNIE C <CATHCART<
PH		3749	JAKE P <ELSBERND<
PH		3750	RACHEL L K <HODGES<
PH		3751	JENNIFER J Y <YAM<
PH		3752	ANGELA MAE F <ALFONZO<
PH		3753	ANNE E <HARTHMAN<
PH		3754	CYNTHIA C <WARREN<

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN			BP NAME PART 1
				ST	BUSN ZIP		
PHY	856	1090 KEOLU DR STE #112/113	KAILUA	HI	96734		KAILUA FAMILY PHARMACY LLC

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN		BP NAME PART 1
				ST	BUSN ZIP	
PMP	1039	5455 WEST WATERS AVE STE 214	TAMPA	FL	33634	PRAXIS SPECIALTY PHARMACY LLC
PMP	1040	2705 N SEPULVEDA BLVD	MANHATTAN BEACH	CA	90266	RAINDROP PHARMACY INC
PMP	1041	85 MACK BAYOU LP	SANTA ROSA BEACH	FL	32459	MACK BAYOU PHARMACY LLC
PMP	1042	2040 ROUTE 130 NORTH	BURLINGTON	NJ	08016	EXPRESS SCRIPTS PHARMACY INC
PMP	1043	8325 SOUTH PARK CIR STE 201	ORLANDO	FL	32819	WALGREEN PHARMACY SERVICES MIDWEST LLC
PMP	1044	700 NW ARGOSY PKWY	RIVERSIDE	MO	64150	APRIA HEALTHCARE LLC DBA STAR MEDICAL RX
PMP	1045	550 HEMPHILL ST	FORT WORTH	TX	76104	THE MEDICINE STORE PHARMACY INC
PMP	1046	433 KINGS HWY	BROOKLYN	NY	11223	DMR PHARMACY INC
PMP	1047	4401 SHERIDAN ST	HOLLYWOOD	FL	33021	LATE DRUG COMPANY
PMP	1048	151 TEXAS RD	OLD BRIDGE	NJ	08857	WOODS PHARMACY
PMP	1049	16530 VENTURA BLVD STE #610	ENCINO	CA	91436	SHORELINE PHARMACEUTICALS INC
PMP	1050	2815 WATTERSON TR	LOUISVILLE	KY	40299	PET 360 INC DBA PETSRIPTIONS
PMP	1051	395 ELAINE DR STE #110	LEXINGTON	KY	40504	BLUEGRASS PHARMACY OF LEXINGTON LLC
PMP	1052	20612 N CAVE CREEK RD #150	PHOENIX	AZ	85024	TOPICAL SOLUTIONS PHARMACY LLC
PMP	1053	521 W AVALON AVE	MUSCLE SHOALS	AL	35661	WALGREEN PHARMACY SERVICES MIDWEST LLC
PMP	1054	1840 OUTER LOOP RD	LOUISVILLE	KY	40219	UPS SUPPLY CHAIN SOLUTIONS INC
PMP	1055	1838 ELM HILL PIKE STE #125	NASHVILLE	TN	37210	LIFE-Q LLC

BOARD OF PHARMACY

October 23, 2014 Ratification List

Miscellaneous Permits (PMP)

Change of PIC:

Lynnfield Drug Inc. dba Freedom Fertility Pharmacy (PMP 459)

12 Kent Way #120F

Byfield, MA. 01922

New PIC: Hilary Thibault

Effective: 8/16/14

CHD Pharmacy (PMP 745)

255 Phillipi Rd., Ste. 300

Columbus, OH. 43228

New PIC: Joanne Colegrove

Effective: 8/23/14

Well Pharmacy Network LLC (PMP 797)

1210 SW 33rd Ave.

Ocala, FL. 34474

New PIC: Rita S. Weiss

Effective: 8/21/14

Prime Therapeutics Specialty Pharmacy LLC (PMP 774)

2354 Commerce Park Dr. Ste. 100

Orlando, FL. 32819

New PIC: Sabeen Hasno

Effective: 8/20/14

Prime Therapeutics LLC (PMP 508)

4580 Paradise Blvd. NW

Albuquerque, NM. 87114

New PIC: Johnny Garcia

Effective: 8/29/14

Costco Wholesale Corporation dba Coscto Pharmacy #562 (PMP 623)

215 Deninger Cir.

Corona, CA. 92880

New PIC: Katharine Nguyen

Effective: 6/18/14

Veterinary Mart Corp (PMP 699)

9500 NW 79th Ave. #6

Hialeah, FL. 33016

New PIC: Susan Emily Casas De Betancourt

Effective: 9/17/14

North Sunflower Medical Center dba Sunflower Discount Pharmacy (PMP 890)

840 N. Oak Ave.

Ruleville, MS. 38771

New PIC: Thomas Spell

Effective: 9/8/14

National Pharmaceutical Network Inc. dba Eiris Health Services #6012 (PMP 917)

4284 New Getwell

Memphis, TN. 38118

New PIC: Sherrill Benson

Effective: 8/29/14

RX of Boca LLC (PMP 928)

5801 N Federal Hwy.

Boca Raton, FL. 33487

New PIC: Judith Perez

Effective: 9/19/14

American Rx LLC (PMP 977)

412 S Court St. #300

Florence, AL. 35630

New PIC: William Stapp Harrison

Effective: 9/16/14

Sentrix Pharmacy and Discount LLC (PMP 1009)

6910 Sterling Rd.

Hollywood, FL. 33024

New PIC: Thomas Dobry

Effective: 9/30/14

Life Extension Pharmacy Inc. (PMP 507)

5990 N Federal Hwy.

Ft. Lauderdale, FL. 33308

New PIC: Hien Le

Effective: 10/2/14

Relocation:

Eagle Pharmacy LLC dba Eagle Pharmacy (PMP 815)

350 Eagles Landing Drive

Lakeland, FL. 33810

Effective: 8/22/14

Halls IV & Institutional Pharmacy Inc. (PMP 981)

1000 W. Weatherford St., Ste. 120

Fort Worth, TX. 76102

Effective: 8/4/14

Currant Health Florida LLC (PMP 1013)

11001 Roosevelt Blvd., Suite 1400

Petersburg, FL. 33716

Effective: 8/25/14

Modernhealth Specialty (PX) LLC dba PX Drugstore (PMP 922)

7373 Lincoln Way
Garden Grove, CA. 92841
Effective: 8/18/14

Name Change:

Soleo Health (PMP 524)

950 Calcon Hook Rd., Ste. 15
Sharon Hill, PA. 19079
Effective: 8/20/14

Sentrix Pharmacy and Discount LLC (PMP 1009)

6910 Sterling Rd.
Hollywood, FL. 33024
Effective: 9/8/14

Sina Drug LLC dba Onco360 (PMP 526)

225 Community Dr. Ste. 100
Great Neck, NY. 11021
Effective: 9/15/14

Closure:

DS Pharmacy Inc. (PMP 370)

407A Heron Dr.
Swedesboro, NJ. 08085
Effective: 8/1/14

Pharmacy (PHY)

Change of PIC:

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

850 Kamehameha Hwy. Ste. 107
Pearl City, HI. 96782
New PIC: Joni Murai
Effective: 8/24/14

Longs Drug Stores California LLC dba Longs Drugs #9303 (PHY 737)

1215 S. Kihei Rd., Ste. B
Kihei, HI. 96753
New PIC: Amber Sullivan-Friezner
Effective: 9/14/14

Wal-Mart Stores Inc. dba Wal-Mart Pharmacy #10-3290 (PHY 620)

101 Pakaula St.
Kahului, HI. 96732
New PIC: Bennie Gonzales
Effective: 8/18/14

Mina Pharmacy LTC LLC dba Mina Pharmacy #15 (PHY 813)

275 W. Kaahumanu Ave. #1C01AB

Kahului, HI. 96732

New PIC: Shawn Tavares

Effective: 9/14/14

Cardinal Health 414 LLC (PHY 825)

525 Kokea St., Ste. B2

Honolulu, HI. 96817

New PIC: Seung Yoon Yeo

Effective: 10/1/14

Relocation

Nineteen Fifty-One Partners Inc. (PHY 845)

dba Malama Pharmacy South

82-6066 Mamalahoa Ste. 14

Captain Cook, Hawaii 96704

Effective: 10/8/14

Malama Compounding Pharmacy Inc. (PHY 642)

82-6066 Mamalahoa Ste. 14

Captain Cook, Hawaii 96704

Effective: 10/8/14

Closure:

Scripts Pharmacy Hawaii Incorporated dba Puna Pharmacy (PHY 803)

15-2660 Keaau Pahoa Rd. #205

Pahoa, HI. 96778

Effective: 9/22/14