BOARD OF PHARMACY

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

MINUTES OF MEETING

| Date: | Thursday, February 13, 2014 | | | | |
|--|---|--|--|--|--|
| <u>Time</u> : | 9:00 a.m. | | | | |
| <u>Place</u> : | 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 | | | | |
| <u>Members Present</u> : | Todd Inafuku, Pharmacist Mary Jo Keefe, Pharmacist Kerri Okamura, Pharmacist Carolyn Ma, Pharmacist Jill Oliveira Gray, Public Member Lydia Kumasaka, Public Member | | | | |
| Members Excused: | Garrett Lau, Pharmacist | | | | |
| <u>Staff Present</u> : | Lee Ann Teshima, Executive Officer ("EO") Stephen Levins, Deputy Attorney General ("DAG") Lisa Kalani, Secretary | | | | |
| <u>Guests:</u> | Patrick Adams, Foodland Paul Smith, Walgreens Shannon Terayama, CVS/Longs Marcella Chock, HPHA Keiko Hiraoka, Lilly Eden Chik, Creighton University – student Greg Edwards, DOH, Food and Drug Branch Tiffany Yajima, Ashford, Winston Albert Lau, Kaiser Permanente Dennis McAllister, Express-Scripts Wendy Taylor, Wal-Mart Nancy Huang, Walgreens Dan Purcell, Public | | | | |
| Guests from the UH Hilo College of Pharmacy via webcast: | Lara Gomez Jennifer Aguiar Christina Method Arnold Sarvo Thao Le | | | | |

> Jake Babbel Zack Campbell Jynelle Tangonan Venus Ho Yen Dao Barnes Chau Dang Tony Huynh Jared Crowther Camilla Kim Aryn Meguro Thuy-Vi Le Yolette Quach Andrew Hayashi Sarah Osellanu Melissa Monette Okezie Irondi Kelsey Chang Jerilyn Gudoy Bryce Fukunaga Christopher Thai Tina Liu Thuy-Tien Diep John Hoang Blake Johnson Jane Penho Katherine Lee Albert Lee Mireya Talavera Joseph Nguyen Walter Domingo David Ung Julianna Aguino Josen Ho Eric Tsuji Joshua Day Katrina Spinola Perry Kim Kevin Flores Keetae Kim Ornella Fassu Amber Goodloe Sisay Girmay Raymond Okanihira Carlo Tiano Andy Wong George Karvas Eric Sanders Voc Le Necole Miyazaki

| | Jeremy Lozano |
|-----------------|--|
| | Beth Earles |
| | Rachel Ebbett |
| | Nick Rovany |
| | Amy Anderson |
| | Tina Kordkheili |
| | Christina Yeh |
| | Alexander Guimaraes |
| | |
| | Samantha Chang David Choe |
| | |
| | Brandon Tuzon |
| | Nancy Le |
| | Quynh Le |
| | Moanilehua Hagmann |
| | Melissa lida |
| | Keun Wang |
| | Leilani Isozaki |
| | Alexander Galiciano |
| | Daryl Sakudo |
| | Allen Bagalso Andy Takahata |
| | Thuy-Tien Pham |
| | Jamie Mizusawa |
| | Bert Matsuo |
| | Jairus Mahoe |
| | Josen Perreira |
| | Kasia Lynn Quintal |
| | Shanon Makanui |
| | Anissa Marzuk |
| | Micah Kim Han |
| | Samantha Hanabaga |
| | Thy Ta |
| | Lance Cabanting |
| | Kim Duong |
| | Allen Higa |
| | Mimi Thong |
| | Kimberly Victorina |
| <u>Agenda</u> : | 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"). |
| Call to Order: | There being a quorum present, the Chair called the meeting to order at 9:03 a.m. |
| | Announcements and Introductions |
| | The Chair asked the Board members and audience to introduce themselves. |

Additions/Additional Distribution to Agenda

Upon a motion by the Chair, seconded by Ms. Okamura, it was voted on and unanimously carried to add the following to the agenda.

Additions

- 8. Applications
 - b. Applications
 - 1) Miscellaneous Permit
 - ii. Leiter's Enterprises Inc., dba Leiter's Compounding
 - 2) Pharmacy
 - i. Wal-Mart Stores Inc., dba Wal-Mart Pharmacy 10-3149
 - c. Request for Unconditional Approval
 - 1) Miscellaneous Permit
 - i. LCRX, LLC. dba Alpha Direct Compounding

Approval of the Previous Minutes – January 23, 2014

The Chair called for a motion in regards to the minutes of the January 23, 2014 meeting.

The Chair stated on page 3, second paragraph, should read, The Chair stated the issues the Rules Committee will be focusing on in 2014 are collaborative agreements, miscellaneous permits and the definition of the practice of pharmacy.

Dr. Oliveira Gray stated on the Executive Session minutes it states she is present, however she was absent from that meeting.

Upon a motion by Dr. Ma, seconded by Dr. Oliveira Gray, it was voted on and unanimously carried to approve the minutes for the January 23, 2014 meeting as amended.

Laws and Rules The Chair reported on the Committee's January 23, 2014 meeting. Committee Report:

The Chair stated the Committee talked about the collaborative agreement section. Collaborative agreements are currently the focal point of the Committee. The Chair sent a preliminary draft to the committee members as a starting point, and will be discussing the draft at the next Committee meeting which is following today's Board of Pharmacy meeting.

Executive Officer's 2 Report:

2014 Legislature

<u>SB 3005 – Relating to Compounding Pharmacies</u> The EO reported this bill requires pharmacies to obtain a separate sterile compounding permit from the Board of Pharmacy in order to engage in sterile compounding activities.

The EO stated this bill was referred to both the Commerce and Consumer Protection Committee and the Ways and Means Committee. The first lateral deadline is 2/14/14, which means in order for this bill to move forward, it has to be referred to the second committee by tomorrow.

EO Report of Attendance at the January 29, 2014 Board of Veterinary Examiners Meeting

The EO reported she attended the January 29, 2014 Board of Veterinary Examiners Meeting to respond to any questions that they had. The letter that the Board of Veterinary Examiners (BOVE) had sent to the Board of Pharmacy with questions and answers has been posted to the Board of Pharmacy's webpage along with the guidance document from the BOVE. The EO stated the BOVE's concerns are that manufacturers of veterinary products are supposed to only be selling to the veterinarians, yet somehow pharmacies and distributors are obtaining these products. The EO informed the BOVE that is not something the Board of Pharmacy can control.

The EO stated HB 2106, which is the bill that would require a pharmacist who fills veterinary prescriptions be required to take a veterinary course, was deferred.

Immunizations of Minors - Clarification on Training Requirements

The EO reported she has been getting a lot of inquiries about immunizations of minors and therefore wanted to provide clarification.

The EO stated section 461-11.4, HRS states:

(d) All pharmacists who administer the influenza vaccine to persons between the ages of fourteen and seventeen years shall complete a training program approved by the Accreditation Council of Pharmacy Education for which a certificate of completion is issued. The pharmacist shall complete the training program and submit the completion certificate for the training program to the board prior to administering the influenza vaccine to persons between the ages of fourteen and seventeen years.

The EO reported she has been receiving calls saying that the immunizations are being administered to minors at these locations, but the pharmacist has not submitted a copy of their completion certificate for the training program to the Board.

The EO reported she wants to make it clear for everyone, even though you took the course; you have to notify the Board prior to administering the vaccines.

The EO also stated section 461-8, HRS states:

(e) A pharmacist who administers the influenza vaccine to persons between the ages of fourteen and seventeen years shall complete a training program approved by the board within every other biennial renewal period and submit proof of successful completion of the training program to the board; provided that the pharmacist shall meet these requirements prior to administering the influenza vaccine to persons between the ages of fourteen and seventeen years.

Conferences/Meetings/Seminars

MPJE Item-Development Workshops, March 20-21, 2014

The EO reported Ms. Okamura will be attending the MPJE Item-Development Workshop. Mr. Mark Brown, the former Board of Pharmacy Chair will also be in attendance.

National Association of Boards of Pharmacy ("NABP") 110th Annual Meeting, May 17-20, 2014 Phoenix, Arizona

The EO reported Ms. Keefe will be attending the NABP 110th Annual Meeting.

Correspondence: National Association of Boards of Pharmacy (NABP)

<u>NABP Works with Member Boards, FDA to Implement New Compounding Law for the Protection</u> of Public Health (Guidance Document)

The Chair reported on November 27, 2013, the Drug Quality and Security Act (Act) was signed into law. This law removes the unconstitutional provisions from Section 503A and adds a new Section 503B to the Federal Food, Drug, & Cosmetic Act. The law also provides for the Food and Drug Administration (FDA) to consult with a Pharmacy Compounding Advisory Committee prior to issuing certain regulations pertaining to outsourcing facilities.

NABP has received a variety of questions related to "outsourcing facilities," as defined in the Act. Specifically, it has been asked whether or not and how the states should be licensing these types of entities even if they are solely operating as an "outsourcing facility." This is an issue that NABP is discussing with the states and FDA, specifically as to how the "outsourcing facilities" will be licensed at the state level.

USP Posts FAQs to Address Common Questions About USP-NF Chapters (FAQs)

The Chair reported that in response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters and, USP has created a new <u>frequently asked</u> <u>questions</u> (FAQ) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use-dating, and the differences between testing stability with strength (potency) or stability-inducing methods.

Email Inquiry from Melissa Sanders, Regarding Prescriptions, Formatting and How Many Medications May be Printed on a Prescription

The Board reviewed an inquiry from Melissa Sanders. Ms. Sanders questions with the Board's responses are as follows:

- 1. Are there formatting measurement requirements for printed forms? The pharmacy laws and rules (HRS Chapter 461 and HAR Chapter 95) do not specify any formatting measurement requirements for printed prescriptions.
- 2. How many medications may be on a printed form? Can controlled and non-controlled be on the same form? The pharmacy laws and rules do not address this. There is nothing in regards to prescriptions for non-controlled substances, however for controlled substances, that is regulated by HRS Chapter 329 under the Department of Public Safety, Narcotics Enforcement Division. You may wish to contact that office to see if the Uniform Controlled Substances Act prohibits multiple medications listed on one prescription.

Email Inquiry from Karen DiStefano, Transfer of a Prescription That Has Not Been Filled The Board reviewed an inquiry from Karen DiStefano asking if a prescription that has not been filled by a pharmacy can transfer the information from that prescription to another pharmacy.

After a brief discussion that included the Board and Mr. Greg Edwards of the Department of Health, Food and Drug Branch, it was determined that based on HRS 461-1(g) and 328-16(e)

| | and HAR 16-95-84, a prescription that has not been filled may be transferred between pharmacies in compliance with the previously mentioned statutes and administrative rules. | | | | | | |
|---------------------|--|--|--|--|--|--|--|
| | Email Inquiry from Jennifer Schneider Licensure of Clinical Lab Receiving and Shipping Drugs Not Intended for Patient Use The Board reviewed an inquiry from Jennifer Schneider stating she has a client that wishes to open a clinical lab to be used strictly for research and development. Periodically, they will need to receive and ship small amounts of drugs not intended for patient use. Will this company be required to hold a distribution license in order to ship legend drug products to another licensed location or professional within the state? | | | | | | |
| | After a brief discussion, the Board determined that since it was not clear who "this company" is, if it is referring to an out-of-state wholesale distributor that would ship prescription drugs, non-controlled substances, to a pharmacy, physician's office, hospital or another wholesale distributor in this State, then no license is required since Hawaii does not require out-of-state wholesale distributors to obtain a license. Also, since no indication was made if the prescription drug being distributed was a controlled substance, it was suggested that Ms. Schneider also check with the Department of Public Safety, Narcotics Enforcement Division. | | | | | | |
| Old Business: | HAR Title 16, Chapter 95 – Status Report | | | | | | |
| | The EO reported she will have the report sent to the DAG for review. | | | | | | |
| <u>Open Forum</u> : | Guest Dan Purcell stated in September of 2013 he attended a Hawaii Board of Nursing (BON) meeting where Diane Corn, who is a RICO staff attorney, reported to the BON that Hawaii was first in the nation in under-reporting of clinical thefts of hydrocodone and other drugs. | | | | | | |
| | The EO stated if Mr. Purcell has concerns regarding controlled substances, she can provide him with the Department of Public Safety, Narcotics Enforcement Division's contact information. | | | | | | |
| | Mr. Purcell asked the Board who is responsible for addressing this. | | | | | | |
| | The Chair attempted to explain to Mr. Purcell about the different regulatory bodies that may be related to pharmacy but do not come under the Board of Pharmacy ("Board") and are not regulated by the Board. | | | | | | |
| | Guest Pat Adams asked if for the next agenda the Board could look at discussing pharmacy regulations as a whole. | | | | | | |
| Applications: | Ratification List | | | | | | |
| | Upon a motion by Ms. Kumasaka, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the attached ratification lists. | | | | | | |
| Executive Session: | At 10:16 a.m., upon a motion by the Chair, seconded by Dr. Ma, 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 10:51 a.m. upon a motion by the Chair, seconded by Dr. Oliveira Gray it was voted on and unanimously carried to move out of executive session. | | | | | |
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| Applications: | Applications | | | | | |
| | <u>Miscellaneous Permit</u> Upon a motion by the Chair, seconded by Ms. Kumasaka, it was voted on and unanimously carried to issue a conditional approval pursuant to Hawaii Revised Statutes, §436B-19(7), (9) and (13) and 461-21(2) and (5). | | | | | |
| | CAP Rx, Inc., dba Central Avenue Pharmacy | | | | | |
| | <u>Miscellaneous Permit</u> Upon a motion by the Chair seconded by Dr. Oliveira Gray it was voted on and unanimously carried to approve the following application. | | | | | |
| | Leiter's Enterprises Inc., dba Leiter's Compounding | | | | | |
| | <u>Pharmacy</u> Upon a motion by the Chair seconded by Dr. Ma it was voted on and unanimously carried to approve the following application. | | | | | |
| | Wal-Mart Stores, Inc., dba Wal-Mart Pharmacy 10-3149 | | | | | |
| Applications: | Request for Unconditional Approval | | | | | |
| | <u>Miscellaneous Permit</u> Upon a motion by the Chair seconded by Dr. Oliveira Gray it was voted on and unanimously carried to deny the request due to no new evidence was submitted to grant such a request. | | | | | |
| | LCRX, LLC., dba Alpha Direct Compounding | | | | | |
| <u>Chapter 91, HRS</u> Adjudicatory Matters: | The Chair called for a recess from the meeting at 10:51 a.m. to discuss and deliberate on the following adjudicatory matter(s) pursuant to Chapter 91, HRS: | | | | | |
| | In the Matter of the Pharmacist's License of Jodi M. Miller; PHA 2008-11-L, Monitor's Report for Period Covering November 2013 – January 2014: | | | | | |
| | Upon a motion by the Chair, seconded by Ms. Keefe it was voted on and unanimously carried to accept the monitor's report for period covering November 2013 – January 2014. | | | | | |

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

Thursday, March 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 10:58 a.m.

Taken and recorded by:

Reviewed and approved by:

/s/ Lisa Kalani Lisa Kalani, Secretary <u>_/s/ Lee Ann Teshima</u> Lee Ann Teshima, Executive Officer

3/5/14

[x] Minutes approved as is.[] Minutes approved with changes; see minutes of ______

BOARD OF PHARMACY

February 13, 2014 Ratification List

Miscellaneous Permits (PMP)

<u>Change of PIC:</u> **Summit Pharmacy Inc. (PMP 629)** 2320 West Peoria Avenue, Suite D132 Phoenix, Arizona 85029 New PIC: Kristin Wolter Effective: 1/13/2014

ESI Mail Pharmacy Service Inc. (PMP 18) dba Express Scripts

4600 North Hanley Road St. Louis, Missouri 63134 New PIC: Charles Conroy Effective: 1/12/2014

Wells Pharmacy Network LLC (PMP 797)

1210 SW 33rd Avenue Ocala, Florida 34474 New PIC: David Joseph Effective: 1/13/2014

Name Change/Conversion/Addition of TN or DBA: Jaspreet Lalli (PMP 677) dba CPP Pet Care 3250 Arden Road Hayward, California 94545

Relocation: ESI Mail Pharmacy Service Inc. (PMP 18) dba Express Scripts 4600 North Hanley Road St. Louis, Missouri 63134

Relocation and Name Change: Walgreens Specialty Pharmacy LLC (PMP644) dba Walgreens Specialty Pharmacy #15438 41460 Haggerty Circule South Canton, Michigan 48188

<u>Closure:</u> **Miami Executive Pharmacy Inc. (PMP 757)** 7400 N. Kendall Dr. #100 Miami, Florida 33156

1/17/2014

Effective:

Pharmacy (PHY)

Change of PIC:

Longs Drug Stores of California (PHY 719)

dba Longs Drugs #9275

850 Kamehameha Hwy, Ste. 107 Pearl City, Hawaii 96782 New PIC: Paul Hironaka Effective 12/29/2013

Longs Drug Stores of California (PHY 790) dba Longs Drugs #7098

15-1454 Kahakai Blvd. Pahoa, Hawaii 96778 New PIC: Jenna Yamashita Effective 1/12/2014

Longs Drug Stores of California (PHY 715) dba Longs Drugs #9228

1330 Pali Hwy. Honolulu, Hawaii 96813 New PIC: Jackwayne Fernandez Effective 1/12/2014

Malama Compounding Pharmacy (PHY 642)

81-6629 Mamalohoa Hwy Kealakekua, Hawaii 96750 New PIC: Patricia Balzarini Effective 1/21/2014

<u>Closure:</u>

The Pharmacy Group Inc. (PHY 714) dba Paia Pharmacy 96 Hana Hwy Paia, Hawaii 96779 Effective: 12/31/2013

Relocation and Name Change:

Apria Healthcare LLC (PMP767) 900 Kalae Hwy, Ste. 203 Kualapuu, Hawaii 96757 PHARMACIST RAT LIST 02-2014

LTYPE LIC NUM BP NAME PART 1 -----

PH 3622 TANYA R <VERDIS< PH 3623 JESSICA K <KU< PH 3624 LINDSEY Y <YUAN< PH 3625 ASHLEY A K <FUCHIGAMI< PH 3626 JAMES M <LIONETTI <

LTYPE TEMP LIC NUM VAM_BPR_LEGAL_NAME_1

PHI T140116003 JORDAN T <SHLENSKY<
PHI T140115001 ANDREW D <REHER<
PHI T140116006 DENISE C <NGO<
PHI T140115002 BLAE R T <PARACUELLES<</pre>

PHI T140116005 CHELSEA C <ARAKAWA<

PHI T140128001 AMANDA K <RAMSEY<

PHI T140116001 NATALIE N <NGUYEN<

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| | | | | | BUSN | I | |
|-----------|-----|--------------------------|-------------------------|-----------|------|----------|----------------------|
| LTYPE LIC | NUM | LIC NAME PART 1 | BUSN ADDR 1 | BUSN CITY | ST | BUSN ZIP | BP NAME PART 1 |
| | | | | | | | |
| PHY | 847 | | 700 WAIALE RD | WAILUKU | HI | 96793 | WALGREEN OF MAUI INC |
| PHY | 848 | NATIONAL ANIMAL HOSPITAL | 300 OHUKAI RD STE C-315 | KIHEI | HI | 96753 | VET MEDS N MORE INC |

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|-----------|-----|------------------------------|-------------------------------|-------------|------|----------|---|
| LTYPE LIC | NUM | LIC NAME PART 1 | BUSN ADDR 1 | BUSN CITY | ST | BUSN ZIP | BP NAME PART 1 |
| | | | | | | | |
| PMP | 918 | | 6040 TARBELL RD | SYRACUSE | NY | 13206 | NOBLE HEALTH SERVICES INC |
| PMP | 919 | VALLEY VEIW DRUG | 13966 VALLEY VIEW AVE | LA MIRADA | CA | 90638 | VALLEY VEIW DRUG INC |
| PMP | 920 | | 1007 CANAL BLVD | RICHMOND | CA | 94804 | CARDINAL HEALTH 414 LLC |
| PMP | 921 | PHARMACY SOLUTIONS | 1921 W PIONEER PKWY | ARLINGTON | ТΧ | 76013 | TOMELDON CO INC |
| PMP | 922 | PX DRUGSTORE | 5300 LANKERSHIM BLVD STE 100 | N HOLLYWOOD | CA | 91601 | MODERNHEALTH SPECIALTY (PX) LLC |
| PMP | 923 | VIDASCRIPT | 7432 SW 48 ST | MIAMI | FL | 33155 | TECH-PHARMACEUTICALS INC (D/B/A) V |
| PMP | 924 | STERLINGTON VILLAGE PHARMACY | 10374 HWY 165 N STE C | STERLINGTON | LA | 71280 | RX PROS INC |
| PMP | 925 | | 2730 S EDMONDS LN STE 400 | LEWISVILLE | TX | 75067 | SONEXUS HEALTH PHARMACY SERVICES L |
| PMP | 926 | MCDANIEL PHARMACY | 1005 MARKET ST | PORT GIBSON | MS | 39150 | RX PRO OF MISSISSIPPI INC |
| PMP | 927 | PHARMAZY | 9990 PARK MEADOWS DR | LONE TREE | CO | 80124 | ZYNEX MEDICAL INC |
| PMP | 928 | | 5801 N FEDERAL HWY | BOCA RATON | FL | 33487 | RX OF BOCA LLC |
| PMP | 929 | INVERNESS APOTHECARY TRINITY | 24333 GORDAN TERRY PKWY STE B | TRINITY | AL | 35673 | INVERNESS APOTHECARY TRINITY LLC |
| PMP | 930 | | 125 E THOMAS ST | HAMMOND | LA | 70401 | CENTRAL REXALL DRUGS INC |
| PMP | 931 | | 2490 PARR AVE STE 9 | DYERSBURG | TN | 38024 | C & C PHARMACY LLC |
| PMP | 932 | | 1910C RAE BLVD | VICTOR | NY | 14564 | FPR SPECIALTY PHARMACY LLC |
| PMP | 933 | | 735 JOHN R READ STE 150 | TROY | MI | 48083 | HENRY <ford< advantage="" pharmacy="" so<="" td=""></ford<> |
| PMP | 934 | | 2907 W EMPIRE AVE | BURBANK | CA | 91504 | SCRIPTE CORPORATION |
| | | | | | | | |