BOARD OF PHARMACY

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

MINUTES OF MEETING

<u>Date</u>: Thursday, October 18, 2012

<u>Time</u>: 9:00 a.m.

<u>Place</u>: King Kalakaua Conference Room

King Kalakaua Building

335 Merchant Street, First Floor

Honolulu, Hawaii 96813

Members Present: Mark E. Brown, Pharmacist, Chair

Patrick Adams, Pharmacist, Vice Chair

Todd Inafuku, Pharmacist

Lydia Kumasaka, Public Member

Garrett Lau, Pharmacist Carolyn Ma, Pharmacist

Jill Oliveira Gray, Public Member

Staff Present: Lee Ann Teshima, Executive Officer ("EO")

Stephen Levins, Deputy Attorney General ("DAG")

Lisa Kalani, Secretary

Guests: Marcella Chock, Hawaii Pharmacist Association ("HPhA")

Paul Smith, Walgreens Nancy Huang, Walgreens Albert Lau, Kaiser Permanente Stacy Pi, Kaiser Permanente

Keiko Hiraoka, Lilly

<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 Vice Chair called the meeting to order at 9:00 a.m.

<u>Chair's Report</u>: Announcements and Introductions

The Chair asked the audience to introduce themselves.

Additions/Additional Distribution to Agenda

The Chair called for a motion to add the following to the agenda:

Upon a motion by the Vice Chair, seconded by Mr. Lau, it was voted on and

unanimously carried to add the following to today's agenda:

<u>Additions</u>

- 6. Correspondence
 - g. Request from Oregon State Board of Pharmacy Prescription Fees

The Chair announced the following items had additional distribution:

Additional Distribution

- 6. Correspondence
 - a. National Association of Boards of Pharmacy ("NABP")
 - 3) Meningitis Outbreak
 - v. Article from Executive Update, NCPA Compounding Under a Spotlight
- 7. Applications
 - a. Ratification Lists
- 8. Chapter 91, HRS, Adjudicatory Matters
 - In the Matter of the Pharmacist's License of Jodi M. Miller, PHA 2008-11-L

Approval of the Previous Minutes - September 20, 2012

The Chair called for a motion to approve the minutes of the September 20, 2012 meeting.

The Chair stated that on page 5, first line, should be corrected to read HAR §16-95-2(5).

There being no further amendments or discussion, upon a motion by the Vice Chair, seconded by Dr. Ma, it was voted on and unanimously carried to approve the minutes of the September 20, 2012 meeting as amended.

Report on 2012 MPJE State-Specific Review

The Chair deferred to Mr. Lau to provide a brief report on his and Mr. Lau's participation at the MPJE State-Specific Review session.

Mr. Lau reported that they reviewed a pool of 10,000 questions but based on the minimum changes to the pharmacy laws and rules, there was not a lot of changes to be made.

Report on 2012 NABP Board Member Forum

The Chair reported on his attendance at the NABP Board Member Forum. He stated the following topics appeared to be the issues of interest: "How can pharmacist be recognized as healthcare providers?", "What are pharmacies doing about the drug shortages?", "Should the 5% rule be eliminated?" and a discussion on fingerprinting and background checks as part of the application for license process. There was also discussion on national certification, ACPE CE, new practice models, how technology is changing the practice of pharmacy, diversion by pharmacy technicians and prescription monitoring, including a program called NARX, which

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checks a individual's prescription history across all states.

At this time, the EO reminded the Board members who have received approval from the Department to travel, to submit their travel report in a timely manner.

Vice Chair's Report:

The Vice Chair reported on his attendance at the National Community Pharmacists Association's ("NCPA") annual meeting at which concerns were expressed regarding the pharmacist's presence in Walgreens' model, "orders" vs. "prescriptions", final check of prescriptions, automation, lack of control over prescription wholesale distributors and DEA's concerns with electronic refill request.

Laws and Rules Committee Report:

Mr. Inafuku reported that the Laws and Rules Committee continued their discussion on proposed amendments to HRS Chapter 461, that includes the use of the term "prescription" used throughout the chapter.

Mr. Inafuku also reported that the Committee will be considering a definition for "pharmacy technician" and "pharmacy intern" and also language on a pharmacist diversion program and asked the EO to provide a document that the Committee can work from.

Mr. Inafuku reported that the Committee also started discussion on a question regarding a prescription left on a voice mail and if this was considered an "oral" prescription.

Executive Officers Report: Can the "Practice of pharmacy" be done somewhere else or does it have to be in licensed/permitted pharmacy?

> The EO explained that based on the Board's previous informal interpretations, the "practice of pharmacy" may be done in a place other than a licensed/permitted pharmacy, for example the administration of immunizations, the Board previously determined that a pharmacy intern may administer immunizations at a wellness or health fair, not within the premises of a pharmacy.

The Board discussed the following questions:

- 1. Will the Board allow a pharmacy intern, under the supervision and precepted by a licensed pharmacist, to provide immunizations outside of a pharmacy, e.g. wellness fair?
- 2. Will the Board allow a pharmacist to perform remote order entry outside of a pharmacy?
- 3. Will the Board allow a pharmacist to perform telephone consultation, e.g. medication therapy management, to be performed outside of a pharmacy?
- 4. Will the Board allow activities listed under the "practice of pharmacy" to be performed outside of a pharmacy?

After some discussion, it was the consensus of the Board that a pharmacy intern may administer immunizations in a location other than a licensed/permitted pharmacy, if the pharmacy intern has received the appropriate training and is supervised/precepted by a licensed pharmacist, that a pharmacist may perform remote order entry outside of a licensed/permitted pharmacy, and that a pharmacist may perform telephone consultation and/or medication therapy management outside of a licensed/permitted pharmacy.

Correspondence:

National Association of Boards of Pharmacy ("NABP")

The Chair reported on the following:

NABP State News Roundup, September 2012

- "Delaware Board Revises Rules and Regulations Related to Pharmacy Requirements, Dispensing, and Crimes Related to the Practice Pharmacy". Effective August 11, 2012, the changes create a requirement that pharmacists-in-charge complete annual selfinspections; clarifies that a cabinet is not an acceptable storage location for controlled substances; removes the requirement that the Office of Narcotics and Dangerous Drugs be notified in the event of pharmacy construction; and adds a list of crimes to those defined as substantially related to the practice of pharmacy.
- "Idaho Joins NPLEx to Track Illegal PSE Purchases. The Idaho State Board of Pharmacy encourages all pharmacies and retailers in the state to begin using this system by September 18, 2012.
- Idaho Board Enforces New License Registration for Prescriber Drug Outlets. A drug
 outlet in which prescription drugs or devices are dispensed directly to patients under the
 supervision of a prescriber, except where delivery is accomplished only through on-site
 administration or the provision of drug samples. In addition, some prescribers may be
 engaging in sterile product preparation, which requires a separate registration and an
 on-site Board inspection prior to engaging in such activity.
- lowa's PMP Continues to Reduce Number of Patients Using Multiple Pharmacies,
 Prescribers for CS. The program is continuing to reduce the incidence of patients who
 utilize multiple pharmacies and multiple prescribers to obtain controlled substances
 (CS). The number of patients who received Schedule II, III, and IV controlled
 substances from five or more prescribers or pharmacies decreased 53% between 2009
 and 2011, from 3,293 incidents in 2009 to 1,769 in 2011. This downward trend is
 continuing in 2012. As of June 30, 2012, 830 incidents were reported.
- lowa Board of Pharmacy and lowa Pharmacy Association Form CPD Task Force for Pharmacist Re-Licensure. The task force has two goals: (1) to create a mechanism for pharmacists to seek re-licensure by means of CPD in lieu of, or in addition to, traditional continuing education (CE) requirements; and (2) to develop components of a CPRD portfolio and a systematic rubric to evaluate CPD as a method of re-licensure for practicing pharmacists.
- New Kentucky Legislation Reduces Monthly and Annual Limit of PSE. SB 3 was passed and signed into law, which reduces the monthly limit of PSE from 9 grams in a 30-day period to 7.2 grams in a 30-day period. SB 3 also lowers the annual limit from 108 grams to 24 grams. After this, a patient would need a prescription to obtain PSE.
- New Mexico Board Amends PMP and CS Prescription Regulations. Changes were made to clarify what is required on a prescription and what may be added by the pharmacy.
- North Dakota Board Participating in Pharmacy Intern License and Registration Program.
 Once fully implemented, PILAR would offer the following benefits: With a single online
 registration, a pharmacy intern could acquire and obtain internship credit for practice
 experience in any of the participating District 5 jurisdictions. The new program would
 expand practice experience opportunities, decrease paperwork, and decrease costs for
 interns in District 5.
- Tennessee Amends Controlled Substance Monitoring Database Statute. Pursuant to TCA 53-10-306, all pharmacists (defined in this statute as health care practitioners and dispensers) and health care practitioner extenders are required to obtain their own user name and password to access the CSMD. Furthermore, the amended TCA 53-11-

309(a) defines pharmacist as health care providers. Therefore, any pharmacist who has actual knowledge that a person has knowingly, willfully, and with intent to deceive, obtained or attempted to obtain CS in the manner prohibited by TCA 53-11-402(a)(6) shall cause a report to be submitted regarding such activity within five business day of obtaining such knowledge.

NABP e- News – Illinois Pharmacists' Right to Refuse Dispensing Emergency Contraceptives Upheld by Appellate Court

The court decision allowing pharmacies and pharmacists in Illinois to refuse dispensing emergency contraceptives on religious grounds was upheld by an Illinois appellate court on Friday, September 21, 2012. "Illinois Health Care Right of Conscience Act protects pharmacists decision not to dispense the contraceptives due to their beliefs," as indicated in Reuters article.

Meningitis Outbreak

A meningitis outbreak that has stricken at least 26 people in five states has been reported. The New England Compounding Center ("NECC") located in Framingham, Massachusetts has voluntarily recalled intrathecal methlprednisolone, a product they have compounded and distributed which appears to be the cause of the outbreak. According to NECC, these products were provided to facilities in CA, CT, FL, GA, ID, IL, IN, MD, MI, MN, NH, NC, NJ, OH, NV, PA, RI, SC, TN, TX, VA and WV. The lot numbers of the drug that are suspected of being contaminated are:

05212012@68 06292012@26 08102012@51

The Center for Disease Control and the Food and Drug Administration are coordinating a multistate investigation of fungal meningitis among patients who received an epidural steroid injection. Several of these patients also suffered strokes that are believed to have resulted from their infection. As of October 4, 2012, five deaths have been reported.

The local Department of Health, Disease Outbreak Control Division has distributed a medical advisory to State clinicians regarding the methylprednisolone acetate injections.

Discontinuation of USP Pharmacists' Pharmacopeia

NABP has been informed by the United States Pharmacopeial Convention (USP) that the Pharmacist 'Pharmacopeia has been discontinued and additional updates to that publication will not be provided. In June 2012, USP launched a new electronic publication entitled USP on Compounding: A Guide for the Compounding Practitioner, which like the Pharmacist 'Pharmacopeia, contains official material from USP-National Formulary relevant to compounding practitioners.

Telepharmacy (Remote Dispensing) - Act 96, SLH 2009, January 2, 2014 Repeal Date

The Board discussed Act 96, SLH 2009 and its scheduled repeal date of January 2, 2014. This Act established the sections regarding remote dispensing.

The EO asked the Board in preparation of next year's legislative session, if a bill is introduced for to delete or extend the repeal date, what would be the concerns of the Board?

Mr. Lau recused himself.

The Vice Chair stated that he would be okay with deleting the repeal date provided there are no changes to the existing language.

The Chair and Dr. Ma stated they would also be okay with deleting the repeal date.

Ms. Oliveira Gray and Ms. Kumasaka had no comment at this time.

Hospital Pharmacy Cart Check Waiver Question

The Board reviewed an email inquiry asking if the Board would "waive" the pharmacist checking of daily medication carts from 100% to a random sample check, e.g. 5 – 10% quality assurance check.

After some discussion, it was the consensus of the Board that based on their laws and rules; the Board has no authority to "waive" the requirement that a pharmacist check all medications that are dispensed.

Repackaging of Patient's Medications in a Long Term Care Facility

The Board reviewed an email inquiry asking if, "In the State of Hawaii, is there any guidance on whether or not we can take a nursing home patient's medication from a vial, that they had filled at a local pharmacy, and put into our own 30 day blister packs?"

After some discussion, it was the consensus of the Board that a pharmacy may not take back a prescription drug pursuant to HAR §16-95-87 to repackage the drug. The Board had concerns with the re-labeling of the drug in its new package, including the change of the expiration date.

Question Regarding Central Fill Pharmacies

The Board reviewed an email inquiry asking if a non-resident pharmacy is allowed to engage in the central fill process, by receiving a prescription, entering the prescription information into a database and performing drug utilization review before sending the prescription to a pharmacy in Hawaii to be filled.

After some discussion, it was the consensus of the Board to defer this discussion and ask for more information for clarification.

Pharmacy Support Services from a Mainland Facility

Mr. Inafuku recused himself.

The Board reviewed an inquiry regarding a proposed mail order workflow.

After some discussion, it was the consensus of the Board to defer this discussion and ask for more information for clarification.

Request from the Oregon State Board of Pharmacy – Prescription Fees

The Board reviewed an inquiry from the Oregon State Board of Pharmacy asking "Does your state have a fee, percentage or flat fee, per prescription? How is the revenue used?

After some discussion, it was the consensus of the Board that the pharmacy laws and rules do not address "fees" a pharmacy may charge for a prescription.

Old Business:

HAR Title 16, Chapter 95 – Status Report

The Executive Officer reported she is still working on the justification for the proposed amendments to the rules.

APRN-Rx for Controlled Substances – Status Report on Guidance Document

The EO reported that the guidance document has been posted on the web page for the Board of Pharmacy and will be posted on the Nursing Board web page.

Open Forum:

The Chair asked the audience if they had any comments on the issues on today's agenda or for the next Board meeting.

There was none.

Applications:

Ratification List

Upon a motion by the Vice Chair, seconded by Garrett Lau, it was voted on and unanimously carried to approve the attached ratification list.

Executive Session:

At 11:23 a.m., upon a motion by the Vice Chair, seconded by Mr. Lau, 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 11:46 a.m. upon a motion by Dr. Ma, seconded by Mr. Lau, it was voted on and unanimously carried to move out of executive session.

The Chair and Ms. Oliveira Gray were excused.

<u>Chapter 91, HRS,</u> <u>Adjudicatory Matters:</u>

At 11:47 a.m. the Vice Chair called for a recess from the Board's meeting to discuss and deliberate on the following adjudicatory matter, pursuant to Chapter 91, HRS:

In the Matter of the Pharmacist's License of Dennis R. Birk, PHA 2008-38-L, Compliance with Board's Final Order

Upon a motion by Dr. Ma, seconded by Mr. Lau, it was voted on and unanimously carried to send another letter, the Board's third request, to respondent regarding his current status of Phase III of

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treatment at Lakeside Milam Treatment Centers.

In the Matter of the Pharmacist's License of Jodi M. Miller, PHA 2008-11-L, Affidavit of Denise P. Balanay; Exhibits "1" – "3" – Deferred from September 18, 2012 Meeting

Mr. Lau recused himself.

Upon a motion by the Vice Chair, seconded by Dr. Ma, it was voted on and unanimously carried to accept the monitor's report for compliance of the Board's Final Order.

In the Matter of the Pharmacist's License of Reena G. Chesla, PHA 2011-10-L, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1" – Compliance with Board's Final Order

Upon a motion by the Chair, seconded by Dr Ma, it was voted on and unanimously carried to accept the information submitted from the Missouri Board of Pharmacy regarding respondent's completion of the terms of Probation and that respondent appears to have complied with the above mentioned case.

Following the Board's review, deliberation and decision on these matters, pursuant to Chapter 91, HRS, the Vice Chair announced that the Board was reconvening its scheduled meeting at 12:13 p.m.

Applications:

Applications

Pharmacist

Upon a motion by Dr. Ma, seconded by Mr. Inafuku, it was voted on and unanimously carried to approve the application for the following individual:

Sara Singh

Miscellaneous Permit

Upon a motion by Mr. Inafuku, seconded by the Vice Chair, it was voted on and unanimously carried to approve the following application with the condition that the approval does not include pharmacists Mr. Loomis and Ms. Manis based on their prior disciplinary actions:

DaVita Rx, LLC

Consequently, Mr. Loomis and Ms. Manis may not fill, adjudicate or verify any prescription coming into this State.

It was the consensus of the Board to defer decision making on the following application:

4th Street Pharmacy, Inc., dba University Compounding Pharmacy

The Board requested more information for John Grasela, Vice President of the pharmacy whose California pharmacist license was subject to disciplinary action.

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Next Meeting: Thursday, November 15, 2012

9:00 a.m.

King Kalakaua Conference Room King Kalakaua Building, First Floor

335 Merchant Street Honolulu, Hawaii 96813

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 12:20 p.m.

Taken and recorded by:

<u>/s/ Lee Ann Teshima</u> Lee Ann Teshima Executive Officer

11/5/12

[] Minutes approved as is.

[X] Minutes approved with changes; see minutes of 11/15/12

BOARD OF PHARMACY

October 18, 2012 Ratification List

Miscellaneous Permits (PMP)

Change of PIC:

ASL Pharmacy (PMP 737)
New PIC: Douglas Martin
Effective: 8/31/2012

Prime Therapeutics LLC (PMP 508)

New PIC: Laura Watkins Effective: 8/23/2012

Wells Pharmacy Network LLC (PMP 773)

New PIC: Scott Anthony Cerami

Effective: 9/26/2012

Closure:

Franck's Lab Inc., dba Franck's Compounding Pharmacy (PMP 390)

1210-A SW 33 Ave Ocala, Florida 34474 Effective: 9/28/2012

General Home Pharmacy (PMP 694)

755 Lakefield Rd. #D

Westlake Village, California 91361

Effective: 10/4/2012

CuraScript, Inc., dba CuraScript SP Specialty Pharmacy (PMP 527)

5653 Stoneridge Drive, Suite 109 Pleasanton, California 94588 Effective: 10/11/2012

CuraScript, Inc., dba Curascript SP Specialty Pharmacy (PMP 369)

10841 Q Street, Suite 102 Omaha, Nebraska 68137 Effective: 10/11/2012

Pharmacy (PHY)

Change of PIC:

Walgreen of Hawaii LLC (PHY 761)

New PIC: Michael Eudy Effective: 9/18/2012

Walgreen of Hawaii LLC (PHY 700)

New PIC: Sheena Hokutan

Effective: 10/4/2012

Walgreen of Hawaii LLC (PHY 819)

New PIC: Brent Wolford Effective: 10/4/2012

Walgreen of Hawaii LLC (PHY 799)

New PIC: Susan Korf Effective: 9/21/2012

5 Minute Pharmacy LLC (PHY 783)

New PIC: Derek Tengan

Effective: 9/21/12

5 Minute Pharmacy Kalihi LLC (PHY 807)

New PIC: Mia Kawamura

Effective: 9/21/12

Name Change:

5 Minute Pharmacy Kalihi, LLC (PHY 807)

fka 5 Minute Pharmacy, LLC

Wholesale Distributor (PWD)

Name Change:

Animal Health International, Inc. (PWD 136)

fka Lextron, Inc.

PH	3409	RACHAEL S <taira<< td=""></taira<<>
PH	3410	ROXANE L <batalon<< td=""></batalon<<>
PH	3411	CATRINA R <schwartz<< td=""></schwartz<<>
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PH	3427	CHERYL E <kobayashi<< td=""></kobayashi<<>
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PH	3429	TILDEN-CHRISTEN M <miguel<< td=""></miguel<<>
PH	3430	KEEGAN K W M <sugimoto<< td=""></sugimoto<<>
PH	3431	RYAN P <wilkin<< td=""></wilkin<<>

VAM_TEMP_LICENSE_VIEW Tuesday October 09, 2012 11:48 AM Page 1

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PHI	3235			KYLE M <dewitt<< th=""></dewitt<<>
DIIT	2226			CITET DOM A SEDOCES

PHI	3235	KYLE M < DEWITT <
PHI	3236	SHELDON A <frost<< td=""></frost<<>
PHI	3239	SHONNA L <meyer<< td=""></meyer<<>
PHI	3240	NICOLE A <ng<< td=""></ng<<>
PHI	3241	KELLY T <nguyen<< td=""></nguyen<<>
PHI	3234	LUIS J <caragan<< td=""></caragan<<>
PHI	3238	ANH TUAN <pham<< td=""></pham<<>

VLI_LICENSE_VIEW Tuesday October 09, 2012 11:51 AM Page

9905 WAIMEA RD

PHY

821

BUSN LTYPE LIC NUM LIC NAME PART 1 BUSN ADDR 1 BUSN CITY ST BUSN ZIP BP NAME PART 1 1121 S BERETANIA ST 819 HONOLULU HI 96814 WALGREEN OF HAWAII LLC PHY HI 96793 LONGS DRUG STORES CALIFORNIA LLC
HI 96796 SUNSHINE DRUG AND SUNDRY LLC 135 KEHALANI VILLAGE DR 9905 WAIMEA RD PHY 820 LONGS DRUGS #10060 WAILUKU

WAIMEA

VLI_LICENSE_VIEW Tuesday October 09, 2012 11:53 AM Page

BUSN

LTYPE LIC NUM LIC NAME PART 1 BUSN ADDR 1 BUSN CITY ST BUSN ZIP BP NAME PART 1

PMP 801 AMERICAN SPECIALTY PHARMACY 2743 W 15TH ST PLANO TX 75075 PAREEK INC

VLI_LICENSE_VIEW Tuesday October 09, 2012 11:55 AM Page

BUSN

BUSN ADDR 1 BUSN CITY ST BUSN ZIP BP NAME PART 1

PWD 159 931 HAUSTEN ST STE 103 HONOLULU HI 96826 HAUSTEN HEALTHCARE LLC

PWD 160 DSR LOGISTICS CO 91-312 KOMOHANA ST KAPOLEI HI 96707 DIRECT SUPPORT RESOURCES INC