

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

**MINUTES OF MEETING**

Date: Thursday, June 21, 2012

Time: 9:00 a.m.

Place: King Kalakaua 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

Excused: Jill Oliveira Gray, Public Member

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

Guests: Charissa Duncan, Pharmamerica Wailuku  
Samantha Woods, Pharmamerica Wailuku  
Greg Edwards, Department of Health, Food and Drug Branch  
Rovigel Gelviro, UH Hilo College of Pharmacy  
Lyell Hirashiki, Kaiser Permanente  
Albert Lau, Kaiser Permanente  
Stacy Pi, Kaiser Permanente  
Nancy Huang, Walgreens  
Keiko Hiraoka, Hawaii Pharmacists Association  
Dexter Mar, Ohana Health Plan

Agenda: 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 9:06 a.m.

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

The Chair excused Ms. Oliveira Gray and asked the audience to introduce themselves.

### **Additions and Additional Distribution**

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

#### **Additions**

5. Correspondence
  - g. Ivy Home Infusions, an Alaska Licensed Pharmacy, Distributing Blood Products to Westside Pharmacy, a Hawaii Pharmacy
  - h. Pharmacies Not Filling APRN-Rx's Prescriptions
  - i. Article, "U.S. war on drugs moves to pharmacy from jungle"
  - j. Pre-printed Prescription Pads for Medical Device
  - k. Questions on Hawaii Compounding Laws
  - l. Medical Devices
  - m. National Community Pharmacists Association Article, "I Have Met an Enemy, and It Is Us?"

### **Approval of the Previous Minutes – May 31, 2012 Meeting**

The Chair asked if there were any amendments to the minutes of the May 31, 2012 meeting.

Mr. Lau stated that on page 6, the fifth paragraph under "Prescriber Information Leaflet", Mr. Inafuku made the statement regarding the federal regulations regarding the Medication Guides for Prescription, not him.

Mr. Inafuku stated that in that same paragraph, he would like to correct the paragraph to read, "Mr. Inafuku added that the federal regulation regarding the Medication Guides for Prescription Drug Products are for outpatient. The medication guide must be provided for the initial fill and each time the drug is dispensed."

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

#### **Vice Chair's Report:**

#### **Report on Attendance at NABP 108<sup>th</sup> Annual Meeting, Philadelphia, Pennsylvania, May 19,-22, 2012**

The Vice Chair gave a brief verbal report on his attendance at the NABP 108<sup>th</sup> annual meeting that included presentations and discussions on topics such as drug abuse, where have all the drugs gone (referring the drug shortages), online drug safety, and pharmacy investigations. He stated that he would submit a written report.

Mr. Inafuku added that there was also discussion on the USP proposal for standardizing prescription labels.

At 9:13 a.m., Ms. Kumasaka arrived.

Correspondence:           **NABP State News Roundup, May 2012\**

The Chair mentioned that the Ohio Board of Pharmacy issued a reminder to their pharmacists about the Ohio Automated Rx Reporting System (OARRS) reportable drugs, that includes controlled substances and tramadol containing products to run an OARRS report if certain conditions occur for that prescription and provided a list of "red flags" for pharmacists to consider. He also stated that in Hawaii, pharmacist have to submit information on prescriptions for controlled substances to the Department of Public Safety, Narcotics Enforcement Division (DPS-NED), but do not have the ability to review information within the reporting system.

The EO wanted to clarify that pharmacists may input information into the prescription drug monitoring system, however, could not check or be immediately notified if there were issues with the patient or prescriber before dispensing the drugs?

The response was "yes".

Mr. Inafuku stated that this may change and the provisions are there to allow access.

**Articles from Other State Boards of Pharmacy's Newsletters**

Kentucky

Regulation Update 2012, Computerized Recordkeeping

The Chair reported that the Kansas Board of Pharmacy included new regulations requirements for computerized recordkeeping, that included the length of time a prescription must be maintained, requirements of the computer system and that a computer malfunction or data processing services provider's negligence shall not be a defense against charges of improper recordkeeping.

North Dakota

Students Graduating and Seeking Licensure

The Chair stated that North Dakota reported that they will have one of the highest amounts of graduating students that have applied for the license in recent years and that the national trend of pharmacist employment has quickly changed from the shortage, just five years ago, to the current surplus of pharmacists.

The EO asked Dr. Ma about the UH Hilo College of Pharmacy graduates and if the college assist their graduates in job placement.

Dr. Ma stated that the UH Hilo College of Pharmacy holds job fairs and posts job openings on their website.

The Vice Chair stated that about 50% of the graduates return to their home state/country.

Dr. Ma also stated the industry is saturated so much that it is affecting the students, residency programs.

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

The Chair reported that according to the National Pharmacy Compliance News, there was an article from the Institute for Safe Medication Practices regarding how patients and practitioner have become desensitized to change in medication appearance and that pharmacies may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. The Chair noted that Hawaii does not require the description of the shape, color or imprint code of the medication to be indicated on the label.

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

The Chair stated that the FDA is encouraging health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the U.S. There are concerns that due to the drug shortage, especially of injectable cancer medications, there may be an opportunity for "unscrupulous" individuals to introduce non-FDA approved products into the drug supply.

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

The Chair stated that a report prepared by the Office of the Chief Pharmacist, US Public Health Services, calls for support of pharmacist-delivered patient care models.

Prescription Drug Repository Program

The Chair stated that North Dakota reported on their "Prescription Drug Repository Program", in operation since 2007, that allows for the collection and distribution of unused medications so that pharmacies and physicians can dispense them to those who need them.

The EO stated that HRS Chapter 461 had a section that would allow a pharmacy to take back drugs from an institutional facility that met certain criteria, to be redispensed and that HRS Chapter 328C addresses donations.

Mr. Inafuku stated that Hawaii has a Good Samaritan law.

Mr. Edwards indicated that HRS 328B was amended to repeal the section regarding "reuse".

The Chair recommended this be deferred to the Laws & Rules Committee ("Committee").  
Vermont

Institutional Chart Orders Not Valid for Outpatients

The Chair reported that the Vermont Board of Pharmacy sent a reminder to their pharmacists that it was unacceptable to fill prescriptions off a chart order from a medical institution for a patient who has been discharge from a hospital, nursing home, or correctional facility. He also stated that the Committee is in the process of defining "chart order" and recommended this be referred to the Committee.

#### Wyoming – Keeping Prescribers in the Loop

The Chair stated that the Wyoming Board of Pharmacy reported that they have received complaints from patients about pharmacies dispensing different medications than what they had been taking previously or what the prescriber had told them and that due to the increasing number of drug shortages, many pharmacists have had to substitute a higher strength or lower strength of the same medication, but have not been consulting the prescriber when the switch is made. The Board encourages the pharmacists to consult with the prescriber and to document the consultation on the prescription and more importantly, the patient should be counseled on the change so that he/she is taking the proper dose.

#### Honing in on Compounding Regulations

The Chair stated that the Wyoming Board of Pharmacy also included an article on their regulations regarding pharmacy compounding.

#### **Hawaii Regulations on Blood Tests**

The Chair asked Dr. Ma to lead the discussion on this inquiry.

Dr. Ma read the email inquiry asking if Hawaii pharmacists can conduct blood tests (e.g. A1C, Glucose, Cholesterol) and administer injections in a pharmacy setting (e.g. B12, RA, hormone therapy shots).

The Vice Chair stated that pursuant to HRS 461-1, under the definition of "Practice of pharmacy", states, (2) Performing the following procedures or functions as part of the care provided by and in concurrence with a "health care facility" and "health care service" as defined in section 323D-2, or a "pharmacy" or a licensed physician, or a "managed care plan" as defined in section 432E-1, in accordance with policies, procedures, or protocols developed collaboratively by health professionals, including physicians and surgeons, pharmacists, and registered nurses, and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols: (D) Administering drugs orally, topically, by intranasal delivery, or by injection, pursuant to the patient's licensed physician's order, by a pharmacist having appropriate training that includes programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board of pharmacy; and that based on this definition, it appears that pharmacist may administer injections.

The Vice Chair stated that this section appears to be broad enough to allow the Board to interpret it to allow for pharmacists to administer injectables.

Dr. Ma stated that HRS 461-1(2)(A) under the definition of "Practice of pharmacy" would also appear to allow a pharmacist to perform routine drug therapy related patient assessment procedures and (2)(B) allows a pharmacist to order drug therapy related laboratory tests.

Mr. Inafuku stated that this may not be what this section intended and that perhaps the Board should adopt administrative rules to clarify.

After some discussion, upon a motion by the Vice Chair, seconded by Dr. Ma, it was voted on and unanimously carried that it is the Board's informal interpretation that a Hawaii pharmacist may order or perform routine drug therapy related patient assessment procedures and administer injections, pursuant to the patient's licensed physician's order, by a pharmacist having appropriate training, pursuant to HRS 461-1, definition of "Practice of pharmacy" (2)(A), (B) and (D).

This is an informal interpretation for informational and explanatory purposes only and is not an official opinion or decision and therefore is not to be considered binding on the Board.

#### **Surescripts: Update on Industry Progress in Implementing Electronic Prescribing for Controlled Substances**

A copy of an update on industry progress in implementing electronic prescribing for controlled substances prepared by Surescripts was distributed to the Board members for their information.

#### **Letter from Suzie Maria Ohlen Regarding Prescriptions by Dr. Sian Evans**

The Chair asked the Vice Chair to lead the discussion on Ms. Ohlen's letter.

The Vice Chair read Ms. Ohlen's letter in which she stated that pharmacies on Kauai are refusing to fill prescriptions written by her physician whose practice is dedicated to pain management for no good medical reason. Ms. Ohlen asks why are pharmacies allowed to withhold medication from patients and why are pharmacies being allowed to run her (physician) out of town against the patient's wishes when they don't have a reason to refuse her doctor's scripts? She stated that because pharmacies on Kauai are refusing to fill the physician's prescription, legitimate patients with legitimate chronic pain are being denied access to the medication that they need in order to live comfortably and are flying to another island to get their prescriptions filled. She asks the Board to make the pharmacies on Oahu fill prescriptions from her physician.

The Vice Chair stated that the DEA has raided pharmacies and levied fines against wholesalers in an effort to block the diversion of prescription drugs (controlled substances).

The DAG stated that the DEA has guidelines.

The Vice Chair referred to quotas for controlled substances that are monitored by the DEA through the wholesaler.

Mr. Inafuku said he thinks the bottom line question is does a pharmacist have to fill a prescription presented to them and that the pharmacy laws and rules do not require this. He also referred to HRS 329-38.

The Chair referred to the professional judgment by a pharmacist when filling a prescription.

After some discussion, upon a motion by the Vice Chair, seconded by Dr. Ma, it was voted on and unanimously carried that it is the Board's informal interpretation that a pharmacist must use their professional judgment in filling a prescription that includes the responsibility for determining the effectiveness of a prescription for a controlled substance pursuant to HRS 329-38(f)(1).

Mr. Inafuku requested that this letter be referred to the DPS-NED.

The EO also asked the Board if they would like someone from the DPS-NED and DEA to attend a Board meeting so that they can respond to questions. The Board agreed.

### **Administration of Non-immunization Drugs by a Pharmacist**

The Chair asked Mr. Lau to lead the discussion on this inquiry.

Mr. Lau read the email from a student at the UH Hilo College of Pharmacy in which she asks if a pharmacist can administer non-immunization injections in a retail setting if so, is a special type of license or other requirements necessary.

It was the consensus of the Board to inform the student of HRS 461-1(2)(D).

### **Ivy Home Infusions, an Alaska Licensed Pharmacy, Distributing Blood Products to Westside Pharmacy, a Hawaii Pharmacy**

The EO stated that before the Board discussed this next inquiry, she had additional information regarding the out-of-state entity that would be pertinent in the Board's discussion. She stated that she checked with the Alaska Board of Pharmacy on Ivy Home Infusions and was informed that this particular pharmacy located in Alaska fell under one of their wholesale exemptions and could distribute blood products. She further stated that previously, the entities involved were not wholesalers or exempt from the wholesale licensing requirements. So it appears that in this case, Ivy Home Infusions may distribute blood products to a Hawaii pharmacy, which in turn, would be able to dispense the blood product pursuant to a valid prescription and appropriately labeled pursuant to HRS 328-16.

It was the consensus of the Board to direct the EO to respond to the email inquiry with the information and explanation previously stated.

### **Pharmacies Not Filling APRN-Rx's Prescriptions**

The Chair asked Mr. Inafuku to lead the discussion on this inquiry from an APRN with prescriptive authority (APRN-Rx) of a pharmacy informing her that the pharmacy company "feels" that APRN-Rx's need a collaborative agreement in order to prescribe controlled substances and until one is on file, they will not fill any prescriptions for schedule II and IIN medications.

After some discussion, it was the consensus of the Board to inform the APRN-Rx of the joint meeting planned between representative of the Board of Nursing and the Board to discuss and clarify the APRN-Rx's scope of practice for pharmacists.

It was also recommended that the EO contact the pharmacy to clarify if their company is requiring a collaborative agreement in order to fill a prescription for schedule II or IIN for APRN-Rxs.

#### **Article, "U.S. war on drugs moves to pharmacy from jungle"**

The Chair shared an article regarding DEA's efforts to block the diversion of prescription drugs to the black market, using many of the techniques it employs to combat illegal drug use, including wire taps, undercover operations and informants.

#### **Pre-printed Prescription Pads for Medical Device**

The Chair asked Ms. Kumasaka to lead the discussion.

Ms. Kumasaka read the email inquiry in which they ask if a device can be pre-printed on prescription pads.

Dr. Ma stated that the laws and rules do not specifically address pre-printed prescriptions but HAR 16-95-82 does list the requirements for a valid prescription.

#### **Questions on Hawaii Compounding Laws**

The Chair read the email inquiry from a pharmacy student at the University of New Mexico asking:

1. What are the state laws in Hawaii pertaining to "office use" for sterile and non-sterile compounding? Can pharmacies in Hawaii compound preparations in advance that prescribers can use in their office without a patient-specific prescription for either (or both) sterile and non-sterile compounds?
2. Has Hawaii recently amended their laws so that compounding pharmacies may help with the drug shortage crisis?

Mr. Inafuku stated that HRS 461-15 under the miscellaneous permit, (a)(6) states, "For any person, as principal or 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;".

The Vice Chair stated that pharmacies may not compound a product unless they have a patient specific prescription.

Mr. Inafuku stated that a miscellaneous permit holder who compounds will still be subject to FDA requirements.

The Vice Chair stated it's compounding vs. manufacturing. A compounded product is manufacturing but a pharmacist may compound a product pursuant to a patient specific prescription and that compounding for office use is considered manufacturing.

That was the consensus of the Board.



### **Medical Devices**

The Chair read an email regarding medical device supplies. In an email from Ms. McGowan questioning why the electrodes for the Bioness L300 wearable electrical stimulation device cannot be delivered directly to her residence. She was informed by the company that they must send the electrodes to the doctor or therapist since they are considered a prescription device. Ms. McGowan asks if there have been any reported problems with sending the electrodes directly to the end user and if not this change in procedure serves no benefit.

After some discussion, it was the consensus of the Board to refer this email to the Laws and Rules Committee.

### **National Community Pharmacists Association Article, "I Have Met an Enemy, and It Is Us?"**

A copy of this article was distributed to the Board members for their information.

### Old Business:

#### **HAR Title 16, Chapter 95 – Status Report**

The EO reported that she is still working on the justification but hope to have it completed and sent to the Licensing Administrator, Director and DAG before the next Board meeting.

#### **Approved APRN-Rx for Controlled Substances – Joint Meeting with the Board of Nursing**

The EO reported that the next Board of Nursing meeting is on July 12, 2012.

After some discussion, it was the consensus of the Board to move their July 19<sup>th</sup> meeting to **July 12<sup>th</sup> at 1:00 p.m.** and the joint meeting between the Board of Nursing and the Board of Pharmacy will be scheduled for **July 12, 2012 from 11:00 a.m. – 12:00 p.m.** Dr. Ma said she would not be available for the July meeting. Ms. Kumasaka and Mr. Lau said they would check their schedules. The Chair, Vice Chair and Mr. Inafuku stated they would be available.

Mr. Lau also stated that he would prefer the Vice Chair be one of the representatives for the Board since he brought up the issue.

There being no objections, it was the consensus of the Board to reschedule the July meeting and to amend the representatives for the joint meeting as follows:

Joint meeting with representatives from the Board of Nursing, July 12, 2012, 11:00 a.m. – 12:00 p.m., representing the Board: the Chair, Ms. Kumasaka and the Vice Chair.

Board meeting is rescheduled to July 12, 2012, 1:00 p.m.

### **Issuing of a Pharmacy Permit Number Prior to the Pharmacy Submitting a Complete Application**

The EO stated that she has been unable to complete the research on the NCPDP, DEA and NED process.

Open Forum: None.

Applications: **Ratification List**

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

Executive Session: At 11:08 a.m., upon a motion by Dr. Ma, 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 11:15 p.m. upon a motion by the Vice Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to move out of executive session.

### Miscellaneous Permit

#### **RX Remote Solutions, Inc.**

Upon a motion by Dr. Ma, seconded by Ms. Kumasaka, it was voted on and unanimously carried to defer the application for miscellaneous permit as an out-of-state pharmacy for more information pertaining to the director of pharmacy and further clarification of the activities of the pharmacy.

Chapter 91, HRS, Adjudicatory Matters: At 11:15, the Chair called for a recess from the Board's meeting to discuss and deliberate on the following adjudicatory matter, pursuant to Chapter 91, HRS:

#### **Dennis R. Birk, PHA 2008-38-L, Board's Final Order; Hearings Officer's Findings of Fact; Conclusions of Law and Recommended Order; Errata; Proposed Monitoring Plan**

The Chair recused himself.

Upon a motion by Mr. Inafuku, seconded by the Vice Chair, it was voted on with the Vice Chair, Mr. Inafuku, Dr. Ma, Mr. Lau and Ms. Kumasaka voting yes to request additional information for the Board's consideration in regards to his compliance with the Board's Final Order.

Next Meeting: Thursday, July 12, 2012 – New Date  
1:00 p.m. – New Time  
**Exam Conference Room – New Room**  
King Kalakaua Building, **Third** Floor  
335 Merchant Street  
Honolulu, Hawaii 96813

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 11:26 a.m.

Taken and recorded by:

/s/ Lee Ann Teshima  
Lee Ann Teshima  
Executive Officer

6/25/12

[ ] Minutes approved as is.

[ X ] Minutes approved with changes; see minutes of 7/12/12

## BOARD OF PHARMACY

June 21, 2012 Ratification List

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### **Miscellaneous Permits (PMP)**

#### Change of PIC:

#### **Acro Pharmaceutical Services LLC (PMP 626)**

New PIC: Renee Licwinko

#### **CuraScript, Inc. (PMP 522)**

New PIC: Arpan Pravin Patel

#### Closure:

#### **Coram Healthcare Corporation of Northern California (PMP 555)**

9332 Tech Center Drive, Suite 100

Sacramento, CA 95826

**Effective: 5/30/2012**

#### **Option Care Enterprises Inc. (PMP 723)**

1989 Palomar Oaks Way, Ste. A

Carlsbad, CA 92001

**Effective: 5/23/2012**

### **Pharmacy (PHY)**

#### New PIC:

#### **Wal-Mart Stores Inc., dba Wal-Mart Pharmacy #10-2314 (PHY 587)**

New PIC: Joseph Parriott

#### **Walgreen of Hawaii LLC (PHY 817)**

New PIC: Paul Smith

#### **Wal-Mart Stores Inc., dba Wal-Mart Pharmacy #310-3883 (PHY 810)**

New PIC: Ji Yeun Ku

#### **Kmart Corporation, dba Kmart Pharmacy #9430 (PHY 611)**

New PIC: Lea Anna Trujillo

#### **Longs Drug Stores of California LLC, dba Longs Drugs #9988 (PHY 745)**

New PIC: Kara Tsukamoto

**BOARD OF PHARMACY**  
**June 21, 2012**  
**RATIFICATION LIST**

**PHARMACIST LICENSE as of June 13, 2012**

**LIC**

**LTYPE NUM BP NAME PART 1**

PH 3352 KAREN C <YEE<  
 PH 3353 BETTY J <LYMAN<  
 PH 3354 SUSAN J <SCHROEDER<

**PHARMACY as of Monday, June 13, 2012**

**LIC**

**LTYPE NUM LIC NAME PART 1**

PMP 773  
 PMP 774  
 PMP 775 AMBER PHARMACY  
 PMP 776  
 PMP 777  
     RETAIL PHARMACY  
 PMP 778 CUSTOMER CARE CENTER

**BUSN ADDR 1**

11120 S CROWN WAY STE 11  
 2354 COMMERCE PARK DR STE 100  
 10004 S 152ND ST STE A  
 1234 LAKESHORE DR #200  
 262 DANNY THOMAS PL  
 2100 HIGHLAND CORPORATE PK DR

**BUSN CITY**

WELLINGTON  
 ORLANDO  
 OMAHA  
 COPPELL  
 MEMPHIS  
 CUMBERLAND

**BUSN**

**BUSN**

**ST**

**ZIP**

**BP NAME PART 1**

FL 33414 WELLS PHARMACY NETWORK LLC  
 FL 32319 PRIME THERAPEUTICS SPECIALTY PHARM  
 NE 68138 AMBER ENTERPRISES INC  
 TX 75019 DAVITA RX LLC  
 TN 38105 ST JUDE CHILDREN'S RESEARCH HOSPIT  
 RI 02864 CVS RX SERVICES INC