

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

MINUTES OF MEETING

Date: Thursday, August 16, 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
Garrett Lau, Pharmacist
Carolyn Ma, Pharmacist

Excused: Lydia Kumasaka, Public Member
Jill Oliveira Gray, Public Member

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

Guests: Jason Okazaki, UH Hilo College of Pharmacy
Keiko Hiraoka, Lilly
Stacy Pi, Kaiser Permanente
Marcella Chock, Hawaii Pharmacist Association ("HPhA")
Paul Smith, Walgreens
Ryan Gaspar, UH Hilo College of Pharmacy
Albert Lau, Kaiser Permanente
Thomas Bodendorfer

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 9:05 a.m.

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

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

Additions and Additional Distribution

None.

Approval of the Previous Minutes – July 12, 2012 Meeting

The Chair stated that on page 2, under Correspondence, it should read “NCPA Guide to Supreme Court Ruling on Health Reform Law...”.

The Chair then called for a motion for the minutes of the July 12, 2012 meeting.

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

Vice Chair's Report:

None.

Correspondence:

National Association of Boards of Pharmacy (“NABP”)

NABP State News Roundup, July 2012

The Chair reported on the following:

“Louisiana Board Adopts New Rules Related to Pharmacy Practice”

The Louisiana Board of Pharmacy reported that effective May 20, 2012, they have adopted new rules related to pharmacist-in-charge requirements, cognitive services, hospital and penal pharmacies, and remote order processing.

“Minnesota Board to Require Pharmacy Technician Training for Registration”

Effective January 1, 2014, the Minnesota Board of Pharmacy will not renew the registration of a pharmacy technician unless the individual has completed a pharmacy technician training program.

“Oklahoma to Classify Tramadol and Tramadol-Containing Products as Schedule IV”

Effective November 1, 2012, tramadol and all tramadol-containing products will be classified as a Schedule IV in the State of Oklahoma.

“Virginia Legislature Reports Updates to PMP”

Effective July 1, 2012, the method of payment for a controlled substance prescription has been added as a required element for report to the PMP (prescription monitoring program). In addition, the Code of Virginia was also updated to remove the restriction on how many licensed health care professionals a prescriber could designate to serve as a delegate.

“Washington Pharmacies Now Have Authority to Dispense Prescriptions Written by Out-of-State Licensed ARNPs”

As of June 7, 2012, Washington pharmacies can dispense controlled substance prescriptions written by ARNP licensed in another state. The prescription must be within the ARNP's scope of practice and does not apply to Canadian licensed ARNPs since Canadian practitioners do not hold a registration from the US DEA.

"West Virginia Board Expands List of Vaccines Pharmacist Can Administer"

The West Virginia Board of Pharmacy went through a joint rulemaking with the Board of Medicine and the Board of Osteopathy to amend its rules to allow for four more vaccines that pharmacists can administer: flu; pneumonia; Hepatitis A; Hepatitis B.; Herpes Zoster; and Tetanus, Tetanus-Diphtheria, and Tetanus-Diphtheria-Pertussis vaccines. The Board notes that pharmacists do not have to have a prescription and can follow the Centers for Disease Control and Prevention protocols.

"New Legislation Prompts Changes to West Virginia's Rules on its Controlled Substances Monitoring Program and Pseudoephedrine Sales"

New provisions require pharmacies and their staff to report all dispensings of Schedule II-IV controlled substance prescriptions to the Controlled Substances Monitoring Program within 24 hours, requires filing "zero" reports if a pharmacy does not have any dispensings within 24 hours, limits the amount of grams a person may purchase in any 30-day period to 7.2 grams (pseudoephedrine) and on every sale of pseudoephedrine products from behind the counter, an offer to counsel the purchaser must be given.

Nevada State Board of Pharmacy – Diversion of Controlled Substances within a Pharmacy, Medical Spas

The Board recommends pharmacies establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances as they note that pharmacy technicians have been diverting controlled substances.

The Board has investigated several consumer complaints involving medical spa facilities and have found illegal drugs purchased from foreign countries or other state and also counterfeit drugs. They have also found that these dangerous drugs are being purchased, administered and dispensed by people with no authority or license to do so. They have also found that some of these facilities are buying drugs from local pharmacies.

West Virginia Board of Pharmacy – Expansion of Pharmacist Immunizations, Animal Drug Product Added as Approved Generic Substitute

The Chair previously reported on West Virginia's expansion of pharmacists immunizations.

In regards to the animal drug product, West Virginia, an *Orange Book* state for generic substitution, like Hawaii, reported that pursuant to West Virginia law, the board approved a request to add PetTrust Plus Chewable Tablets as an acceptable generic substitute for Tri-Heart Plus and Heartguard Plus Chewable Tablets.

Shipping Prescription Medications to Dialysis Patients

This matter was deferred from the July 12, 2012 meeting for more information.

The original inquiry from Tony J. Park:

"My client is a registered out-of-state pharmacy who specializes in servicing the needs of kidney dialysis patients.

As part of its overall prescription services offered, it would like the option of shipping prescription medications to dialysis patients that want the convenience of having all their medications shipped and stored in the dialysis clinic that they visit multiple times every week.

Is this practice acceptable to the Board?"

The Chair asked the Vice Chair to lead the discussion on this issue.

The Vice Chair reported that Mr. Park clarified that his client would ship/dispense an already-filled prescription by an out-of-state mail order pharmacy to the patient pursuant to the patient's request to have their prescriptions mailed to the dialysis clinic for the clinic to hold until the patient's next dialysis appointment and that some of the drugs are for non-dialysis purposes.

The Vice Chair also stated that about a year ago, the Board considered a request by a mail order pharmacy to ship prescription drugs to other than the patient and that the Board determined that was not allowed. He added that his concern in this case would be a storage issue and counseling.

Mr. Lau stated that in 2006, he thought the Board allowed the patient to specify a person but at that time, there was no discussion on the storage of the drugs.

The Chair asked once the drugs are delivered, is the pharmacy responsible on how it is stored?

The Vice Chair stated that he was also concerned with the out-of-state pharmacy "dictating" which dialysis clinic they would mail the patient's drugs to.

Dr. Ma stated that this is not a pharmacy to pharmacy transfer and that patient safety should be the issue, not competition.

Mr. Inafuku stated that there is a distinction between mail order and out-of-state pharmacy and that we should also consider the dialysis center as an institutional facility that is able to properly store prescription drugs.

The Vice Chair stated that he thinks there is a difference if shipping prescription drugs to a dialysis center for the patient and not for administration.

Mr. Inafuku stated that he believes the dialysis center meets the definition of an institutional facility.

The Chair asked the audience if they he would anything to add to the discussion. There being none, upon a motion by the Vice Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to inform Mr. Park that based on the definition of "institutional facility" in HRS 461-1 and HAR 16-95-2 and "Dispense" or "dispensing" in HAR 16-95-2, if his client is an out-of-state pharmacy, who holds a miscellaneous permit as an out-of-state pharmacy, they may dispense/ship prescription drugs for a specific patient/individual to the dialysis center for the patient to pick up while having dialysis treatment. Furthermore, the

dispensing of prescription drugs shall be in accordance with all prescription and labeling requirements of HRS chapters 461 and 328 and HAR 16-95. This determination does not apply to the dispensing of any controlled substances.

This is an informal interpretation based solely on the information provided and is for informational and explanatory purposes only and is not an official opinion or decision and therefore, not to be viewed as binding on the Board.

Prescription Drug Wholesale Distributor Selling Drugs to a Clinical Lab

The Chair asked Mr. Lau to lead the discussion on an inquiry from Jennifer Bowers of Cardinal Health asking what sort of license would a wholesale drug distributor need to obtain from a clinical lab to sell prescription drugs to that lab?

After some discussion, it was the consensus of the Board to refer the inquiry to Greg Edwards of the Department of Health, Food and Drug Branch, since HRS chapter 328 addresses prescription drug wholesale distributors.

Regulation of Wholesalers of Medical Foods

The Chair asked Dr. Ma to lead the discussion on the inquiry from Cynthia Johnson asking if the Board regulates wholesalers of medical foods, if so what license is required.

After some discussion, it was the consensus of the Board to refer the inquiry to Greg Edwards of the Department of Health, Food and Drug Branch to see if HRS chapter 328, the Food, Drug and Cosmetics Act, addresses this issue.

Pharmacy Consultation by Out-of-State Pharmacist

The Chair asked Mr. Inafuku to lead the discussion on the inquiry from Marko Stankovic in which he asks if our state allows out of state pharmacists to conduct phone consultation with residents of our state and that this activity would not be in any way linked to medication dispensing. Mr. Stankovic further clarified that the pharmacist would be conducting medication therapy management ("MTM") assessment via phone that would include discussion on medications that patient is currently taking (indication, side effects, drug-drug interactions, etc.), compliance with current drug therapies, general health assessment and education (diabetes, HTN, etc.)

After some discussion, upon a motion by Mr. Inafuku, seconded by the Vice Chair, it was voted on and unanimously carried that it is the Board's informal interpretation that the pharmacist who only performs telephone consultation with residents of this State, must be licensed as a Hawaii pharmacist and that no drugs may be dispensed by that pharmacist.

This is an informal interpretation based solely on the information provided and is for informational and explanatory purposes only and is not an official opinion or decision and therefore, not to be viewed as binding on the Board.

Pharmacy Consultation by Out-of-State and Out-of-Country Prescribers

The Chair asked Mr. Lau to lead the discussion on the inquiry from Mr. Khan asking if pharmacists in Hawaii are allowed to take prescriptions written by prescribers from a different state and if pharmacists in Hawaii are allowed to transfer prescriptions to and from another state and if pharmacists in Hawaii are allowed to fill prescriptions written by a prescriber from Canada, Mexico or other country.

After some discussion, upon a motion by Mr. Inafuku, seconded by the Vice Chair, it was voted on and unanimously carried to inform Mr. Khan that HRS section 328-17.6 defines an out-of-state practitioner and that HRS Chapter 328 and HAR 16-95 also addresses transferring of prescriptions between pharmacies and that his inquiry will be referred to Greg Edwards, Department of Health, Food and Drug Branch, who has the authority over HRS Chapter 328.

FDA Statement on Compounding of Pergolide Products for Animal Use

Information was distributed to the Board members for their information.

Limited TB Stock Meds for Neighbor Island PHN Clinics

The Chair asked Mr. Inafuku to lead the discussion on the inquiry from Lynn Donovan, pharmacist for the State Department of Health, TB Branch Pharmacy asking if they would be allowed to transfer stock bottles of TB medication to the public health nurses on the neighbor islands at the TB Branch clinics for physician dispensing.

After some discussion, it was the consensus of the Board that based solely on the information provided, it would appear that the distribution of the stock bottle of TB medications to the neighbor island TB clinics may be considered an intracompany sales under HAR 16-95-2(1), under the definition of "Wholesale distribution".

This is an informal interpretation based solely on the information provided and if for informational and explanatory purposes only and is not an official opinion or decision and therefore, not to be viewed as binding on the Board.

Electronic Prescriptions Filing

The Chair asked the Vice Chair to lead the discussion on the inquiry asking if electronic prescriptions (e-scripts) which can be printed out on demand, can be kept electronically rather than printing out and filing the prescriptions.

After some discussion, it was the consensus of the Board that based solely on the information provided, HAR section 16-95-94, records of dispensing may be maintained using an automated data processing system.

This is an informal interpretation based solely on the information provided and if for informational and explanatory purposes only and is not an official opinion or decision and therefore, not to be viewed as binding on the Board.

Remote Dispensing Pharmacy

The Chair asked Mr. Lau to lead the discussion on the inquiry from a group of pharmacists and doctors interested in providing pharmacy services through remote dispensing machines. In the email inquiry submitted, the practice is based on urgent care where they service patients with acute symptoms but does not require them to go to the ER. They had reviewed HRS section 461-10.5 but questioned whether an urgent care clinic qualified (institutional facility).

After some discussion, it was the consensus of the Board that based solely on the information provided, an urgent care clinic may fall under the definition of "institutional facility" and that compliance with HRS section 461-10.5 would apply, including section 461-10.5(c).

Old Business:

HAR Title 16, Chapter 95 – Status Report

Mr. Inafuku gave the following report on the Laws and Rules Committee's discussion on HRS 461:

- Corrections to the first draft of the definitions section;
- Committee would like more feedback in regards to the first draft of the definitions section;
- Discussion of definition of "Collaborative agreement"; and
- Changes/Additions to the Advisory Committee

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

The EO reported that she is still working on the draft and hopes to get it to the joint working group by the end of the month.

Open Forum:

The Chair asked the audience if they had anything they wanted to discuss.

Ms. Chock asked if the Board was disseminating the information on the new immunization law.

The EO stated that she is working on FAQ's based on the Board's previous discussion and that a list should be posted shortly of pharmacists who have submitted proof of their immunization training and wish to immunize minors between the age of 14 and 17 and the pharmacy they are affiliated with so that the public can locate the pharmacy and pharmacist.

Applications:

Ratification List

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

Executive Session:

At 10:49 a.m., upon a motion by Dr. Ma, seconded by Mr. Inafuku, 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 11:19 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.

Pharmacist

Thomas Bodendorfer – Deferred from July 12, 2012 Meeting

Upon a motion by the Vice Chair, seconded by Mr. Lau, it was voted on with the Chair, Vice Chair, Mr. Lau and Dr. Ma voting "yes" and Mr. Inafuku voting "no", to uphold the Board's previous decision to deny the application for Mr. Bodendorfer. The motion carried.

Roger Ly

Upon a motion by Mr. Inafuku, seconded by Dr. Ma, it was voted on and unanimously carried to deny the application for Mr. Ly based on the information provided and pursuant to the following sections:

HAR §16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit. (a) In addition to any other acts or conditions provided by law, the board may revoke, suspend, refuse to renew or restore, deny, or condition a license or permit for any one or more of the following acts or omissions:

- (11) Professional misconduct, gross carelessness, or manifest incapacity;
- (12) Violation of any state or federal drug, controlled substance, or poison law;

HRS §461-21 **Disciplinary action.** (a) In addition to any other actions authorized by law, the board shall have the power to deny, revoke, or suspend any license or permit applied for or issued by the board in accordance with this chapter, and to fine or otherwise discipline a licensee or permit holder for any cause authorized by law, including but not limited to the following:

- (2) Professional misconduct, gross carelessness, or manifest incapacity;
- (5) Violation of any state or federal drug, controlled substance, or poison law;

HRS §436B-19 **Grounds for refusal to renew, reinstate or restore and for revocation, suspension, denial, or condition of licenses.** In addition to any other acts or conditions provided by law, the licensing authority may refuse to renew, reinstate or restore or may deny, revoke, suspend, or condition in any manner, any license for any one or more of the following acts or conditions on the part of the licensee or the applicant thereof:

- (5) Procuring a license through fraud, misrepresentation, or deceit;
- (7) Professional misconduct, incompetence, gross negligence, or manifest incapacity in the practice of the licensed profession or vocation;
- (12) Failure to comply, observe, or adhere to any law in a manner such that the licensing authority deems the applicant or holder to be an unfit or improper person to hold a license;
- (13) Revocation, suspension, or other disciplinary action by another state or federal agency against a licensee or applicant for any reason provided by the licensing laws or this section;

Miscellaneous Permit

Evergreen Pharmaceutical LLC, dba Bridgeport Pharmacy Services

Upon a motion by the Vice Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to approve the miscellaneous permit as an out-of-state pharmacy for Evergreen Pharmaceutical LLC, dba Bridgeport Pharmacy Services.

Chapter 91, HRS,
Adjudicatory Matters:

At 11:19 p.m. 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:

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

The Chair recused himself.

Upon a motion by the Vice Chair, seconded by Dr. Ma, it was voted on and unanimously carried to request that documentation be submitted for the Board's consideration at their September 20, 2012 meeting, including but not limited to a "current" letter from Mr. Birk's counselor and/or other persons involved with Mr. Birk's compliance with the Board's Final Order.

**In the Matter of the Pharmacist's License of Jodi M. Miller, PHA 2008-11-L,
Compliance with Board's Final Order**

Mr. Lau recused himself.

It was the consensus of the Board to refer this matter to the Regulated Industries Complaints Office for possible noncompliance with the Board's Final Order.

Following the Board's review, deliberation and decision on these matters, pursuant to Chapter 91, HRS, the Chair announced that the Board was reconvening its scheduled meeting at 12:00.p.m.

Next Meeting: Thursday, September 20, 2012
9:00 a.m.
King Kalakaua Conference Room
King Kalakaua Building, First Floor
335 Merchant Street
Honolulu, Hawaii 96813

The Chair and Mr. Inafuku stated that they would not be able to attend the September 20, 2012 meeting.

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 12:03 p.m.

Taken and recorded by:

/s/ Lee Ann Teshima
Lee Ann Teshima
Executive Officer

8/31/12

Minutes approved as is.

Minutes approved with changes; see minutes of _____

BOARD OF PHARMACY

August 16, 2012 Ratification List

Miscellaneous Permits (PMP)

Change of PIC:

Liberty Healthcare Pharmacy of Nevada LLC (PMP 498)
6225 Annie Oakley Dr., #100
Las Vegas, Nevada 89120
New PIC: Corey Johnson

New Trade Name:

Great Lakes Medical Supply, LLC
dba Brightsky (PMP 732)

Relocation:

Medfusion Rx LLC (PMP 488)
New location: 1100 Lee Branch
Birmingham, Alabama 35242

Pharmacy (PHY)

Change of PIC:

Caremark Hawaii Mail Pharmacy LLC (PHY 811)
2969 Mapunapuna Pl, Ste. 110
Honolulu, Hawaii 96819
New PIC: Steven Aun

Longs Drug Stores California LLC, dba Longs Drugs #4405 (PHY 815)
95-1077 Ainamakua Drive
Mililani, Hawaii 96789
New PIC: Anne Kimura

Closure:

Hawaii IRX LLC, dba Hawaii Ascend Pharmacy (PHY 782)
1035 Kikowaena Place
Honolulu, Hawaii 96819

Wholesale Distributor (PWD)

Closure:

BOARD OF PHARMACY
August 16, 2012
RATIFICATION LIST

PHARMACIST LICENSE as of August 2, 2012

<u>LIC</u>		
<u>LTYPE</u>	<u>NUM</u>	<u>BP NAME PART 1</u>
PH	3360	TRACY K <TOY<
PH	3361	SHELBY M <MIZUMOTO<
PH	3362	ALEXANDRA M <PEREZ<
PH	3363	AMY E <HARVEY<
PH	3364	AMY H <SONG<
PH	3365	LAURA A <GARZA<
PH	3366	BRIAN K <NIIMI<
PH	3367	LESLIE A <RODRIGUEZ<
PH	3368	EMILY A <SPARKS<
PH	3369	JONATHAN V <DOSS<
PH	3370	JENNIFER L <MATTOON<
PH	3371	JANA K <ENOKAWA<
PH	3372	PAULA M <HEDIN<
PH	3373	SEFERINA K <MILEY<
PH	3374	STACIE E <KUKINO<
PH	3375	KELLY P L <KWOK<
PH	3376	CINDY <TRINH<

PHARMACY INTERN PERMIT as of August 2, 2012

<u>LIC</u>		
<u>LTYPE</u>	<u>NUM</u>	<u>BP NAME PART 1</u>
PHI	3205	SARA S <KUMUSAKA<
PHI	3206	CHELSIE H <NEVES<
PHI	3207	DIANE M <BANET<
PHI	3208	ALYCIA M <HATASHIMA<
PHI	3210	ERIN M <YAMASAKI<
PHI	3211	WILDER M <MCANDREWS<
PHI	3212	KAILANI B <NAKANISHI<
PHI	3213	KIMBERLY K <HO<
PHI	3214	PHUNG C <DANG<
PHI	3215	LAUREN H <OOKA<
PHI	3216	DALJINDER K <SIDHU<
PHI	3217	LINDA <TRINH<
PHI	3218	KIM N <TRAN<
PHI	3219	NICOLE M <WILSON<

**BOARD OF PHARMACY
August 16, 2012
RATIFICATION LIST**

PHARMACY MISCELLANEOUS PERMIT as of August 2, 2012

<u>LTYPE</u>	<u>LIC</u> <u>NUM</u>	<u>LIC NAME PART 1</u>	<u>BUSN ADDR 1</u>	<u>BUSN CITY</u>	<u>BUSN</u> <u>ST</u>	<u>BUSN</u> <u>ZIP</u>	<u>BP NAME PART 1</u>
PMP	788		3951 HAVERHILL RD N #120-121	WEST PALM BEACH	FL	33417	UNITED PHARMACY LLC
PMP	789		4545 E CHANDLER BLVD #100	PHOENIX	AZ	85048	FOOTHILLS PROFESSIONAL PHARMACY LT
PMP	790	TRUAX PATIENT SERVICES	602 BELTRAMI AVE NW STE 105	BEMIDJI	MN	56601	BRIAN W <TRUAX<
PMP	791	DAILYMED PHARMACY	9320 PRIORITY WAY WEST DR	INDIANAPOLIS	IN	46240	MEDICAL ADHERENCE SOLUTIONS LLC
PMP	792	BROADWAY APOTHECARY	1515 OAK ST	EUGENE	OR	97401	TRINITY COMPOUNDING PHARMACY INC
PMP	793		1831 COMMERCE ST STE 104	CORONA	CA	92880	ACCREDO HEALTH GROUP INC