

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

MINUTES OF MEETING

Date: Thursday, March 21, 2013

Time: 9:00 a.m.

Place: King Kalakaua Conference Room
King Kalakaua Building
335 Merchant Street, First Floor
Honolulu, Hawaii 96813

Members Present: Patrick Adams, Pharmacist, Vice Chair
Todd Inafuku, Pharmacist
Lydia Kumasaka, Public Member
Carolyn Ma, Pharmacist
Jill Oliveira Gray, Public Member

Excused: Mark E. Brown, Pharmacist, Chair
Garrett Lau, Pharmacist

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

Guests: Paul Smith, Walgreens
Rafael del Castillo, HCPA
Mike Dolson, Unique Pharm
Peter Harty, CVS/Caremark
Greg Edwards, Dept. of Health, Food and Drug Branch
Keiko Hiraoka, Lilly
Stacy Pi, Kaiser Permanente
Lyell Hirschle, Kaiser
Dexter Mar, Ohana Health Plan
Albert Lau, Kaiser Permanente

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 Vice Chair called the meeting to order at 9:05 a.m.

Vice Chair's Report: **Announcements and Introductions**

The Vice Chair asked the audience to introduce themselves.

Additions/Additional Distribution to Agenda

The Vice Chair called for a motion to add the following to today's agenda:

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

Additions

- 5. Correspondence
 - h. Pharmacy technician ratio, Pamela White

- 8. Applications
 - c. Applications – Pharmacy Miscellaneous Permit
 - 1) Diabetic Care Rx, LLC – Request to Remove Condition

Approval of the Previous Minutes – February 8, 2013

The Vice Chair called for a motion in regards to the minutes of the February 8, 2013 meeting.

Dr. Oliveira Gray made the following recommendations:

Page 3, paragraph 9, should read: "Mr. Lau agrees with Mr. McAllister's suggestion to incorporate an attestation onto the miscellaneous permit application that the PIC signs to acknowledge his/her compliance with Hawaii law."

Page 4, paragraph 7, under SB 667 Relating to Health, should read: "The EO reported that this bill requires the registration of and regulates the practices of pharmacy benefit management companies."

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

Executive Officer's Report:

2013 Legislature

The EO reported on the status of the following bills:

SB 971/HB 652 Relating to Remote Dispensing

SB 971 was not heard by any Senate Committees.

HB 652 crossed over to the Senate and was heard by the Senate Health Committee yesterday who made the following recommendations:

1. Prohibit new remote dispensing pharmacies from operating within 10 miles of any pharmacy, except those in operation prior to the effective date; and
2. Extend the repeal date to January 1, 2016

After some discussion, upon a motion by Ms. Kumasaka, seconded by Mr. Inafuku, it was voted on with Ms. Kumasaka, Mr. Inafuku, Dr. Ma and Dr. Oliveira Gray voting "yes" and the Vice Chair voting no to oppose the amendments to HB 652.

HB 61 Relating to Pharmacy

Was not scheduled for hearing by any House Committees.

HB 63 Relating to Pharmacy

Was not scheduled for hearing by any House Committees.

HB 606 Relating to Death with Dignity

Was not scheduled for hearing by any House Committees.

SB 667 Relating to Health

Was not heard by the Senate Judiciary Committee.

HB 723 Relating to Health

Was not scheduled for hearing by any House Committees.

HB 62 Relating to Pharmacy Benefit Managers

Heard by Senate Health Committee which made technical, nonsubstantive amendments for purposes of clarity and consistency. Referred to the Senate Committee on Commerce and Consumer Protection.

HB 65 Relating to Prescription Drugs

Heard by the Senate Committees on Commerce and Consumer Protection and Judiciary, passed out with the following amendments:

1. Requiring affected entities to submit a report to the Legislature no later than twenty days prior to the convening of the Regular Session of 2018; and
2. Inserting an effective date of July 1, 2013 and repeal date of June 30, 2018.

HB 64 Relating to Controlled Substances

Was not scheduled for hearing by any House Committees.

SB 972 Relating to Electronic Prescriptions

Was heard by House Committees on Health and Public Safety, passed out unamended.

Conferences/Meetings/Seminars

National Association of Boards of Pharmacy 109th Annual Meeting, May 18-21, 2013, St. Louis, Missouri

The EO stated that she sent the members the email announcement and only the Vice Chair responded that he was interested in attending.

Upon a motion by Dr. Ma, seconded by Ms. Kumasaka, it was voted on and unanimously carried to elect the Vice Chair to attend the NABP Annual Meeting as the Board's delegate.

Report from Laws & Rules Committee:

Mr. Inafuku reported that the Committee started their review and discussion on the miscellaneous permit categories in HRS 461-15 to determine if the categories are still valid.

Correspondence: **Request from Kentucky Board of Pharmacy on Pharmacy Emergency Preparedness**

The Board discussed and responded to the following questions from the Kentucky Board of Pharmacy:

1. Does the Board of Pharmacy have a pharmacy emergency preparedness program in place?

No, but the Board just adopted some policies and procedures.

2. If so, is there a mobile pharmacy that can be utilized in the event of a disaster?

No.

3. What regulations are in place for both the emergency preparedness program and/or the mobile pharmacy?

No "regulations", Board adopted policies and procedures at their February 8, 2013 meeting.

4. Some states have a pharmacy emergency preparedness program but it falls under the Department of Health or the state pharmacists association? Please indicate if this is the case.

Yes, the Hawaii State Department of Health.

5. Please provide contact name and contact information for the emergency preparedness program.

Mr. Inafuku stated he would forward that information to the EO.

Pre-printed Prescription Pads and Generic Substitution

The Board reviewed and discussed a request from MediScripts regarding pre-printed prescription forms and generic substitution.

MediScripts provided examples of a pre-preprinted generic substitution and prescription for controlled and non-controlled substances for the Board's review.

After some discussion, it was the consensus of the Board to refer MediScripts to Hawaii Administrative Rules §16-95-82 Valid prescriptions, HRS 328-92(b) in regards to drug product selection and to the Hawaii State Department of Public Safety, Narcotics Enforcement Division in regards to controlled substance prescriptions.

Wholesale Distribution Exemption Questions, Lauren Breithaupt

The Board reviewed the following email from Ms. Breithaupt:

"I am contacting you to inquire about some of the exceptions to wholesale drug distribution under the Pharmacy Rules. I would be very grateful if you could assist me.

First, I wanted to ask you about the emergency medical exception under wholesale distribution. The exception expressly allows for transfers from a pharmacy to another pharmacy to alleviate a temporary shortage. Could this exception also cover a drug transfer from a clinic or practitioner to a pharmacy or vice versa in order to alleviate temporary shortages? For instance, if a clinic and a pharmacy are located in the same building or nearby and the pharmacy had a temporary shortage of vaccines and the clinic had excess supplies?

Second, under the common control exemption, what is considered a "health care entity"? Is a retail pharmacy a "health care entity"?

Third, what are the recordkeeping requirements for drug transfers that are exempted from the definition of wholesale distribution? I am assuming if a drug transfer is not considered a "wholesale distribution" then the rest of the provisions pertaining to wholesale distributors would not be applicable. Therefore, is there a separate record keeping standard?

Fourth, could a drug transfer originating from an out of state pharmacy or clinic be exempted from the definition of wholesale distribution, as long as all of the other criteria under the exception were met? Say, for instance, a pharmacy or provider in another state made a transfer to another pharmacy or provider in a temporary shortage? What about a transfer originating in Hawaii and being transferred out-of-state?

And lastly, on a different topic, are pharmacists permitted to administer vaccines off-site (i.e., not at the pharmacy). For instance, if a nearby clinic was overwhelmed with patients could a pharmacist administer vaccinations at that clinic?

After some discussion, the Board determined they were not prepared to respond to specific questions and decided to defer this matter to the Laws and Rules Committee.

Wholesale/Device Distributor Question

The Board reviewed the following email inquiry regarding wholesale distribution of medical devices:

"Recently, a home health care agency has approached this wholesaler regarding fulfilling certain prescription medical devices for its patients. As you may be aware, a home health agency employs licensed nurses to care for patients who are homebound and who are unable to receive traditional care in a hospital or clinic. The devices at issue include catheters, CPAP machines, and other devices used in home infusion or respiratory care settings. There are no drugs at issue.

Here is a proposed scenario:

The wholesaler contracts with a Hawaii-licensed home health care agency to supply prescription devices for a patient. The home health agency is the provider/customer, so the wholesaler is selling to the home health care agency, and NOT to the patient directly. However, because of the patient's unique location, the home health agency would like to have the product delivered to the patient's home, so that the nurse may administer the device.

Understanding that wholesalers cannot "dispense" to patients, this is apparently viewed in the industry not as dispensing, but as a wholesale transaction between the wholesaler and the home health care agency, with a "drop ship" delivery to the patient's home.

The delivery would, in effect, be to the home health care agency (which has paid for the device) in care of the patient, at the patient's home address. The home health care agency would retain the prescription order. The wholesaler will, of course, comply with all recordkeeping and other requirements under Federal and State law.

We have talked to several state Boards of Pharmacy, and they all allow this in some fashion. Most allow this conduct under a wholesaler's license, while other States further regulate it by requiring a separate DME or medical device supplier license.

Our ultimate questions are:

Does Hawaii require the wholesaler to be licensed in Hawaii?

Does Hawaii allow this practice under a wholesaler license?

If not, would it require the entity to obtain some other license?

Does anything change if it's a non-prescription device?"

After some discussion, it was the consensus of the Board, to respond to the questions above as follows:

Does Hawaii require the wholesaler to be licensed in Hawaii?

No, if out-of-state wholesale distributor and distribution of medical devices.

Does Hawaii allow this practice under a wholesaler license?

A prescription wholesale drug distributor may only "distribute" prescription drugs, not "dispense" prescription drugs to the end user/patient.

If not, would it require the entity to obtain some other license?

If the entity is out-of-state, the entity must be licensed/permitted as a pharmacy in that state and apply for a Hawaii miscellaneous permit as an out-of-state pharmacy.

Does anything change if it's a non-prescription device?

Yes, no permit or license is required to sell a non prescription drug or device.

Compounded Products, Controlled and Non-controlled, Sandra Erickson

The Board reviewed an email from Ms. Erickson. The questions, with the Board's responses are as follows:

1. **Can a licensed Non-Resident Pharmacy ship compounded non-controlled products into the state for "Office Use"?**

It was the consensus of the Board that if permitted by the domicile state board of pharmacy regulations to compound for "office use".

2. **Can such a Pharmacy ship Compounded Controlled Substances into the state for "Office Use"?**

It was the consensus of the Board to refer her to the Department of Public Safety, Narcotics Enforcement Division.

3. **If they may, for either scenario, is a prescription needed (i.e. for a specific patient)?**

A prescription is required to dispense a prescription drug.

Administration of Influenza Vaccine to Minors by Pharmacy Interns

The Board reviewed the following email inquiry:

"I am trying to determine whether pharmacy interns may administer the influenza vaccine to minors ages 14 to 17 pursuant to Hawaii Revised Statute § 461-11.4. I know the Board has stated that pharmacy interns may administer adult immunizations pursuant to a valid collaborative agreement (I've provided a link to the Board minutes below), but I'm wondering if the same reasoning applies to the administration of the influenza vaccine to minors pursuant to a valid prescription.

Board Minutes: http://hawaii.gov/dcca/pvl/boards/pharmacy/board-meeting-minutes/Pharmacy_110714.pdf ("[I]f the supervising pharmacist has received the appropriate training and has a collaborative agreement with a licensed physician . . . a pharmacy intern under the pharmacist's supervision may also administer immunizations provided that the pharmacy intern has also received the appropriate training and the collaborative agreement with the licensed physician also covers the pharmacy intern being supervised by the pharmacist.")"

After some discussion, it was the consensus of the Board that a pharmacy intern may administer the influenza vaccine to minors pursuant to HRS §461-11.4 provided the pharmacy intern has received the appropriate training, has a collaborate agreement with a licensed physician and is in compliance with all statutory and regulatory requirements.

Providing Medication Therapy Management Services from Out-of-State

The Board reviewed an email inquiry asking if a pharmacist that is licensed to practice pharmacy in a state other than Hawaii can provide medication therapy management services to patients that live in Hawaii and if the pharmacist must have a current and valid Hawaii pharmacist license?

For further clarification, the pharmacist would be providing the medication therapy management services telephonically from another state from a HIPAA-compliant office setting, either their home or business location and not from a dispensing pharmacy

After some discussion, it was the consensus of the Board that an out of state pharmacist who provides medication therapy management services from another state, including telephonic medication therapy management , must also be a Hawaii licensed pharmacist and the activities must be conducted in a licensed/permitted pharmacy that holds a Hawaii miscellaneous permit as an out-of-state pharmacy.

Technician to Pharmacists Ratio

The Board reviewed an email inquiry from Ms. Pamela White in which she states that the Florida Legislature is proposing an increase to the technician to pharmacist ratio from 3:1 to 6:1 and noted from the NABP survey that Hawaii does not have a ratio. She is requesting information as to why Hawaii does not have a ratio and if there are additional requirements if there is no ratio and if there is any data that reflects an increase in medication errors because of no ratio. The questions and Board responses are as follows:

- **Why did Hawaii decide not to have a ratio?**

Hawaii has never had a ratio

- **Is no ratio limited to certain practice setting, e.g., community pharmacies, hospital pharmacies, central fill facilities, mail order facilities?**

No

- **Are there additional requirements of the practice site to qualify for no ratio? If so, must application be made to and approved by the Board to have not ratio?**

No

- Are there additional requirements of the technicians such as education or certification? Boards response

No

- Lastly, do you have any data that reflects an increase in medication errors since implementation of no ratio?

Hawaii has never had a ratio. Therefore, there is no data.

Old Business:

HAR Title 16, Chapter 95 – Status Report

The EO reported that she's completed a draft of the justification and will be sending it to the DAG for a preliminary review before starting the formal rules adoption process as this will streamline the process once the DAG has reviewed the proposed rules.

Open Forum:

None

Applications:

Ratification List

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

Executive Session:

At 10:55 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 10:57 a.m. upon a motion by Dr. Ma, seconded by Ms. Kumasaka, it was voted on and unanimously carried to move out of executive session.

Applications:

Applications

Pharmacist

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

Robert Moresco

Miscellaneous Permit – Diabetic Care Rx LLC

The Board reviewed a request from Jasara Mohammed, Vice President of Administration for Diabetic Care Rx LLC requesting the Board remove the "conditions" imposed on their miscellaneous permit.

Upon a motion by Dr. Ma, seconded by Mr. Inafuku, it was voted on and unanimously carried to remove the condition placed on Diabetic Care Rx LLC.

Chapter 91, HRS,
Adjudicatory Matters:

At 10:58 a.m., the Vice Chair called for a recess from the Board's meeting to discuss and deliberate on the following adjudicatory matters, pursuant to Chapter 91, HRS:

In the Matter of the Miscellaneous Permit of **New England Compounding Pharmacy Inc., dba New England Compounding Center, PHA 2012-34-L**, Settlement Agreement prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1"-**"8"**.

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

In the Matter of the Pharmacist's License of **Thomas J. Britton; PHA 2012-17-L**, Settlement Agreement prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1"-**"2"**.

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

Next Meeting:

Thursday, April 18, 2013
9:00 a.m.
King Kalakaua Conference Room
King Kalakaua Building, First Floor
335 Merchant Street
Honolulu, Hawaii 96813

Dr. Ma stated that she will not be able to attend the May meeting.

Adjournment:

With no further business to discuss, the Vice Chair adjourned the meeting at 11:04 a.m.

Reviewed and approved by:

Taken and recorded by:

/s/ Lee Ann Teshima
Lee Ann Teshima,
Executive Officer

/s/ Lisa Kalani
Lisa Kalani,
Secretary

4/10/13

[x] Minutes approved as is.

[] Minutes approved with changes; see minutes of _____

LTYPE	LIC NUM	BP NAME PART 1
PH	3468	KRISTEN K <ATEBARA<
PH	3469	SARA K <SINGH<
PH	3470	CHRISTINA N <BREAUX<
PH	3471	TIARRA D <KAH<
PH	3472	ROBERT M <MOBUS<
PH	3473	EVAN R <BRAYTENBAH<
PH	3474	GAYANIE S <KURUPPU<
PH	3475	ANN M <SALIH<
PH	3476	MAIKA T <MURASHIGE<
PH	3477	RAFFEE D <JOHNS< II
PH	3478	ROBERT J <BAARS<
PH	3479	TIARE P <GOROSPE<
PH	3480	MICHAEL T <HOLBROOK<
PH	3481	KAREN R <LAZO<
PH	3482	DENISE M <NEEDHAM<
PH	3483	ERIC J <PENDARVIS<
PH	3484	WILLIAM E <FIXLER<
PH	3485	RUSSELL B <MANTOOTH<
PH	3486	JENNIFER <CERVONE<
PH	3487	TANYA M H <LEE<
PH	3488	ALAN D <KIM<

LTYPE	TEMP	LIC	NUM	VAM_BPR_LEGAL_NAME_1
PHI	3260			FELICIA L <STROM<
PHI	3267			JAMES C <HAWKINS<
PHI	3262			YUKIKO <HAYASHIDA<
PHI	3266			FLOR M <OSORIO<
PHI	3269			CARLIN M <VENTURA<
PHI	3265			IHILANI F T <HARU<
PHI	3270			KERIANN <MIYASHIRO<
PHI	3261			CANDACE M Y <NAKANISHI<
PHI	3271			RAMON <TRAN TANG<
PHI	3264			RYAN T H <KINOSHITA<
PHI	3268			SIN U <MOK<
PHI	3259			ANWYN E <PRITCHARD<
PHI	3263			NATALIE M <SOSA<

LTYPE	LIC NUM	LIC NAME PART 1	BUSN ADDR 1	BUSN CITY	BUSN		
					ST	BUSN ZIP	BP NAME PART 1
PHY	831	TIMES PHARMACY	3350 LWR HONOAPIILANI HWY	LAHAINA	HI	96761	QSI INC

LTYPE	LIC NUM	LIC NAME PART 1	BUSN ADDR 1	BUSN CITY	BUSN		BP NAME PART 1
					ST	BUSN ZIP	
PMP	823	BRIOVARX	53 DARLING AVE	S PORTLAND	ME	04106	BRIOVARX OF MAINE INC
PMP	824		2175 BUSINESS CENTER PARK DR	MEMPHIS	TN	38134	ADVANTAGE PHARMACY LLC
PMP	825	NOVIXUS PHARMACY SERVICES	13159 W NINE MILE RD	NOVI	MI	49375	NOVIXUS LLC
PMP	826	BRIOVARX	2441 WARRENVILLE RD STE 610	LISLE	IL	60532	BRIOVARX OF NEVADA LLC
PMP	827		6380 POLARIS AVE #B	LAS VEGAS	NV	89118	NURO PHARMA INC
PMP	828	EHS PHARMACY SERVICES	5640 HUDSON INDUSTRIAL PKWY	HUDSON	OH	44236	EDWARDS HEALTH CARE SERVICES INC
PMP	829	ITC COMPOUNDING & NATURAL WELLNESS PHARMACY	651 TOPEKA WAY STE 600	CASTLE ROCK	CO	80109	INFUSION TREATMENT CENTERS INC
PMP	830		85 TECHNOLOGY PKWY	ROME	GA	30165	DERMATRAN HEALTH SOLUTIONS LLC
PMP	831		6520 N IRWINDALE STE 228	IRWINDALE	CA	91702	INSTITUTIONAL PHARMACY SOLUTIONS L

LTYPE	LIC NUM	LIC NAME PART 1	BUSN ADDR 1	BUSN CITY	BUSN		
					ST	BUSN ZIP	BP NAME PART 1
PWD	162		820 MILILANI ST #703	HONOLULU	HI	96813	MED WHOLESALE CORP