

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

MINUTES OF MEETING

Date: Thursday, April 18, 2013

Time: 9:00 a.m.

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

Members Present: Mark E. Brown, Pharmacist, Chair
Garrett Lau, Pharmacist
Patrick Adams, Pharmacist, Vice Chair
Todd Inafuku, Pharmacist
Lydia Kumasaka, Public Member
Jill Oliveira Gray, Public Member

Excused: Carolyn Ma, Pharmacist

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

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

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

The Chair asked the audience to introduce themselves.

Additions/Additional Distribution to Agenda

None.

Approval of the Previous Minutes – March 21, 2013

The Chair called for a motion in regards to the minutes of the March 21, 2013 meeting.

There being no discussion, upon a motion by the Vice Chair, seconded by Dr. Oliveira Gray, it was voted on and unanimously carried to approve the minutes for the March 21, 2013 meeting as circulated.

Report on Participation at National Association of Boards of Pharmacy (NABP) MPJE Item-Development Workshop, March 21, -22, 2013

The Chair reported that at the MPJE Item-Development workshop, they revised test questions which will be reviewed in the Fall. There was also discussion on APRN prescriptive authority, compounding sterile products and NABP inspectors.

Executive Officer's Report:

2013 Legislature

The EO reported on the status of the following bills:

HB 652 Relating to Remote Dispensing

This bill is scheduled for a conference committee hearing tomorrow.

HB 62 Relating to Pharmacy Benefit Managers

This bill is scheduled for a conference committee hearing tomorrow.

The Vice Chair noted that this bill defines "pharmacy benefit managers".

HB 65 Relating to Prescription Drugs

This bill is scheduled for a conference committee this afternoon.

Report from Laws & Rules Committee:

Mr. Inafuku stated that the Committee continued their review of the miscellaneous permit categories to determine if they were necessary. The Committee is recommending that the categories listed under the miscellaneous permit 1. and 2. be deleted, 3., 4., and 5. will be reexamined, 6. will be clarified further and 7. will also be reexamined. The Committee members were also tasked with adding 5 more categories that they have determined to be applicable to this section for discussion at the next meeting.

Correspondence:

The Chair took the agenda out of order and deferred the first item under "Correspondence".

Pharmacies Reimbursing Veterinarians a Percentage for Authorization to Dispense

The Chair asked Mr. Lau to lead the discussion on whether it is permissible for pharmacies to reimburse veterinarians for authorization to dispense.

Mr. Lau read a letter from Martin Dix in which he states that there is a website that is not a pharmacy, where owners of pets can purchase a variety of products on-line, prescription and non-prescription. The web site allows customers to order prescription drugs through a pharmacy. The pharmacy contacts the customer's veterinarian to obtain a prescription for the drug(s). The pharmacy then reimburses the veterinarian a percentage of the purchase price for each medication dispensed and he believes, the web site also receives a share of the purchase price. Mr. Dix also refers to a federal regulation which prohibits payments from pharmacies to prescribers, but states that this law only applies to human patients where a federal program pays for the drugs.

Mr. Lau stated that the pharmacy laws and rules do not specifically address this issue.

Mr. Edwards stated that HRS 328-16(b)(3)(D) refers to no undisclosed rebate, refund, commission, preference, discount or other consideration...has been offered to the practitioner as compensation or inducement to dispense or prescribe any specific drug...and offered to review Mr. Dix's request and report back to the Board.

The DAG also recommended that Mr. Dix's letter be referred to the Board of Veterinary Examiners for their consideration and with a request to report back to the Board.

The consensus of the Board was to send Mr. Dix's letter to Mr. Edwards and the Board of Veterinary Examiners for their review and consideration in regards to their laws and rules and to respond to Mr. Dix directly with a cc to the Board.

Mr. Carter called in for the first agenda item under "Correspondence" so the Chair resumed the order of the agenda.

Supervision of Pharmacy Technicians/Personnel by a Pharmacist

The Board received a request from the Vice Chair to re-visit the Walgreens model that was presented at the Board's January 2013 meeting. The Vice Chair had concerns with the immediate supervision of the pharmacy technicians as the model, specifically the floor plan, indicates the pharmacist is separated by walls from the pharmacy technicians and other personnel.

Mr. Carter stated that when he addressed the Board in January, he thought the Board had allowed Walgreens to do a pilot project based on this model with reports to the Board.

The Chair stated that he recalls that the Board did have several concerns, one of them being the supervision of the pharmacy technicians and personnel.

Mr. Carter stated that he remembers the Board having concerns and questioned the pharmacist verifying the final product before it is dispensed and diversion issues.

Mr. Inafuku stated that he remembers talking about a pilot program, but that the pharmacist sits within the pharmacy and that the pharmacy is still secured from unauthorized access and that we discussed supervision and immediate supervision and that the pharmacist was present in the area so that's why the Board agreed to this pilot project.

The Vice Chair stated that the pharmacist is "supervising" through video conferencing, like remote dispensing. He explained that a pharmacist had to immediately supervise a pharmacy technician so a "remote dispensing technician" had to be created that would allow a pharmacist to supervise the remote dispensing technician through video conferencing.

Mr. Carter stated that if a pharmacy is located on two floors in a hospital, the pharmacist is still accessible since he/she is on the premises, but for remote dispensing, that is two different locations and that we are comparing apples and oranges.

Mr. Inafuku stated that we are not comparing the same thing and asked if the video link is used for consultation for the patient and the pharmacist?

Mr. Lau stated that the video link for remote dispensing is for consultation and supervision.

The Vice Chair stated that the Board is changing the supervision of a pharmacy technician.

The Chair stated that the supervision by video link is not considered immediate supervision since the pharmacist is not physically present.

The Vice Chair stated that if the model says video supervision, then this is not in compliance with the law and he does not consider this safe or legal practice.

The Chair read from the minutes of the January 17, 2013 meeting where the Board made a determination in response to Mr. Carter's presentation as follows:

"After further discussion, it was the consensus of the Board that:

- The program presented must be in compliance with the pharmacy laws and rules, including but not limited to the pharmacist supervision of the pharmacy technician and other pharmacy personnel and the "initialing" of all prescriptions filled;
- Walgreens contact the Department of Public Safety, Narcotics Enforcement Division for compliance with HRS 329, the Uniform Controlled Substances Act;
- The Board accepts Walgreens offer to submit their policies and procedures for this program, not for Board approval but for informational purposes only;
- The Board be notified, in writing, of the implementation date for this program for Walgreens pharmacies located in this State; and
- Walgreens provide a status report 3-6 months after the implementation date on any issues, including comments from pharmacist working in this program in Hawaii."

Mr. Carter stated that he thought the Board's interpretation of the floor plan was that the pharmacist was included within the pharmacy area.

The Chair stated that pursuant to the model that was presented, the pharmacist was sitting in an area that is not in the production area of the pharmacy.

Mr. Carter stated that the floor plan is for the whole pharmacy, including the dispensing and prescription area.

The Vice Chair asked what if the video was on a second floor, would the pharmacist still be allowed to "supervise" the pharmacy from another floor?

The DAG stated that is not the question and advised the Board to not bring up other scenarios since it does not pertain to the issue.

The EO stated that the pharmacy area is not defined or distinguished between the dispensing area and prescription area.

Mr. Lau stated that according to the laws and rules, the model proposed by Walgreens appear to fall within the confines of the floor plan, the pharmacy premises but that the technology is not addressed.

The Vice Chair stated that he teaches law and that the model does not appear to be in compliance with the current laws or rules.

Mr. Inafuku stated that he thinks that the model appears to be in compliance with the current laws and rules, including the definition of "immediate supervision".

The Vice Chair asked what the difference was between the supervision of a remote pharmacy technician.

The Chair stated that the pharmacist is not present at a remote dispensing pharmacy.

Mr. Inafuku stated that we are comparing the model to remote dispensing but that it is something totally different.

Dr. Oliveira Gray stated that she remembers the consensus statement and wanted to clarify that the pharmacist is physically there.

The Vice Chair stated that pharmacist cannot leave the pharmacy. If the pharmacist is not present, no drug may be sold or dispensed.

Ms. Kumasaka stated that according to the definition of "immediate supervision" it appears that the Walgreens model is in compliance with that definition since the pharmacist is physically present.

The Vice Chair stated that he has access to the counter and can see and hear things.

The Chair moved to reaffirm the Board's January 17, 2013 determination in regards to the Walgreens model, it was seconded by Mr. Inafuku, it was voted on with the Chair, Mr. Inafuku, Dr. Oliveira Gray, Mr. Lau and Ms. Kumasaka voting yes and the Vice Chair abstaining.

Mr. Carter stated that he would send out an invite to the Board once a Hawaii Walgreens pharmacy is fitted for this model.

The Board thanked Mr. Carter for taking the time to call in to the meeting.

Reverse Distributors

The Chair asked Mr. Inafuku to lead the discussion on an email inquiry from Adrienne Vanderfriff regarding unused medication collection regulations.

Mr. Inafuku read the following email:

"I am inquiring to determine rules and regulations for the collection of unused patient medications by pharmacies and long term care facilities in Hawaii. My company, Return Solutions, would like to provide a solution for the growing demand of consumers to have a safe place to dispose of non-controlled prescription and OTC medications that they are no longer using. Pharmacies are a natural choice as a central location to collect these medications, and we are proposing to either provide a large box that the pharmacy would keep behind the counter to collect these items or to provide the pharmacy with envelopes that they could give to their customers to take home and collect the medicine there. Both options would be purchased by the pharmacy and include prepaid shipping to our facility as well as RCRA, DOT, and EPA compliant destruction of all items.

Return Solutions has been in business since 1992 and is a pharmaceutical reverse distributor providing services to retail and hospital pharmacies as well as wholesalers and manufacturers throughout the United States. We return products to manufacturers, securing credit for our customers in a timely manner, and we also offer environmentally sound disposal of pharmaceutical products including hazardous materials."

The Chair stated that HAR §16-95-87 prohibits a pharmacy from taking back drugs but does not prohibit a customer from taking an envelope from the pharmacy to mail drugs to a reverse distributor.

The EO asked if reverse distributors are regulated by any federal agency.

Mr. Edwards stated that the Drug Enforcement Agency regulated the reverse distributors for controlled substances.

CPAP's, BIPAP's Mask Fittings and Set Ups

The Chair asked Dr. Oliveira Gray to lead the discussion on the email inquiry from Susan Martinez asking if their DME company supplies CPAPs and their respiratory therapist is doing CPAP, BIPAP mask fittings and set ups under a physician's order, would a pharmacist in charge be required for their miscellaneous permit.

Dr. Oliveira Gray stated that the EO asked Ms. Martinez for clarification and that according to Ms. Martinez, the DME company is located in this State and so is the respiratory therapist.

The Chair stated that if the CPAP is a prescription device, a pharmacy may dispense it pursuant to a prescription.

Mr. Inafuku stated that a physician can issue a certificate of medical necessity which is not a prescription.

Mr. Edwards stated that he's not sure when the certificate of medical necessity applies.

After some discussion, upon a motion by the Chair, seconded by the Vice Chair, it was voted on with the Chair, Vice Chair, Mr. Lau, Dr. Oliveira Gray and Ms. Kumasaka voting yes and Mr. Inafuku voting no to inform Ms. Martinez that in order to sell any prescription device directly to the end user/patient, the entity must be a permitted pharmacy with a pharmacist in charge and that no license is required for an entity in this State to "distribute" a medical device.

This matter was referred to the Laws and Rules Committee.

Patient names for all prescriptions

The Chair asked Ms. Kumasaka to lead the discussion on the inquiry from Charles Leiter of Leiter's Compounding Pharmacy requesting clarification from the Board in regards to compounding drugs for "office use" and if a patient specific prescription is required.

The Vice Chair stated that at a previous meeting, the Board addressed a similar inquiry from ophthalmologists asking for clarification from the Board for compounding for "office use" and that the Board determined that if the entity was located in another state and is not "dispensing" a prescription drug pursuant to a patient specific prescription but perhaps acting as a wholesaler, that the current laws and rules do not address out of state compounding pharmacies who are not dispensing prescription drugs directly to the end user/patient.

The EO stated that the Board should also clarify that the out of pharmacy that compounds for "office use" should also be licensed/permitted to compound for "office use" by their domicile state board of pharmacy.

After some discussion, upon a motion by the Vice Chair, seconded by Ms. Kumasaka, it was voted on and unanimously carried to reaffirm the Board's previous decision and to add that the out of state pharmacy that compounds for "office use" must be licensed/permitted to conduct this activity by their domicile state board of pharmacy. This matter was also referred to the Laws and Rules Committee.

Clarification of out-of-state entities compounding for office use

The Board determined that their response to Mr. Leiter would also apply to this inquiry.

Old Business:

HAR Title 16, Chapter 95 – Status Report

The EO reported that she will be discussing the draft with the DAG.

Open Forum:

Mr. Dolsen asked that if the Board amends the miscellaneous permit requirements; will they be grandfathering or providing notice for compliance?

The EO stated that any changes to the laws and rules should address time for compliance.

Stacy Pi wanted clarification on the Board's determination of compounding for "office use".

Mr. Lau had comments on HB 65.

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 lists.

The Chair mentioned that it was curious that no pharmacists or miscellaneous permit were listed on the ratification list for new licenses/permits.

The EO stated that she asked the applications clerk about the lack of pharmacists or miscellaneous permits, but did not get a response.

Executive Session:

At 10:36 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 10:38 a.m. upon a motion by Mr. Lau, seconded by the Vice Chair, it was voted on and unanimously carried to move out of executive session.

Applications:

Applications

Miscellaneous Permit – Cardinal Health 414 LLC:

Upon a motion by the Vice Chair, seconded by Dr. Oliveira Gray, it was voted on and unanimously carried to approve the miscellaneous permit application for Cardinal Health 414 LLC.

Chapter 91, HRS,
Adjudicatory Matters:

At 10:38, the 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 Pharmacist's License of Charles Balzarini; PHA 2012-26-L, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1".

Upon a motion by Mr. Lau, seconded by the Vice Chair, it was voted on and unanimously carried to approve the Board's Final Order.

In the Matter of the Wholesale Prescription Drug Distributor License of Owens & Minor Distribution Inc; PHA 2012-36-L, Settlement Agreement prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1".

Upon a motion by the Vice Chair, seconded by Dr. Jill Oliveira Gray, it was voted on and unanimously carried to approve the Board's Final Order.

Next Meeting: Thursday, May 16, 2013
9:00 a.m.
King Kalakaua Conference Room
King Kalakaua Building, First Floor
335 Merchant Street
Honolulu, Hawaii 96813

The Vice Chair stated that he will be out of town and would not be able to attend the meeting.

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 10:45 a.m.

Taken and reviewed by:

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

4/30/13

Minutes approved as is.
 Minutes approved with changes; see minutes of _____

LTYPE TEMP LIC NUM VAM_BPR_LEGAL_NAME_1

PHI T130405001 BLAIR N <WENDT<
PHI T130405002 RACHEL L K <HODGES<
PHI T130405004 DAWN M <GREENE<
PHI T130405003 ROBERT B <KHALER<

LTYPE	LIC NUM	LIC NAME PART 1	BUSN ADDR 1	BUSN CITY	BUSN		
					ST	BUSN ZIP	BP NAME PART 1
PHY	832		200 W KAWILI	HILO	HI	96720	UNIVERSITY OF HAWAII AT HILO STUDE