

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

MINUTES OF MEETING

Date: Thursday September 15, 2011

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
Patrick Adams, Pharmacist, Vice Chair
Todd Inafuku, Pharmacist
Lydia Kumasaka, Public Member
Garrett Lau, Pharmacist
Carolyn Ma, Pharmacist

Members Excused: Jill Oliveira Gray, Public Member

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

Guests: Greg Edwards, Department of Health ("DOH"), Food & Drug Branch
Gerry Fujii, Pharm Assist
Raymond Bihis, Ohana Health Plan
Marcella Chock, Hawaii Pharmacists Association ("HPhA")
Amy Baker, University of Hawaii Hilo College of Pharmacy ("UHHCoP")
Paige Kurosawa, UHHCoP
Kelly Kwok, UHHCoP

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 9:03 a.m.

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

The Chair introduced Lydia Kumasaka as the new public member for the Board and asked the audience to introduce themselves. The Chair also excused Dr. Oliveira Gray from today's meeting.

Additions and Additional Distribution

None

Approval of the Previous Minutes – August 18, 2011 Meeting

The Chair asked if there were any amendments to the minutes.

Mr. Inafuku stated that on page 2, under “Approval of the Previous Minutes – July 14, 2011, third paragraph, should read as follows:

“The Chair stated that on page 7, the last paragraph under Insulin and syringes, Kathy Worthington, the word “vials” should be inserted after “Novolin N insulin.”

There being no further discussion, upon a motion by the Vice Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to approve the minutes of the August 18, 2011 meeting as amended.

Report on Multistate Pharmacy Jurisprudence Examination (“MPJE”) State Specific Review (Chair and Mr. Lau)

Mr. Lau reported that he and the Chair read and evaluated newly written and previously approved pretest questions which were coded and grouped by competency areas and calibrated and analyzed for efficiency.

Mr. Lau stated that 160 of the 971 newly written pretest questions were selected based on current rules and regulations and will be included in the new pool of questions. The previously approved questions were reviewed for validity based on current rules and regulations.

Laws and Rules Committee Report:

Mr. Inafuku reported on the following items discussed at the committee meeting held this morning before the Board meeting:

- The Laws & Rules Advisory Committee should also include pharmacy technicians in the lead contact & discipline responsibilities list. The Committee will be requesting the assistance of the Hawaii Pharmacists Association to recommend at least two (2) pharmacy technicians who are either nationally certified or have at least five (5) years experience as a pharmacy technician, and representing both retail and institutional pharmacies at the next meeting.
- The HAR 95 Draft 1 will be disseminated to the Advisory Committee’s lead contacts for their comments and recommendations.

- The Committee will be discussing the definition of the "Practice of Pharmacy" as it is defined in HRS 461-1 at their next meeting scheduled for 8:00 a.m., October 20, 2011.

Correspondence: **National Association of Boards of Pharmacy ("NABP")**

NABP State News Roundup – August 2011

The Board reviewed the articles in the NABP State News Roundup for August 2011.

The Chair noted the Arkansas Board had regulation changes.

The EO recommended that the members, especially the Laws and Rules Committee members keep the NABP State News Roundup as a reference for examples on what other states are doing to address certain practice of pharmacy issues.

NABP e-News: DEA Guidance Regarding Information Pharmacists May Provide on CS II Prescriptions

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

Non-Resident Nuclear Pharmacy License, Mark Novembre, Nuclear Diagnostic Products

The Chair asked Mr. Inafuku to lead the discussion on Mr. Novembre's email asking if a non-resident pharmacy in the state of Hawaii can send radiopharmaceuticals to hospitals in the state of Hawaii.

Mr. Inafuku clarified that according to a subsequent email from Mr. Novembre the hospital will call the manufacturer, who in turn will send the bulk vial to the out-of-state pharmacy, who in turn will draw up the prescribed quantity and ship to the hospital.

After some discussion, it was the consensus of the Board that in order for an out-of-state pharmacy to ship any prescription drugs into this State pursuant to a prescription, they must have a miscellaneous permit. It was also recommended that the out-of-state pharmacy contact the Department of Health ("DOH") about shipping radiologicals into this State.

Mr. Edwards stated he would get the information on the DOH division that has jurisdiction over shipping radiologicals.

Pharmacy Wholesale Exemption for Blood and Blood Components Intended for Transfusion, Guelsys Lopez-Vieira, WellCare Health Plans, Inc.

The Chair asked the Vice Chair to lead the discussion on Mr. Lopez-Vieira's follow up email listing the following questions:

- 1) Is there an exemption to the statement below if the sale, purchase, or trade is for the blood and blood components intended for transfusion?
- 2) Can you please provide us with the statute that makes this scenario a violation of Hawaii laws? "Based on your email below, if a Hawaii pharmacy receives prescription drugs (non-controlled substances) from an out-of-state entity on a wholesale basis, then the out-of-state entity should be a wholesale distributor in that state (Hawaii does not license out-of-state wholesale distributors). A Hawaii pharmacy may not accept a prescription drug from another "pharmacy" on a wholesale basis."

Mr. Bihis stated that the email inquiry was sent from Ohana Health Plan pharmacy for a member in Kauai and he further explained that the patient is receiving Factor VIII blood and would be picking up the prescription from a local pharmacy that received the non-controlled substance from a pharmacy in Alaska.

The Vice Chair stated that an out-of-state pharmacy cannot dispense to a pharmacy in Hawaii.

The EO stated for clarification that the Factor VIII blood is not for emergency medical use and the Alaska pharmacy is not a wholesale distributor.

Ms. Chock stated that limited distribution for some products is allowed and not all pharmacies can stock these products without training.

Ms. Ma stated that the options are either the pharmacy in Alaska dispenses the product directly to the patient or find a local distributor.

Mr. Inafuku suggested to Mr. Bihis that he should find out who has ownership of the product. Is it the pharmacy in Alaska or the local pharmacy?

Mr. Bihis stated that according to HAR §16-95-2, under the definition of "Wholesale distribution", blood components are not included.

Mr. Edwards informed the Board that a local pharmacy can receive blood products that are not patient specific and that the Alaska pharmacy can sell blood products to a local pharmacy according to Hawaii Revised Statutes §328-112, "Wholesale Distribution" definition.

After further discussion and consideration of the explanations from Mr. Bihis, it was the consensus of the Board that pursuant to the definition of "dispense" in Hawaii Administrative Rules §16-95-2, "Dispense" or "dispensing:" means the furnishing of drugs pursuant to a prescription in a suitable container, appropriately labeled for subsequent administration to, or use by, a patient or other individual entitled to receive the drug." and the definition of "Wholesale distribution"...means the distribution of prescription drugs to persons other than a consumer or patient, but does not include:..."(8) The sale, purchase, or trade of blood and blood components intended for transfusion. For purposes of this section, "blood" means the whole blood collected from a single donor and processed either for transfusion, or further manufacturing; and "blood component" means that part of blood separated by physical or mechanical means.", if the out-of-state pharmacy is "dispensing" the "blood or blood component" into this state to the end user/patient, then the out-of-state pharmacy must obtain a miscellaneous permit. If the out-of-state pharmacy is "distributing" the "blood or blood component" to an in-state pharmacy for dispensing to the end user/patient, this activity is prohibited unless it is for an "emergency medical reason" to alleviate a temporary shortage.

Telepharmacy Laws, Chris Roberts, Medication Review

The Chair asked Mr. Lau to lead the discussion on Mr. Roberts' email requesting information for his company that provides telepharmacy services to rural hospitals that lack 24/7 pharmacy coverage.

Ms. Ma stated there are hospitals that are using these types of services but she is not aware of any local hospitals using the service.

Upon a motion by the Vice Chair, seconded by the Chair, it was voted on and unanimously carried to refer Mr. Roberts to the Hawaii Revised Statutes §461-10.5, "Remote dispensing pharmacy; operations".

The responses to Mr. Roberts' questions are as follows:

- 1.) What telepharmacy laws exist in Hawaii at this time or are there plans to add them anytime soon?

Hawaii Revised Statutes §461-10.5 addresses remote dispensing pharmacy operations. You may download HRS Chapter 461 from the web page listed above under "Statute/rule chapter".

- 2.) Would our out of state company be permitted to provide these services to hospitals in your state?

If the out-of-state pharmacy is performing any activity defined under the "Practice of pharmacy" definition in HRS 461-1, which would include the "prescription entry/verification" by a licensed pharmacist, then the out-of-state pharmacy may be required to obtain a miscellaneous permit as an out-of-state pharmacy and any pharmacist who performs the prescription entry/verification for a Hawaii hospital or pharmacy, will be required to obtain a Hawaii pharmacist license.

- 3.) If so, what steps would we need to take to practice there?

See response to question #2.

- 4.) Would we need to have any of our pharmacists licensed in Hawaii?
Pharmacists in charge only? Or all who would be providing service?

See response to question #3.

- 5.) Do you allow the remote monitoring of technicians?

No.

- 6.) Are there limits to the size of hospitals permitted to use telepharmacy?

No.

Accreditation Council for Pharmacy Education ("ACPE") Memo: Denial of Precandidate Accreditation Status for South College School of Pharmacy, Sharon Hudson, ACPE

The Board reviewed the Notification of Final Decision from the June 22-26, 2011 Meeting of the ACPE Board of Directors: Denial of Precandidate Accreditation Status for the Doctor of Pharmacy Program of the South College School of Pharmacy from Jeffrey W. Wadelin, Ph.D., Associate Executive Director and Director, Professional Degree Program Accreditation sent by Sharon Hudson.

Reverse Distributor License, Susan Hollar, National Pharmaceutical Returns, Inc.

The Chair asked Ms. Ma to lead the discussion on Ms. Hollar's email asking if the laws have changed in the State of Hawaii regarding licensing of pharmaceutical reverse distributors and it is her understanding that a license is not required because her company does not send products into Hawaii but pharmacies in Hawaii may choose to send products to them.

The Vice Chair stated that the Laws and Rules Committee should address reverse distributors.

The DAG advised the Board that it should proceed with caution when addressing regulations involving other jurisdictions because there are many factors that have to be considered.

The EO stated reverse distribution should be referred to the Laws and Rules Committee and the National Association of Boards of Pharmacy ("NABP").

Ms. Ma stated that if there is no statute, then the subject should be referred to the Laws and Rules Committee.

After further discussion, the Board determined that the current Hawaii pharmacy laws (Hawaii Revised Statutes Chapter 461) and rules (Hawaii Administrative Rules Title 16, Chapter 95) do not address reverse distributors and the disposition of controlled substances falls under the jurisdiction of the Department of Public Safety, Narcotics Enforcement Division.

Wholesaler Hypothetical Question, Anonymous

The Board reviewed and discussed the anonymous email asking if a wholesaler can transport labeled prescriptions inside a sealed container from one licensed pharmacy to another and determined that the current pharmacy laws and rules do not regulate or address the "delivery" of prescription drugs and that under the definition of "Wholesale distributor" under Hawaii Administrative Rules §16-95-2, "The term "wholesale distributor" shall not include any carrier for hire or person or entity hired solely to transport prescription drugs."

The Board recommends the anonymous inquirer contact Greg Edwards at the Department of Health, Food and Drug Branch for more information on wholesale distributors as referred to in Hawaii Revised Statutes Chapter 328.

Old Business:

Naturopathic Formulary – Amended Draft (July 25, 2011) of “Important Notice Regarding the Prescriptive Authority of Naturopathic Physicians”

Mr. Inafuku stated that he and Mr. Adams participated in a teleconference to

discuss the draft of the "Important Notice Regarding the Prescriptive Authority of Naturopathic Physicians" ("Notice") prepared by the Board of Naturopathic Medicine.

The DAG stated that under the "Sunshine Law", the letter may be brought to the attention of the Board at this meeting and any decision making and deliberation must be made at a subsequent meeting.

The draft of the "Important Notice Regarding the Prescriptive Authority of Naturopathic Physicians" ("Notice") by the Board of Naturopathic Medicine was distributed to the Board and at the next scheduled Board meeting the Board will be having discussion and decision making on this matter.

Open Forum: Jerry Fujii was asked by the EO to send his comments and recommendations regarding the administrative process to her and she will forward the information to the administrative branch as it did not pertain to the Board.

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 10:31 a.m. upon a motion by Mr. Inafuku, seconded by the Vice Chair, 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 11:12 a.m. upon a motion by Mr. Lau, seconded by Ms. Ma, it was voted on and unanimously carried to move out of executive session.

At this time, the Chair announced that he was taking the agenda out of order to recess and take up the HRS 91, Adjudicatory Matters.

Chapter 91, HRS
Adjudicatory Matters:

At 11:12 a.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 Miscellaneous Permit of Caremark Texas Mail Pharmacy LLC, dba CVS Caremark; PHA 2011-16-L; Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

The Chair and Mr. Inafuku recused themselves. Upon a motion by the Vice Chair

seconded by Mr. Lau, it was voted on by the Vice Chair, Mr. Lau, Ms. Ma and Ms. Kumasaka to approve the Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1" for Caremark Texas Mail Pharmacy LLC, dba CVS Caremark.

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 11:16 a.m. pursuant to Chapter 92, HRS.

The Chair resumed the agenda order.

Applications

Pharmacist

- **Jonathan M. Tam**

Upon a motion by the Vice Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to approve the pharmacist application for Mr. Tam.

- **Kimberly A. Bartholomew**

Upon a motion by the Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to deny the pharmacist application for Ms. Bartholomew based on:

Hawaii Administrative Rules ("HAR") Title 16, Chapter 95

HAR §16-95-22.5(c) The board may deny licensure by reciprocity if the applicant has had any disciplinary action taken or if any unresolved complaints are pending.

HAR §16-95-32.2(a) An application for issuance of a license or permit shall be denied when an application is insufficient or incomplete; is not accompanied with the required fees; or when an applicant has failed to provide satisfactory proof that the applicant meets the requirements for the license or permit. In addition, the board may deny issuance of a license or permit;

- (2) If the applicant has had any disciplinary action taken by any jurisdiction, including any federal or state regulatory body.

Hawaii Revised Statutes ("HRS")

HRS §461-8.5(a) Any pharmacist who is registered or licensed under the laws of any state or territory of the United States with qualifications for licensure which equal or exceed those of this State, shall be eligible for licensure; provide that:

- (4) The pharmacist does not have an encumbered license or a pending disciplinary action or unresolved complaint in the practice of pharmacy in any state or territory of the United States, or if any license has been or is encumbered, the pharmacist shall provide any information requested by the board;

HRS §461-21(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 license or permit holder for any cause authorized by law, including but not limited to the following:

- (7) Any other conduct constituting fraudulent or dishonest dealings;

HRS §436B-19 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:

- (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

- **Option Care Enterprises**

Upon a motion by the Vice Chair, seconded by Ms. Ma, it was voted on and unanimously carried to defer the decision on the Miscellaneous Permit application for Option Care Enterprises for additional information.

- **University Pharmacy**

Upon a motion by the Vice Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to approve the Miscellaneous Permit application for University Pharmacy.

- **Wellpartner, Inc.**

It was the consensus of the Board to defer the decision on the Miscellaneous Permit application for Wellpartner, Inc. until the October 20, 2011 meeting.

Miscellaneous Permit – Pharmacy Closure

- Walgreens Specialty Pharmacy #12313 (PMP 456)

Upon a motion by the Vice Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to approve the closure of Walgreens Specialty Pharmacy #12313 (PMP 456).

Next Meeting:

Thursday, October 20, 2011
9:00 a.m.
King Kalakaua Conference Room, First Floor
King Kalakaua Building
335 Merchant Street
Honolulu, Hawaii 96813

Mr. Lau said he will not be able to attend the October meeting.

Adjournment:

With no further business to discuss, the Chair adjourned the meeting at 11:23 a.m.

Taken and recorded by:



Christine Hironaka
Secretary

Reviewed and approved by:



Lee Ann Teshima
Executive Officer
9/30/11

Minutes approved as is.

Minutes approved with changes; see minutes of 10/20/11.

BOARD OF PHARMACY

September 15, 2011 Ratification List

Miscellaneous Permits (PMP)

Closure: Walgreens Specialty Pharmacy LLC (PMP 456)
dba Walgreens Specialty Pharmacy #12313
412 Mount Kemble Avenue, Suite 300N
Morristown, NJ 07860

New PIC: Roadrunner Pharmacy (PMP 520)
New PIC – Rebecca Sheehan

Pharm Plus Acquisition Inc., dba US Bioservices (PMP 584)
New PIC – Nisha Chirag Parekh

Diplomat Specialty Pharmacy LLC (PMP 574)
New PIC – Jeffrey M. Rowe

Pharmacy (PHY)

New PIC: Kalihi-Palama Health Center, dba KPHC (PHY 797)
Roy Yamauchi replacing Gavin A. Sanjume

Prescription Wholesale Distributor (PWD)

Relocation: Pharmanutra Inc. (PWD-12)
560 N Nimitz Hwy #201E
Honolulu HI 96817
Eff. 8/24/11

BOARD OF PHARMACY – September 15, 2011 – RATIFICATION LIST

VLI_LICENSE_VIEW

Tuesday August 30, 2011 10:46 AM

LTYPE LIC NUM BP NAME PART 1

PH	3233	TRICIA L M <ANDERSON<
PH	3234	REBECCA L <SNYDER<
PH	3235	BARRY J <BOUDREAU<
PH	3236	SCOTT J <MARTIN<
PH	3237	STEPHEN <WURZBURGER<
PH	3238	JENNIFER M <KAWAI<
PH	3239	MANDY J <MEDINA<
PH	3240	PAUL B <NARCISO<
PH	3241	LONDON S <SAKUDA<
PH	3242	RYAN T <TROMBLEY<
PH	3243	BEN <LAURENT<
PH	3244	STACY Y <SASAKI<
PH	3245	ERIN K <SAMURA<
PH	3246	DAWN M <YARA<
PH	3247	WING YAN <CHAN<
PH	3248	CARL J <FONTENOT<
PH	3249	JERI ANNE J Y <NGAI<
PH	3250	KELLY K <WATANABE<
PH	3251	TIFFANY R <CHUNG<
PH	3252	SHANNON K <TAMURA<
PH	3253	QUINN K <TAIRA<
PH	3254	YEONG AE <KIM<

VLI_LICENSE_VIEW

Wednesday August 31, 2011 09:14 AM

LTYPE	LIC NUM	LIC NAME PART 1	BUSN ADDR 1	BUSN CITY	BUSN ST	BUSN ZIP	BP NAME PART 1
PHY	803	PUNA PHARMACY	15-2660 KEAAU PAHOA RD #205	PAHOA	HI	96778	SCRIPS PHARMACY HAWAII INCORPORATE

VLI_LICENSE_VIEW

Tuesday August 30, 2011 10:58 AM

LTYPE	LIC NUM	LIC NAME PART 1	BUSN ADDR 1	BUSN CITY	BUSN ST	BUSN ZIP	BP NAME PART 1
PMP	703		376 NORTHLAKE BLVD	ALTAMONTE SPRINGS	FL	32701	BIOPLUS SPECIALY PHARMACY SERVICES
PMP	704		1289 DEMING WAY	MADISON	WI	53717	RESTORE HEALTH PHARMACY LLC
PMP	705	MESA PHARMACY VII	18013 SKY PARK CIR #D	IRVINE	CA	92614	MESA PHARMACY INC
PMP	706		150 CLEVELAND RD #B	BOGART	GA	30622	PHARMACEUTICAL SPECIALTIES EXPRESS
PMP	707	PETMEDS2GO.COM					ANIMAL PHARM LLC
PMP	708		814 K ST	BELLEVILLE	KS	66935	PET'S CHOICE PHARMACY LLC
PMP	709		1560 SAWGRASS CORP PKWY #140	SUNRISE	FL	33323	NATIONWIDE HOME MEDICAL RETAIL INC
PMP	710	STOKES PHARMACY	18000 HORIZON WAY #700	MOUNT LAUREL	NJ	08054	STOKES HEALTHCARE INC
PMP	711	CVS CAREMARK	180 PASSAIC AVE	FAIRFIELD	NJ	07004	CAREMARK NEW JERSEY SPECIALTY PHAR

PHARMACY BOARD MEETING - 9/15/11

INTERNS:

- 3025: BANGERT, JOSHUA N
- 3026: LAWNHUN, DAVID A
- 3027: FURUKAWA, MATTHEW T
- 3028: HEIMBIGNER, NATASHA J

- 3000: MELGAREJO, STEVEN A
- 3001: PIETRZAK, PRESTON G
- 3002: CHEUNG, MONICA
- 3003: KLEEKORN, PASIKA L
- 3004: KIM, GRACE E
- 3005: HA, ALLEN

TEMPORARY PHARMACIST PERMIT:

NAME CHANGES/TRADENAME: