

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

MINUTES OF MEETING

Date: Thursday December 15, 2011

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
Carolyn Ma, Pharmacist
Jill Oliveira Gray, Public Member

Members Excused: Garrett Lau, Pharmacist

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

Guests: Staci Alli, Foodland Pharmacy
Stacy Pi, Kaiser Permanente
Gerry Fujii
Albert Lau, Kaiser Permanente
Greg Edwards, Department of Health ("DOH")
Marcella Chock, Hawaii Pharmacist Association ("HPhA")
Lyell Hirashiki, Kaiser Permanente
John Houghtby, 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 9:08 a.m.

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

The Chair excused Garrett Lau from the meeting today.

Orientation for Board Chairpersons

The Chair reported that he attended the orientation for Board chairpersons on December 6, 2011 at the State Capitol. Representatives from the Regulated Industries Complaints Office ("RICO"), the Office of Administrative Hearings ("OAH") and the Director's Office spoke on topics covering contested case hearings, ethics in government, review of the Sunshine Law, and personal liability of members of Boards.

Kealii Lopez, Director of the Department of Commerce and Consumer Affairs, emphasized that the primary role of the Board is to update the administrative rules. Senator Rosalyn Baker noted that it would be better for the Boards to revise the rules rather than have the legislature amend the laws because which may be more restrictive.

Additions and Additional Distribution

The Chair announced that the following agenda item had additional distribution:

Additional Distribution

7. Applications
 - b. Applications
 - 1) Pharmacist
 - i. Donald Schumacher

Approval of the Previous Minutes – November 17, 2011 Meeting

The Chair asked if there were any amendments to the minutes of the November 17, 2011 meeting.

The Vice Chair stated that on page 5, paragraph 4 under Request for CME Approvals from Diane M. Ondracek, the motion was **not** to approve the continuing medical education courses.

There being no further amendments to the minutes, upon a motion by Dr. Ma, seconded by Mr. Inafuku, it was voted on and unanimously carried to approve the minutes of the November 17, 2011 meeting as amended.

Executive Officer's Report

The EO introduced Kenyatta Nichols as a new Executive Officer. He will be the Executive Officer for the Board of Massage Therapy, Board of Physical Therapy and the back-up for the Cemetery Program.

Addition to the Regulated Industries Complaints Office (RICO) Advisory Committee

The EO asked the Board for their consideration to add a pharmacist to the RICO Advisory Committee. She explained that the role of the RICO Advisory Committee member is to assist RICO in their investigation of complaints against licensees to review practices and procedures and to provide their expertise as a professional.

There being no questions or further discussion, upon a motion by the Vice Chair, seconded by Mr. Inafuku, it was voted on and unanimously carried to approve the addition to the RICO Advisory Committee.

The EO also stated that if anyone is interested as serving on RICO's Advisory Committee they can contact her.

Meeting with Purdue Representative Report

The EO reported that she met with a representative from Purdue and that information regarding Buprenorphine drug products were distributed to the Board members and that Purdue also has a web page where they offer ACPE accredited continuing education courses.

National Association of Boards of Pharmacy ("NABP") Compliance Officer Forum – Greg Edwards

Mr. Edwards reported he attended the NABP Interactive Compliance Officer Forum with 37 – 48 attendees who handle a variety of responsibilities. Topics covered were drug shortages, counterfeit drugs, pedigree drugs, pill mills, storage compliance issues. The forum consisted of half hour presentations from various attorneys sharing issues from their respective states.

During a session about counterfeit drugs, a statistic brought up from the World Health Organization is that about 50% of the drugs coming out of Asia are counterfeit and that Hawaii would most likely be a route of entry for these drugs.

Report by Mr. Inafuku: Laws and Rules Committee

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

- The Committee has added to the advisory committee, Blaine Ikeda from PharmaRx Hawaii to represent nuclear pharmacists and Paul Gammie from Gammie HomeCare on Maui to represent medical oxygen distributors;

- The Chair stated he will distribute to the committee members all comments he receives after redacting personal information.
- The Committee will look at and discuss the NABP Model Act at the next meeting.

HAR Title 16, Chapter 95 – Consideration of Draft 3/17/2010 Proposed Amendments

Mr. Inafuku reported that the Laws and Rules Committee recommends the Board move forward with a draft of the rules that was previously approved by the Board.

The EO explained that although the Laws and Rules Committee voted to take out the definition of “Collaborative agreement”, Subchapter 16 entitled “Collaborative Agreement” and section §16-95-131 Collaborative agreements for immunizations, she left those sections in for further consideration by the Board. She stated that the Board could agree with the Laws and Rules Committee to move this draft forward through the rules adoption process as is or with amendments or not move this draft forward and refer back to the Laws and Rules Committee.

The Vice Chair stated that he had concerns with the definition of collaborative agreement and the sections pertaining to collaborative agreements. He stated that subsequent to the Board’s previous approval, there have been further discussions and other issues regarding pharmacists and collaborative agreements and that the Board should revisit these issues before including these new sections and the definition in the rules.

Mr. Inafuku stated that the violation for failure to report disciplinary action taken in another jurisdiction should be specified in section 16-95-110.

The EO stated that it is already in a statute under HRS 436B, which the Board has referred to on numerous occasions.

Mr. Inafuku stated that it would be more convenient if the pharmacy rules were specific instead of relying on another chapter.

Dr. Ma stated that the terms “prescriber” and “practitioner” is used throughout the chapter and perhaps one term should be considered to avoid confusion.

Upon a motion by the Vice Chair, seconded by Dr. Ma, it was voted on and unanimously carried to move forward with HAR Title 16, Chapter 95, Draft 3/17/2010 with changes.

After further discussion, upon a motion by the Vice Chair, seconded by Dr. Ma, it was voted on and unanimously carried to move forward with HAR Title 16, Chapter 95, Draft 3/17/2010 with the following changes:

- Delete the proposed definition of "Collaborative agreement";
- Delete the proposed definition of "Deliver" or "delivery";
- Delete the proposed definition of "Dispense" or "dispensing";
- Include language under §16-95-110, similar to HRS §436B-19(15) regarding failure to report disciplinary action;
- Delete the proposed new subsection entitled "§16-95-129 Collaborative Agreement" and "§16-95-131 Collaborative agreements for immunizations" and
- Other non-substantive corrections
 - Change "Pharmacy" to "Pharmaceutical" in §16-95-2 Definitions, second paragraph, line 3.
 - Correct the spelling of "unencumbered" in §16-95-73(2)(C), line 6.
 - Delete proposed language "except as allowed in section §461-11.5, HRS" in §16-95-87.

Correspondence:

National Association of Boards of Pharmacy ("NABP")

NABP State News Roundup – November 2011

The Chair reported that in one article, the Iowa Board of Pharmacy, through new legislation, is allowed to consider only pharmacy pilot projects that expand pharmaceutical care services that contribute to positive patient outcomes and not projects intended only to provide a competitive advantage.

He also reported that the Ohio Board of Pharmacy, due to legislation, has promulgated administrative rules addressing mandatory access to the Ohio Automated Rx Reporting System.

Medi-Scripts Services – Hawaii Prescription Requirements

The Board reviewed the letter from Karen Daniels of Medi-Scripts Services regarding preprinted prescription pads, Hawaii regulations governing generic substitution and Hawaii Administrative Rules §16-95-82 Valid prescription.

If was the consensus of the Board to refer Ms. Daniels to HAR 16-95-82 for prescriptions for non-controlled substances and to Mr. Edwards, Department of Health, Food and Drug Branch regarding the generic substitution laws. The board also refers Ms. Daniels to the Department of Public Safety, Narcotics Enforcement Division for controlled substance prescriptions.

Allison Shelton – License Requirements for Out-of-State Facility Which Provides Diagnostic Health Tests by Mail

The Board reviewed and discussed an inquiry from Ms. Shelton asking if an out-of-state facility providing diagnostic health tests by mail need to be registered or licensed in Hawaii and if there are any licensure or registration requirements for technicians.

According to Ms. Shelton, the facility is what Medicare refers to as an “Independent Diagnostic Testing Facility.” This is the business model of the facility: A patient’s treating physician, who resides in and is licensed in Hawaii, orders a cardiac monitor from the out-of-state facility; the cardiac monitor is a prescription-only device. The facility mails the monitor to the patient residing in Hawaii. The monitor will transmit data to the facility, where technicians will compile data and report the data to the treating physician. The treating physician will use the data to diagnose the patient.

After some discussion, it was the informal interpretation of the Board that pursuant to HRS § 461-15(7), any prescription drug or device may only be dispensed to the end user/patient by a licensed/permitted pharmacy. An out-of-state entity would be required to obtain a miscellaneous permit as an out-of-state pharmacy.

In response to Ms. Shelton’s inquiry of technicians, although it was unclear what kind of “technician” Ms. Shelton was referring to, however, Hawaii does not license/register/certify pharmacy technicians.

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

Laura Norris – Licensing Requirements for Out-of-State Pharmaceutical Manufacturer

The Chair asked the Vice Chair to lead the discussion on an inquiry from Ms. Norris regarding the license requirements for a pharmaceutical manufacturing company located in another state, that does not manufacture in their home state, but outsources all of their manufacturing and distribution to third parties.

After some discussion, it was the consensus of the Board to inform Ms. Norris that Hawaii does not require out-of-state manufacturers or wholesale distributors to obtain a license in this State if these entities do not have a physical location in this State, however, any entity shipping controlled substances into this State must be registered with the Department of Public Safety, Narcotics Enforcement Division.

Expiration of Medical Oxygen Prescriptions

The Chair asked Dr. Ma to lead the discussion on an email asking if there is a time limit on how long a prescription for medical oxygen is valid for in Hawaii.

After some discussion, the Board decided to refer the inquiry to Mr. Edwards since HRS 328 appears to specifically address prescriptions for medical oxygen.

Board of Naturopathic Medicine Letter – Prescription Drug Samples

The Chair asked Mr. Inafuku to lead the discussion on the letter from Ms. Candace Ito, Executive Officer for the Board of Naturopathic Medicine referring to an email from Emily Jacque asking whether a naturopathic physician may receive drug samples.

The DAG advised the Board to enter into Executive Session.

Executive Session:

At 10:20 a.m., upon a motion by Ms. Kumasaka, seconded by the Vice Chair, it was voted on and unanimously carried to move into executive session pursuant to §92-5(a)(4), HRS, "To consult with the Board's attorney on questions and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities;".

At 10:31 a.m. upon a motion by Ms. Kumasaka, seconded by Dr. Ma, it was voted on and unanimously carried to move out of executive session.

After some discussion, it was the consensus of the Board that since a naturopathic physician's scope of practice includes prescriptive authority, they may receive prescription drug samples, within the naturopathic formulary, to dispense to their own patients.

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

Open Forum:

The EO reported that she received a copy of a bill entitled "Relating to Pharmacist Continuing Education" which proposes to amend the definition for "Continuing education courses" by deleting reference to continuing medical education courses, to be discussed at the Board's January meeting.

Mr. Inafuku reported he was working with the Department of Health on identifying Alternate Care Sites to be used during a disaster emergency. These sites will be set up to provide access to prescription drugs for individuals in need of conditional care or with disabilities. Mr. Inafuku asked if HPhA could help identify pharmacies that have back up power.

Mr. Inafuku also stated he suggested Ann Sakaguchi of Emprints contact the HPhA and the UH Hilo College of Pharmacy regarding certification of the course Emprints offers - Training Pacific Professionals For Better Emergency Preparedness and Response.

Ms. Chock stated that any health care provider can reach out to any ACPE administrator and they will work through the process to add that certification to their existing program. The process requires a lead time of 60 days.

Mr. Fujii announced that he is leaving the Laws & Rules Committee Lead Contact group.

Applications:

Ratification List

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

Executive Session:

At 10:46 a.m. upon a motion by the Vice Chair, seconded by Dr. Ma, 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 10:59 a.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.

Applications:

Applications

Pharmacist

Donald R. Schumacher

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

Joseph Paul Harris

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. Harris.

Miscellaneous Permit
Revival Animal Health

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 Revival Animal Health.

Medco Center for Pharmacotherapeutic Research

Upon a motion by Dr. Ma, seconded by Mr. Inafuku, it was voted on and unanimously carried to defer the decision making on the miscellaneous permit application for Medco Center for Pharmacotherapeutic Research for more information and clarification on the name of the applicant.

Meds at Home

Upon a motion by Mr. Inafuku, seconded by the Vice Chair, it was voted on and unanimously carried to defer decision making on this miscellaneous permit application for Meds at Home for more information and clarification on the applicant's affiliation with other entities listed with the application.

Next Meeting: Thursday, January 19, 2012
9:00 a.m.
King Kalakaua Conference room
King Kalakaua Building, First Floor
335 Merchant Street
Honolulu, Hawaii 96813

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 11:02 a.m.

Taken and recorded by:

/s/ Christine Hironaka
Christine Hironaka, Secretary

Reviewed by:

/s/ Lee Ann Teshima
Lee Ann Teshima, Executive Officer
1/9/12

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

BOARD OF PHARMACY

December 15, 2011 Ratification List

Miscellaneous Permits (PMP)

Closure:

Relocation:

Change of Pharmacist-in-charge: New PIC Barrett Karl Manning
Pharmedium Services, LLC (PMP 633)

New PIC Melinda Griffin
Express Scripts (PMP 643)

Pharmacy (PHY)

Change of Pharmacist-in-charge:

Relocation:

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

Prescription Wholesale Distributor (PWD)

Name Change:

Cardinal Health 200, Inc. to Cardinal Health 200 LLC (PWD 49)

BOARD OF PHARMACY
December 15, 2011
RATIFICATION LIST

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<u>LTYPE</u>	<u>LIC</u> <u>NUM</u>	<u>BP NAME PART 1</u>
PH	3298	COURTNEY K <SHISHIDO<
PH	3299	KAREN R <ROBERTS<
PH	3300	JODI T <WATANABE<
PH	3301	MIA E <KAWAMURA<
PH	3302	KESHA T <MORGAN<

VAM_TEMP_LICENSE_VIEW Saturday December 03, 2011 03:15 PM Page 1

<u>TEMP LIC</u> <u>LTYPE</u>	<u>TEMP</u> <u>LIC</u>	<u>VAM BPR LEGAL NAME 1</u>
PHI	3033	MEGAN C <GOLDBERG<
PHI	3034	KELLY A <HANCOCK<

**BOARD OF PHARMACY
December 15, 2011
RATIFICATION LIST**

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<u>LTYPE</u>	<u>LIC NUM</u>	<u>LIC NAME PART 1</u>	<u>BUSN ADDR 1</u>	<u>BUSN CITY</u>	<u>BUSN ST</u>	<u>BUSN ZIP</u>	<u>BP NAME PART 1</u>
PHY	808	SAFEWAY PHARMACY #2944	1234 S BERETANIA ST	HONOLULU	HI	96814	SAFEWAY INC

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<u>LTYPE</u>	<u>LIC NUM</u>	<u>LIC NAME PART 1</u>	<u>BUSN ADDR</u>	<u>BUSN CITY</u>	<u>BUSN ST</u>	<u>BUSN ZIP</u>	<u>BP NAME PART 1</u>
PMP	730		7304 JARNIGAN RD	CHATTANOOGA	TN	37421	THE <WELLNESS> CENTER PHARMACY INC
PMP	731		5371 HIATUS RD	SUNRISE	FL	33351	DIABETIC CARE RX LLC