

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

MINUTES OF MEETING

Date: Thursday, July 17, 2014

Time: 9:00 a.m.

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

Members Present: Kerri Okamura, Pharmacist
Mary Jo Keefe, Pharmacist
Carolyn Ma, Pharmacist
Marcella Chock, Pharmacist
Lydia Kumasaka, Public Member

Members Absent: Garrett Lau, Pharmacist

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

Guests: Todd Inafuku
Judy Ung, The Honolulu Pharmacy
Victor Ung, The Honolulu Pharmacy
Fred Cruz, CVS Caremark
Catalina Cross, Times Supermarket
Paul Smith, Walgreens
Tiffany Yajima, Ashford & Winston
Brian Bautista, Creighton University
Cheryl Fujihara, Kaiser Permanente
Dennis McAllister, Express Scripts
Albert Lau, Kaiser Permanente
Patrick Uyemoto, Times
Daniel Leong, UH Hilo College of Pharmacy
Kenna Muramoto, UH Hilo College of Pharmacy
Kellie Naguchi, Times

Call to Order: 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").

There being a quorum present, the meeting was called to order at 9:00 a.m.

Election of Board
Chair Pro Tem: Kerri Okamura volunteered to be Chair Pro Tem.

Upon a motion by Dr. Ma, seconded by Ms. Keefe, it was voted on and unanimously carried to elect Kerri Okamura as the Chair Pro Tem.

Announcements and Introductions

The Chair Pro Tem announced the confirmation of Marcella Chock as a new Pharmacist Board member.

The Chair Pro Tem asked the Board members and audience to introduce themselves.

The Chair Pro Tem excused Garrett Lau from today's meeting.

Additions/Additional Distribution to Agenda

None.

Approval of the Previous Minutes – June 19, 2014

The Chair Pro Tem called for a motion in regards to the minutes of the June 19, 2014 meeting.

Dr. Ma stated next to guest Marcella Chock's name, correct to read HPhA. On page 6, last paragraph, second sentence, the word pharmacist is single, not plural, remove the s.

The Chair Pro Tem stated on page 3, first paragraph, second sentence, correct years to 2014-2015. Also on page 3, last paragraph, 3rd sentence; correct spelling of "out-of-state".

Upon a motion by Dr. Ma, seconded by Ms. Chock, it was voted on and unanimously carried to approve the minutes for the June 19, 2014 meeting as amended.

Laws and Rules Committee Report:

Ms. Keefe reported on the Committee's June 19, 2014 meeting.

Ms. Keefe stated last month's meeting was brief. The Committee will continue to discuss adopting rules regarding collaborative agreements and will also begin discussing further the miscellaneous permit section.

The EO will also be checking with the UH College of Pharmacy when classes resume to get the students help researching and gathering information on collaborative agreements.

Executive Officer's Report:

Dean of Pharmacy John M. Pezzuto to Leave UH Hilo

The EO reported that an announcement made June 27, 2014 states that the founding dean of the University of Hawaii at Hilo Daniel K. Inouye College of Pharmacy, will leave the University at the end of this year to assume his new duties as professor and dean of the Arnold and Marie Schwartz College of Pharmacy and Health Sciences at Long Island University (LIU) located in Brooklyn, New York.

New York State Board of Pharmacy Will No Longer Provide Certification or Verification of Internship and/or Clinic Experience for Pharmacy Students/Graduates

The EO reported that effective June 16, 2014; the New York State Board of Pharmacy will no longer provide certification or verification of internship hours or clinical experiences. All graduates of accredited colleges and schools of pharmacy are required to complete both introductory and advanced practice rotations in pharmacies. Completion of these externship/internship hours is overseen by the colleges. The New York State Board of Pharmacy does not independently audit or reconfirm these experiences.

Guest Dennis McAllister of Express Scripts stated what a lot of states have done now is that they said that any student that graduates from an ACPE accredited school meets the internship requirements.

Dr. Ma stated that UH Hilo College of Pharmacy has not discussed this yet and as far as she knows a ruling has not come down regarding this.

Correspondence:

Compounding for Office Use Out-of-State Pharmacies – Deferred from May 15 and June 19, 2014 Meetings

Compound Hydroxyprogesterone for Office Use

The Board reviewed an email inquiry asking if licensure in Hawaii is required to compound hydroxyprogesterone for office use.

After some discussion, it was the consensus of the Board that an out-of-state pharmacy that compounds for office use must obtain a Hawaii miscellaneous permit and that the pharmacy practice act in the pharmacy's domicile state must permit the pharmacy/pharmacist to compound for office use under the pharmacy permit/license.

Article: "FDA outlines expectations for human drug compounders, including registered outsourcing facilities"

The Board was provided with a copy of an FDA News Release, which included several policy documents that outline expectations for human drug compounders, including registered outsourcing facilities.

The EO stated continuing the discussion of in-state pharmacies compounding for office use, after reviewing the laws and rules, it says under HRS §461-15(6) it shall be unlawful for any person, as principal or agent, to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug without first obtaining a permit from the board to do so. Therefore, if a pharmacy or entity wanted to compound for office use, it appears all they need is a miscellaneous permit.

The Chair Pro Tem asked if this applies to in-state and out-of-state pharmacies or entities?

The EO stated yes.

Guest Victor Ung asked when this will take effect?

The EO stated the Board still needs to discuss and decide.

Executive Session:

At 9:19 a.m., upon a motion by Ms. Kumasaka, seconded by Ms. Chock, 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 9:46 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.

Correspondence:

Compounding for Office Use Out-of-State Pharmacies – Deferred from May 15 and June 19, 2014 Meetings

Article: "FDA outlines expectations for human drug compounders, including registered outsourcing facilities"

After further discussion it was the consensus of the Board to allow in-state pharmacies the same privileges as an out-of-state pharmacy, and in order to compound for office use would be required to obtain a miscellaneous permit.

National Association of Boards of Pharmacy (NABP)

NABP State News Roundup – June 2014

The Chair Pro Tem reported on the following:

- On April 11, 2014, Kansas Governor Sam Brownback signed Senate Substitute for House Bill 2146 in law, making several amendments to the Kansas Pharmacy Practice Act, which will become effective on July 1, 2014; the amendments expand the definition of the practice of pharmacy to include the performance of collaborative drug therapy management.
- With an overwhelming House vote of 98-0 and Senate vote of 32-0, the Tennessee General Assembly voted unanimously to give Tennessee-licensed pharmacists the ability to enter into collaborative pharmacy practice agreements with prescribers to improve the health, safety, and quality of care for their patients.
- Dr. Harry Chen, commissioner of the Vermont Department of Health, has issued an emergency rule to restrict how health care providers prescribe certain single active ingredient hydrocodone products such as Zohydro ER. The emergency rule was released on April 3, 2014, by the Vermont Department of Health.
- During the 2014 regular West Virginia Legislative Session, House Bill 4208 passed and became effective on June 6, 2014. It updates several things in the West Virginia Controlled Substances Act, including adding a number of synthetic cannabinoids to Schedule I, and cleaning up some differences between the state and federal schedules (like moving buprenorphine to Schedule III in the state code to match the federal)

NABP's Comments to the Substance Abuse and Mental Health Services Administration
Regarding the Confidentiality of Alcohol and Drug Abuse Patient Records

The Board reviewed correspondence from NABP commenting on the Substance Abuse and Mental Health Services Administration.

In summary, NABP recommends that all prescriptions delivered to the pharmacy at the direction of the patient be exempt from the confidentiality requirements of 42 CFR Part 2.

NABP's Comments to the CMS, Department of Health and Human Services Final Rule reforms to
Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency,
Transparency, and Burden Reduction; Part II

The Board reviewed correspondence from NABP in response to the CMS, Department of Health and Human Services Final Rule reforms to Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II.

The Pennsylvania State Board of Pharmacy recently brought to NABP's attention a rule issued by the Centers for Medicare & Medicaid Services (CMS) which permits the absence of direct supervision of nuclear technologists.

In summary, NABP hopes that CMS will reevaluate its position and reinstate the previous requirement to have direct supervision of radiology technicians in order to align with current state legislation and to ensure patient safety.

Deliver Inquiry

The Board reviewed an email inquiry asking if specialty drugs can be delivered to a local retail pharmacy of the patient's choice instead of to the patient's home.

It was the Board's informal interpretation that based solely on the information provided in the email, at patient's request, another pharmacy may be designated to receive the prescription drug from the dispensing pharmacy in order for the patient to pick up his/her medication.

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

Return to Stock of Undelivered Medications and Expiration Dates Inquiry

The Board reviewed an email inquiry asking what the Board's position is on return to stock of undelivered medication in regard to expiration dates.

After brief discussion, the Board determined that their rules only address prescription drugs that have left the pharmacy premises and do not specifically address this issue. They also determined that they would defer this matter for further discussion to their Laws and Rules Committee since the Board does not have a current policy or position on this matter.

Article on Painkiller Prescriptions – Hawaii the Least

The Board reviewed an article on painkiller prescriptions that stated Hawaii had the least prescriptions, at 52 per 100 people.

Pre-Printed Prescription Pads

The Board reviewed and email inquiry regarding pre-printed prescription pads. The following are 4 questions asked in the inquiry with the Board's responses:

1. Are pre-printed prescription pads legal in your state? ***The pharmacy laws and rules do not specifically address pre-printed prescription pads, only what is considered a "valid" prescription. HRS §16-95-82 Valid prescriptions (a) A pharmacist may fill and dispense prescriptions provided the prescription is valid. A valid prescription shall be legibly written and contain, at the minimum, the following information:***
 - (1) ***The date of issuance;***
 - (2) ***The original signature of the prescriber;***
 - (3) ***The prescriber's name and business address;***
 - (4) ***Then name, strength, quantity, and directions;***
 - (5) ***The name and address of the owner of the animal for which the drug is prescribed (unless the pharmacy filling the prescription has such address on file);***
 - (6) ***The room number and route of administration if the patient is in an institutional facility; and***
 - (7) ***If refillable, the number of allowable refills.******(b) Except where a written prescription is required by law, a phone order is acceptable from prescribers or their authorized agent provided:***
 - (1) ***Only a pharmacist shall receive the oral prescription;***
 - (2) ***The oral prescription is promptly reduced to writing and kept on file for five years: and***
 - (3) ***The oral prescription contains all of the information required under subsection (a).******(c) A faxed prescription for a prescription for a noncontrolled substance is acceptable from prescribers provided the facsimile is sent by the prescriber or the prescriber's authorized agent, and contains all of the information required under subsection (a) and kept on file for five years.***
 - (d) ***No prescription which is coded shall be filled or dispensed.***
 - (e) ***Any pharmacist shall comply with any applicable state or federal laws or rules governing the validity of prescriptions.***
2. What are the stipulations for these pads (color, number of active formulas, etc.)? ***Not specified.***
3. Can there be multiple doctors on one pad? ***Not specified.***
4. Lastly, what are the penalties for non-conformance, and what enforcement actions are taken in your state? ***If the prescription does not meet the requirements listed above, it may not be filled.***

Licensure of a Veterinary Reference Laboratory

The Board reviewed an email inquiry asking if a veterinary reference laboratory that formulates veterinary biological products falls within the purview of the Hawaii Board of Pharmacy's regulatory authority, or whether an out-of-state pharmacy license in Hawaii is required.

After brief discussion, the Board determined that based solely on the information provided the pharmacy formulating the biological product would have to be licensed/permitted in their domicile state to perform such activities, e.g. a pharmacy and obtain a Hawaii miscellaneous permit in

order to formulate (compound a biological product) and ship directly to a veterinarian for office use and not to the patient.

Board of Pharmacy Questions

The Board reviewed an email inquiry asking the following two questions:

1. Regarding call-in prescriptions that a pharmacist takes from a doctor that is "Brand Medically Necessary", what actually needs to be documented on the prescription? Does it need to say "Brand Medically Necessary" or "Do Not Substitute" verbatim or can it be abbreviated to say "Brandy Only"?
2. Regarding immunization consent forms, can the form be signed and dated by the patient on a different date other than the date they actually receive the flu shot?

Guest Kenna Muramoto, the writer of the email was present and addressed the Board.

Ms. Muramoto stated some pharmacies require that they document verbatim "Brand Medically Necessary" or "Do Not Substitute" and are requiring that the pharmacist or pharmacy intern sign their full name next to that documentation even though it's already a given that the pharmacist is taking that prescription. Ms. Muramoto is asking the Board if that is in fact required.

Ms. Chock stated HRS §328-92(b) says, The pharmacist shall not substitute an equivalent generic drug product if the practitioner indicates "brand medically necessary" or words of similar meaning on the prescription. The designation "brand medically necessary" or other similar words or phrases must be handwritten by the practitioner and shall not be preprinted or stamped on the written prescription. The pharmacist shall not substitute an equivalent generic drug product if a prescription is orally or electronically ordered and the practitioner or authorized employee of the practitioner indicates "brand medically necessary" or other similar words or phrases.

Ms. Muramoto clarified that is does not have be signed with the pharmacist full name then?

The EO stated that is not addressed in the laws and rules and also reminded Ms. Muramoto that HRS §328-92(b) is the Department of Health, Food, Drug and Cosmetics statute, not the Board of Pharmacy's.

Ms. Muramoto asked the Board about her second question regarding the immunization consent forms.

The EO stated the Board does not have an immunization consent form, so that question cannot be addressed.

Old Business:

HAR Title 16, Chapter 95 – Status Report

The EO reported she is still working on getting the draft printed with the non-substantive changes.

Executive Session:

At 10:24 a.m., upon a motion by the Chair Pro Tem, seconded by Ms. Chock, 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 10:27 a.m. upon a motion by Ms. Keefe, seconded by Dr. Ma it was voted on and unanimously carried to move out of executive session.

Chapter 91, HRS .
Adjudicatory Matters:

The Chair Pro Tem called for a recess from the meeting at 10:27 a.m. to discuss and deliberate on the following adjudicatory matter(s) pursuant to Chapter 91, HRS:

In the Matter of the Pharmacist's License of **RICHARD L. SPEARMAN, PHA 2012-11-L**,
Hearings Officer's Findings of Fact, Conclusion of Law and Recommended Order; Exhibit
"A"

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

Applications:

Ratification List

Upon a motion by Ms. Keefe, seconded by Ms. Chock, it was voted on and unanimously carried to approve the attached ratification lists.

Applications

Miscellaneous Permit

Upon a motion by the Chair Pro Tem, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the following application:

Currant Health Florida, LLC

Election of Board
Chair:

The Chair Pro Tem, Kerri Okamura volunteered to be Board Chairperson.

Upon a motion by Ms. Keefe, seconded by Ms. Kumasaka, it was voted on and unanimously carried to elect Kerri Okamura as the new Board Chairperson.

Next Meeting:

The Chair announced the next Board meeting and asked if everyone was available.

Dr. Ma stated she will be unable to attend the August meeting.

Thursday, August 21, 2014
9:00 a.m.
King Kalakaua Conference Room
King Kalakaua Building
335 Merchant Street, 1st Floor
Honolulu, Hawaii 96813

Adjournment:

With no further business to discuss, the Chair adjourned the meeting at 10:37 a.m.

Taken and recorded by:

Reviewed and approved by:

/s/ Lisa Kalani
Lisa Kalani, Secretary

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

7/31/14

☐ Minutes approved as is.

☒ Minutes approved with changes; see minutes of 8/21/14

LTYPE	LIC NUM	BP NAME PART 1
PH	3670	GINA M <LENTO<
PH	3671	BARRY D <NAKAOKA<

LTYPE	LIC NUM	BP NAME PART 1

PMP	998	NUDAK VENTURES LLC
PMP	999	JCB LABORATORIES LLC
PMP	1000	HOLLYWOOD HEALTHCARE CORP
PMP	1001	ALLCARE PLUS PHARMACY INC
PMP	1002	WALGREEN CO
PMP	1003	AMBER ENTERPRISES INC
PMP	1004	ARDON HEALTH LLC
PMP	1005	AXIUM HEALTHCARE PHARMACY INC
PMP	1006	CYSTIC FIBROSIS SERVICES INC

LTYPE	LIC NUM	BP NAME PART 1
PMP	998	NUDAK VENTURES LLC
PMP	999	JCB LABORATORIES LLC
PMP	1000	HOLLYWOOD HEALTHCARE CORP
PMP	1001	ALLCARE PLUS PHARMACY INC
PMP	1002	WALGREEN CO
PMP	1003	AMBER ENTERPRISES INC
PMP	1004	ARDON HEALTH LLC
PMP	1005	AXIUM HEALTHCARE PHARMACY INC
PMP	1006	CYSTIC FIBROSIS SERVICES INC

BOARD OF PHARMACY

July 17, 2014 Ratification List

Miscellaneous Permits (PMP)

Change of PIC:

Canyon Creek Inc. (PMP 909)

2235 Thousand Oaks Drive, #114A

San Antonio, Texas 78232

New PIC: Arvin Zeinali

Effective: 5/15/2014

Coram Healthcare Corporation of Northern California (PMP 751) dba Coram Specialty Infusion Services an Apria Health Company

3160 Corporate Pl.

Hayward, California 94545

New PIC: Patricia Igarashi

Effective: 6/9/2014

Foothills Professional Pharmacy LTD (PMP 789)

4545 E. Chandler Blvd. #100

Phoenix, Arizona 85048

New PIC: Ashley Patrick

Effective: 6/11/2014

Suncoast Radiopharmacy Services Inc. (PMP 912)

3102 Cherry Palm Dr., Ste. 120

Tampa, Florida 33619

New PIC: James Richardson

Effective: 6/5/2014

BioRx LLC (PMP 621)

dba BioRx

3821 71st Street Ste. C

Urbandale, Iowa 50322

New PIC: Adam Reyna

Effective: 6/16/2014

Hotbar LLC (PMP 851)

dba Monroe Clinic Drugs

1470 Garrett Rd., Ste. A

Monroe, Louisiana 71202

New PIC: Patricia Daniel

Effective: 6/3/2014

Biologics Inc. (PMP 454)

120 Weston Oaks Ct.

Cary, North Carolina 27513

New PIC: Gregory Wolfe

Effective: 5/30/2014

Name Change/Conversion/Addition of TN or DBA:

CHD Pharmacy (PMP 745)

255 Phillipi Road, Ste. 300

Columbus, Ohio 43228

Effective: 3/5/2014

CHD Pharmacy (PMP 744)

6225 Annie Oakley Drive, Ste. 300

Las Vegas, Nevada 89120

Effective: 3/12/2014

Relocation:

Caremark Florida Mail Pharmacy, LLC (PMP 372)

dba CVS Caremark

3300 N 28th Terrace

Hollywood, Florida 33020

Davita Rx LLC, dba Davita (PMP 806)

2252 Commerce Park Drive, Suite 350

Orlando, Florida 32819

Linden Care LLC (PMP 895)

130 Crossways Park Drive, Ste. 101

Woodbury, New York 11797

Closure:

Medication Adherence Solutions LLC (PMP 845)

dba Dailymed Pharmacy

975 Industrial road, Ste. E & G

San Carlos, California 94071

Effective: 5/21/2014

Medication Adherence Solutions LLC (PMP 791)

dba Dailymed Pharmacy

9320 Priority Way West Drive

Indianapolis, Indiana 46240

Effective: 6/16/2014

Express Scripts Pharmacy Inc. (PMP 957)

dba Express Scripts

23102 E Appleway Avenue

Liberty Lake, Washington 99019

Effective: 6/17/2014

Pharmacy (PHY)

Change of PIC:

**Wal-Mart Stores Inc. (PHY 551)
dba Wal-Mart Pharmacy 10-2321**

75-1015 Henry St.

Kailua-Kona, Hawaii 96740

New PIC: Jason Okazaki

Effective: 6/1/2014