

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

MINUTES OF MEETING

Date: Thursday, October 23, 2014

Time: Immediately following Board meeting

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

Members Present: Mary Jo Keefe, Pharmacist, Committee Chair
Kerri Okamura, Pharmacist
Garrett Lau, Pharmacist

Staff Present: Lee Ann Teshima, Executive Officer ("EO")
Lisa Kalani, Secretary

Guest: Greg Edwards, Dept. of Health, Food and Drug Branch
Todd Inafuku, Retiree
Marcella Chock, Pharmacist
Tiffany Yajima, Ashford & Winston
Catalina Cross, Times
Kellie Noguchi, Times

Call to Order: The meeting was called to order at 10:49 a.m.

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

The Chair asked the audience to introduce themselves

Approval of the Previous Minutes – August 21, 2014 meeting

The Chair called for a motion to the minutes of the August 21, 2014 meeting.

Upon a motion by Mr. Lau, seconded by Ms. Okamura, it was voted on and unanimously carried to approve the minutes of the August 21, 2014 meeting as circulated.

Old Business:

Miscellaneous Permits

The Committee was provided with the following draft of section §461-15 Miscellaneous Permits for the Committee to review by Mr. Todd Inafuku, who is the Board's former Chair and Laws & Rules Committee former Committee Chair.

§461-15 Miscellaneous permits. (a) It shall be unlawful:

- ~~[(1)]~~ For any person to sell or offer for sale at public auction, or to sell or offer for sale at private sale in a place where public auctions are conducted, any prescription drugs without first obtaining a permit from the board of pharmacy to do so;
- ~~[(2)]~~ For any person to distribute or dispense samples of any prescription drugs without first obtaining a permit from the board to do so; provided that nothing in this paragraph shall interfere with the furnishing of samples or drugs directly to physicians, druggists, dentists, veterinarians, and optometrists for use in their professional practice;]
- ~~[(3)]~~ (1) For wholesalers to sell, distribute, or dispense any prescription drug, except to a pharmacy, pharmacist, physician, dentist, veterinarian, or optometrist who is allowed to use pharmaceutical agents under chapter 459 or to a generally recognized industrial, agricultural, manufacturing, or scientific user of drugs for professional or business purposes; provided that it shall be unlawful for wholesalers to sell, distribute, or dispense any prescription pharmaceutical agent that is not approved by the board of examiners in optometry;
- ~~[(4)]~~ (2) For any wholesale prescription drug distributor to sell or distribute medical oxygen except to a:
 - (A) Licensed practitioner with prescriptive authority;
 - (B) Pharmacist;
 - (C) Medical oxygen distributor;
 - (D) Patient or a patient's agent pursuant to a prescription; ~~[or]~~
 - (E) Emergency medical services for administration by trained personnel for oxygen deficiency and resuscitation; or
 - (F) Pharmacy
- ~~[(5)]~~ (3) For any medical oxygen distributor to supply medical oxygen pursuant to a prescription order, to a patient or a patient's agent, without first obtaining a permit from the board to do so;
- ~~[(6)]~~ (4) 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; and
- ~~[(7)]~~ (5) For any out-of-state pharmacy or entity engaging in the practice of pharmacy, in any manner to distribute, ship, mail, or deliver prescription drugs or devices into the State without first obtaining a permit from the board; provided that the applicant shall:
 - (A) Provide the location, names, and titles of all principal corporate officers;
 - (B) Attest that the applicant or any personnel of the applicant has not been found in violation of any state or federal drug laws, including the illegal use of drugs or improper distribution of drugs;

- (C) Submit verification of a valid unexpired license, permit, or registration in good standing to conduct the pharmacy in compliance with the laws of the home state and agree to maintain in good standing the license, permit, or registration; and
 - (D) Have in its employ a Hawaii registered pharmacist whose registration is current and in good standing.
- (6) For any entity, except a pharmacy, engaging in the distribution, shipment, mailing, or delivery of devices within or into the State without first obtaining a permit from the board; provided that the applicant shall:
- (A) Provide the location, names, and titles of all principal corporate officers; and
 - (B) Attest that the applicant or any personnel of the applicant has not been found in violation of any state or federal device laws, including the illegal use of devices or improper distribution of devices; and
- (7) For any out-of-state pharmacy, pharmacist or entity to engage in the practice of pharmacy within the State without first obtaining a permit from the board; provided that the applicant shall:
- (A) Provide the location, names, and titles of all principal corporate officers or if the applicant is a pharmacist, the pharmacist name and address;
 - (B) Attest that the applicant or any personnel of the applicant has not been found in violation of any state or federal drug laws, including the illegal use of drugs or improper distribution of drugs;
 - (C) Submit verification of a valid unexpired license, permit, or registration in good standing to conduct the pharmacy or to engage in the practice of pharmacy in compliance with the laws of the home state and agree to maintain in good standing the license, permit, or registration; and
 - (D) Have pharmacist(s) engaged in the practice of pharmacy within Hawaii obtain a Hawaii pharmacist license or have in its employ Hawaii registered pharmacist(s) whose registration is current and in good standing.
- (b) A person whose application for a permit has been denied may file for an administrative hearing in conformity with chapter 91. [L 1949, c 175, pt of §1; am L 1953, c 76, §2; RL 1955, §71-15; HRS §461-15; am L 1985, c 294, §5; am L 1993, c 259, §1; am L 2000, c 83, §7; am L 2002, c 164, §5]

After some discussion, the Committee will be using the draft as a starting point to make appropriate changes and/or deletions to the miscellaneous permit section.

Pharmacy Practice

Discussion was deferred.

Pharmacy Inspectors

The EO stated regarding 503B Outsourcing Facilities, the discussion at the Executive Officer's forum that she attended was if you are registered with the FDA as an outsourcing facility, you have to have an inspection done every few years. The majority wanted the facilities inspected every year. The EO has already discussed having an inspector with the Licensing Administrator and is looking at having one inspector that will be housed at RICO, will be responsible for investigating any and all pharmacy complaints and handle all pharmacy inspections.

Next Meeting: December 18, 2014
Immediately following Board meeting
King Kalakaua Conference Room
King Kalakaua Building, 1st Floor
335 Merchant Street
Honolulu, Hawaii 96813

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 11:45 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

10/30/14

[X] Minutes approved as is.

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