

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

MINUTES OF MEETING

Date: Thursday, March 21, 2013

Time: 8:00 a.m.

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

Members Present: Todd Inafuku, Pharmacist, Chair
Patrick Adams, Pharmacist, Member

Excused: Mark E. Brown, Pharmacist, Member

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

Guests: Paul Smith, Walgreens
Peter Harty, CVS Caremark
Mike Dolson, Unique Pharm
Raphael del Acostillo, HSFH
Greg Edwards, Dept. of Health, Food and Drug Branch

Call to Order: The Chair called the meeting to order at 8:00 a.m.

Chair's Report: **Approval of the Previous Minutes – January 17, 2013 meeting**

The Chair called for a motion to approve the minutes of the January 17, 2013 meeting.

The Chair pointed out a spelling error on page 3, second line, should read 'model', not 'mod'.

Upon a motion by Mr. Adams, seconded by the Chair, it was voted on and unanimously carried to approve the minutes of the January 17, 2013 meeting as amended.

HRS §461-15 **Review of the current miscellaneous permit categories to determine if they
Miscellaneous Permits: are necessary**

The Chair reported the Board has been inundated with a lot of request for interpretations on the various types of permits that are issued, and what category they would fall into. Any changes will require statutory change. The Chair stated he forwarded some questions to the EO that may assist the Committee in the discussion of the miscellaneous permit categories. The questions and responses are as follows:

1. What types of miscellaneous permits have been issued?

Unfortunately the license data base does not keep track of the "categories" of the miscellaneous permits so the information is not available.

2. How many miscellaneous permits have been issued for each type?

Not available.

3. How many out of state pharmacies have been required to have pharmacists licensed in Hawaii?

Not available, but only recently has the Board made this determination.

4. How many investigations by RICO for entities holding miscellaneous permits have been settled, and what types of violations have occurred?

RICO does not maintain their case database by license type so this information is not available.

5. What other types of permit request have been brought before the Board?

None since the categories are not specific to different pharmacy settings.

6. Does the Department of Health regulate distributors of medical devices?

No, the definition of "Wholesale distribution" and "Wholesale distributor" refers to "prescription drugs" not devices.

7. How many businesses in Hawaii distribute medical devices?

Unknown.

8. How many permits request has the Board received regarding supplying medical devices from out of state?

Specific number unknown but we do receive quite a few inquiries.

The Committee then proceeded to review the categories under HRS §461-15 Miscellaneous permits ("PMP"):

- "(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;"

The Chair asked if this is necessary.

Mr. Adams stated pharmacy changes faster than the law changes. To get rid of the PMP would hurt us rather than help us if we haven't defined everything that is happening and will happen in the future.

The EO clarified the intent is not to eliminate the PMP, but to look at each category and see which categories are or may still be necessary. She also stated that she is unaware that a PMP was issued under this category and asked the Committee to clarify this category which appears to allow a person or entity to sell prescription drugs at a public auction or private sale.

The Chair asked if someone does this, does it create a problem because they didn't have a permit. The Chair only knows of two provisions that drugs can be sold; a pharmacy or a doctor/clinic office. The only exemption to those provisions is the emergency preparedness side where the Department of Health can have emergency response stockpile of drugs for emergency situations.

Mr. Adams stated if we leave the PMP in place, we will always have the option to license something that may come up in the future and maybe we can look at other state regulations as a model and see if it would work for Hawaii.

The EO agreed but recommended the Committee review their current categories in the meantime. She asked if the Committee knew of anyone conducting this type of business and is this something that should be allowed.

Mr. Adams stated he has never heard of anyone doing this and is okay with eliminating it.

The Chair stated that this section is very old, prior to the PDMA. The PDMA has a lot more requirements because of the wholesale distributors' licensing and that now with PDMA in place, he questioned whether we really need to issue a permit under this category.

Mr. Adams stated the Board needs to change the way the PMPs are handled and/or processed.

The Committee recommends that this first category be deleted.

The Committee reviewed the second category under the miscellaneous permit section that reads as follows:

"(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;"

The Chair asked if this is necessary.

Mr. Adams stated drug samples are very strictly controlled and questioned why anyone would issue samples other than to someone who is already licensed.

The Chair stated the only reason this category may be in this section is if you are supplying samples to someone other than the professions listed in the section, therefore, if this category is deleted, PDMA takes effect.

The EO stated the only ones who can dispense prescription drugs are pharmacies or practitioners authorized to dispense under their scope of practice.

The Chair stated that a major part of the PDMA is "sampling" and that the control of the distribution of samples is by the manufacturer so he would recommend that this category be deleted.

The Committee reviewed the third category under the miscellaneous permit section that reads as follows:

"(3) For wholesalers to sell, distribute, or dispense any prescription drug, except to a 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 examiners in optometry;"

The EO stated that this category appears to be a list of exceptions.

The Chair stated he thinks this category was added because at one time optometrists were not allowed to dispense prescription drugs. This section was probably changed when optometrist received prescriptive authority.

The EO asked the committee, based on this information, if they think this category is necessary.

The Chair asked the committee to defer the decision on this category pending further research.

The Committee reviewed the fourth category under the miscellaneous permit section that reads as follows:

- “(4) 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;”

The EO stated that this also appears to be a list of exceptions.

Mr. Adams stated we already limit them in the laws. So this category should be removed.

The Chair asked Mr. Edwards if he knew of any reason the Board would issue a permit for anything other than what is listed.

Mr. Edwards replied no.

Mr. Adams suggested rewriting this section to clarify the activities of a PMP.

The Chair agreed.

Being that time had run out, the Chair deferred the rest of the agenda items.

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Next Meeting: Thursday, April 18, 2013
8:00 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
9:00 a.m.

Taken and recorded by:

/s/ Lisa Kalani
Lisa Kalani, Secretary

Reviewed and approved by:

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

4/9/13

[x] Minutes approved as is.

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