

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

MINUTES OF MEETING

Date: Thursday, August 15, 2013

Time: Immediately following Board meeting

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

Members Present: Todd Inafuku, Pharmacist, Chair
Mary Jo Keefe, Pharmacist
Kerri Okamura, Pharmacist

Excused: Garrett Lau, Pharmacist

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

Call to Order: The Chair called the meeting to order at 11:30 a.m.

Chair's Report: **Approval of the Previous Minutes – May 16, 2013 meeting**

The Chair called for a motion for the minutes of the May 16, 2013 meeting.

Upon a motion by the Chair, seconded by Ms. Okamura, it was voted on and unanimously carried to approve the minutes of the May 16, 2013 meeting as circulated.

Review and Discussion of HRS 461 and HAR Chapter 95: The Chair gave an overview of what the laws and rules committee does. The laws and rules committee is given information from the Board and take on some of the issues that come before the Board. Then the committee will make a recommendation to the Board if there is something they want to proceed on. The committee doesn't make decisions; they bring their recommendations to the full Board for their consideration. The committee also has an advisory group that they can refer to that have different disciplines, for example retail hospital, nuclear, home health and pharmacy technicians are a few. Should the committee have projects that require information on certain disciplines, they can refer to the advisory group. What the committee was currently working on was looking at the rules, specifically the miscellaneous permits (PMP) section. The reason why the committee is addressing this is because of all the questions and correspondence

that come up regarding a PMP's requirements are or what a PMP covers.

The EO stated the purpose of the committee is to do research and make recommendations to the Board. You can have discussions, but basically this is a research and investigative committee. You gather information to make recommendations to the full Board. If the committee determines that they want to formulate requirements or qualifications, you make a recommendation to the Board and justify why this should happen because of these reasons. The Board will say yes or no and if necessary make changes to the rules. For changes to the laws, it has to go through the legislative process which happens the middle of January to the end of April. There is a review process to submit a bill should the Board decide to. It goes through the administrative process. For example if you introduce a bill to revise a section, the bill will go to your DAG, then to the administration office, the Director's Office, then to the Governor's office. If at any point someone says no, it will not be submitted as an administrative bill. The Board can also support a bill submitted by another agency.

Ms. Keefe asked what is the difference between the Board submitting a bill and another agency submitting a bill.

The EO stated only the Board would have to go through the administrative process.

Ms. Keefe asked how other agencies submit bills.

The Chair stated they have to get a sponsor in the legislature. They would find a senator and a representative to co introduce the bill. The Chair stated the Board is the consumer advocate. The Board is not here to protect its profession; we are here for the consumer. Everything the legislation asks is if this will benefit the consumer, is this going to save the consumer money is this going to protect the consumer. Any decisions they make is from a consumer protection side not from the side of the profession.

The Chair stated, going back to the previous minutes, the committee was discussing the current miscellaneous permit categories. A lot of pressure came onto the Board because of New England Compounding Center. Because of that incident the Board received numerous inquiries about sterile compounding. The Board was approached by organizations like the Ophthalmologists who were using Avastin sterile compounds and the Board found out there was a lot of issues that they couldn't address. Based on that, there was reason for the committee to look at the entire miscellaneous permit section. Some of the things the committee tried to consider was, are these the permits that we really need, does it address all the issues that come before the Board. The big problem was not only does it exist, the question became if someone did apply for it if we have to give the permit. The committee had to look at what is considered dispensing and non-dispensing functions. There are pharmacy activities that do not involve dispensing of drugs.

There are people that are working with hospitals that take and process the order entry but not dispense, they are just validating the order entry and sending it back to a computer. Another thing that comes up regularly is devices. We don't regulate devices in Hawaii but we do regulate devices when they come from out of state and that's because on the out of state pharmacy permit it talks about drugs and devices. There are entities on the mainland that want to do business here but they are not a pharmacy, all they do is medical devices. Historically the Board has said the only miscellaneous permit that can be issued is a non-resident pharmacy permit because the law says drugs and devices. It's the "and devices" that has caused a problem. So when the committee looked at the miscellaneous permit section, it broke down into four criteria, dispensing, non-dispensing, in-state and out-of-state. Some of the areas the committee broke it down to are non-dispensing pharmacy, in-state pharmacy, medical oxygen distributor/devices, wholesale distributors, reverse distributors, durable medical equipment providers, mobile pharmacies, pixis or automated dispensing machines, nuclear pharmacies and compounding pharmacies. Those are the things the committee needs to have further discussion on.

Next Meeting: Thursday, September 19, 2013
Immediately following Board meeting
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 12:00 p.m.

Taken and recorded by:

/s/ Lisa Kalani
Lisa Kalani, Secretary

Reviewed and approved by:

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

9/6/13

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