

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

MINUTES OF MEETING

Date: Thursday, December 18, 2014

Time: 8:00 a.m.

Place: Queen Liliuokalani 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
Tiffany Yajima, Ashford & Winston
Kellie Noguchi, Times
Paul Smith, Walgreens
Bethany Chiksa, Walgreens

Call to Order: The Chair called the meeting to order at 8:05 a.m.

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

The Chair asked the audience to introduce themselves

Approval of the Previous Minutes – October 23, 2014 meeting

The Chair called for a motion to the minutes of the October 23, 2014 meeting.

Upon a motion by the Chair, seconded by Ms. Okamura, it was voted on and unanimously carried to approve the minutes of the October 23, 2014 meeting as circulated.

Correspondence:

FDA Final and Revised Draft for Compounding Facilities

The Committee was provided with a copy of the FDA's final and revised draft documents for compounding facilities under the Drug Quality and Security Act (DQSA). This will be used as a reference when discussing amendments to the rules relating to compounding pharmacies.

The Chair asked guest Todd Inafuku if he had any comments relating to the correspondence.

Mr. Inafuku stated he thinks compounding needs to remain in the Miscellaneous Permit (PMP) section because according to the FDA it does not delineate that it's a pharmacy, it is a "facility" that registers. That way if someone wants to open a compounding facility here, and they are not a pharmacy, they would need to obtain a PMP.

The Chair asked if they are a facility and not a pharmacy, then would they be required to have a pharmacist present.

Mr. Inafuku stated you would need to put in your PMP requirements that they have a pharmacist on staff.

The EO stated when it's decided what kind of requirements and criteria would be involved, if you want to require a pharmacist on staff you can; even if the federal regulations say it's not required.

The Chair asked if they could think about this for the next meeting.

The EO asked the Committee to come up with requirements for compounding pharmacies. If they are not a pharmacy do they still have to have a pharmacist on staff, etc? Once that is done then you can determine if you want them to remain under the PMP section, or carve out a new section.

Old Business:

DME Providers

The Committee was provided with a copy of a program overview of section 302 of the Medicare Modernization Act of 2003 (MMA) establishing requirements for a new Competitive Bidding Program for certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies.

The EO stated this is another area that would need requirements. Currently, under the pharmacy practice act it states, "the practice of pharmacy includes the dispensing of prescription drugs and devices". Therefore, based on that, only a pharmacy can dispense a prescription device. When Medicare and Medicaid services started their competitive bidding a few years ago, there has been at least one phone call a day about an out-of-state DME provider who wants to dispense a

prescription device to a patient in Hawaii. Right now the response is to tell them they have to obtain a PMP as an out-of-state pharmacy, however many of them are not pharmacies. What's happening is residents of this state are not able to receive their devices. When the requirements are developed, you have to take into consideration that not all of the out-of-state licenses are issued by a board of pharmacy and not all are pharmacy licenses. Some states issue DME licenses by their department of health. Last legislative session there was a bill that was introduced for DME providers, however the EO was not made aware of it. The Board needs to be ready this legislative session in case the bill is introduced again. The Committee needs to come up with requirements for DME providers as well, or consider taking "devices" out of their pharmacy practice act.

Ms. Okamura asked if the DME providers would remain under the Board of Pharmacy.

The EO stated if you don't want to regulate them, you have to take out the word "device" from your laws and rules. Then you will not have any jurisdiction over them.

The Chair asked what would advantages and/or disadvantages be.

The EO stated patient safety.

Mr. Lau asked if the EO knows the Department of Health standpoint on this.

The EO stated she does not.

The Chair asked if this is something the Committee can think about.

The EO stated she will prepare draft language for the Committee to review and vote on at their next meeting and then it can be taken to the full Board at the following meeting.

Practice of Pharmacy – Collaborative Practice Agreements

The Committee was provided with information on collaborative practice agreement information from other states and a Program Guide for Public Health from the CDC.

The EO stated regarding the collaborative agreements (CA), there is a lot of information out there about pharmacists' administering prescription drugs like immunizations, etc. It appears the thinking is if you have a collaborative agreement, that is also a standing order from a physician to dispense the drug as well. However your practice act says you need a patient specific prescription in order to dispense the drug.

Ms. Okamura says you create a prescription pursuant to the CA authorized by the physician, and then you take the drug off the shelf and administer it to the patient.

The EO says the CA that the Committee comes up with needs to address and clarify that.

Next Meeting: January 22, 2015
Immediately following the 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 8:51 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

1/5/15

☒ Minutes approved as is.

☐ Minutes approved with changes; see minutes of _____.