

**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 12, 2015

Time: Immediately following Board of Pharmacy meeting

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

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

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

Guest: Greg Edwards, Dept. of Health, Food and Drug Branch
Kellie Noguchi, Times
Marcella Chock, PharmD, Ohana HP

Call to Order: The Chair called the meeting to order at 10:15 a.m.

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

The Chair asked the audience to introduce themselves

Approval of the Previous Minutes – January 22, 2015 meeting

The Chair called for a motion to the minutes of the January 22, 2015 meeting.

Upon a motion by Ms. Okamura seconded by Mr. Lau, it was voted on and unanimously carried to approve the minutes of the January 22, 2015 meeting as circulated.

Correspondence: None.

Old Business:

DME Providers

The Committee discussed the DME bills that the Board continues to support with amendments.

The EO stated SB 307, SD 1 and HB 580, HD 2 are still moving. There was testimony on opening it up to all DME's in and out of state. When speaking with the proponents of the bill they are talking about hospital beds, etc., they say that DME providers in state don't normally have them readily available so they have to call a DME provider on the mainland but it takes time to get here. The EO does not know how these bills will help the items be shipped any quicker or why the in state providers don't have the products.

Dr. Chock stated the in state providers don't have them because it's too expensive, so they only get them on an as needed basis.

The DAG asked is it too expensive for the local providers to have a nominal stock?

Dr. Chock stated a lot of times when you're talking about hospital beds and things of that nature; they are specialized for the individual, for example an obese patient. So they are not just common products that you can order in bulk.

The Chair asked what happens if the bills do not pass?

The EO stated then it falls back onto the Committee. If the Committee would like to submit a bill for the next legislative session, it needs to be ready by August of this year.

The Chair stated if the bills pass it would affect in and out of state providers?

The EO stated she does not know so the Committee should continue to look at creating or adding a section. Look at our miscellaneous permit section and other states sections that regulate DME providers you like, and see if you can come up with something.

Practice of Pharmacy – Collaborative Practice Agreements

The EO provided the Committee with a working draft based on discussions from the last meeting. After some discussion, and a review of the Model Rules of the National Association of Boards of Pharmacy, the following is the current working draft the Committee will be reviewing and recommending:

§16-95-2 Definitions.

“Collaborative pharmacy practice” is that practice of pharmacy whereby a pharmacist has agreed, on a voluntary basis, to work in conjunction with a practitioner, to provide patient care services to achieve optimal medication use and desired patient outcomes and for which the registered pharmacist has received appropriate training required by these policies, procedures, or protocols.

“Collaborative agreement” means the written and signed agreement between a registered pharmacist and licensed practitioner that provides for collaborative pharmacy practice.

§16-95-___ Collaborative agreements. (a) A registered pharmacist may perform procedures or functions pursuant to the definition of “Practice of pharmacy” as part of the care that is provided collaboratively with a licensed practitioner and pursuant to a collaborative agreement. A collaborative agreement shall include, but not be limited to:

- (1) The name, address, and phone number of the pharmacy or place of business of the registered pharmacist;
- (2) The name, signature, and license number of the registered pharmacist; and
- (3) The name, address, phone number and signature of the licensed practitioner.
- (4) The types of decisions that the registered pharmacist is allowed to make may include a detailed description of:
 - (i) The types of disease, drugs or drug categories involved, and the activities allowed in each case;
 - (ii) The methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities; and
 - (iii) The activities the registered pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the licensed practitioner concerning specific decisions made. In addition, to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book or in some other appropriate system.
- (5) A provision to allow either party to cancel the agreement by written notification to the other party; and
- (6) An effective date.

Compounding Pharmacies

The EO asked the Committee what kind of compounding regulations they would like to see.

The Chair asked why would we want to license a “compounding” pharmacy different from a pharmacy?

The EO stated because of the federal regulations for outsourcing facilities.

The Chair stated the Committee had previously said that out of state compounding pharmacies need to be registered as an outsourcing facility.

The EO stated it has to apply to everyone, in state and out of state.

The Chair stated a compounding pharmacy in state would just be a pharmacy license.

The EO stated you are telling an out of state pharmacy that if they want to compound and dispense into this state to be an outsourcing facility. What about the in state pharmacies?

The Chair stated if they are going to do bulk compounding that is not patient specific, we have not decided if we are going to allow that in this state yet. If a pharmacy is doing compounding that is patient specific, that's a pharmacy license.

The EO stated so a pharmacy compounding per patient specific prescription – no other requirements. A pharmacy doing “for office use” or bulk distribution – need to be a registered outsourcing facility with the FDA.

The Chair stated yes, but we still have not decided if we will be allowing “for office use” compounding in this state.

Mr. Lau asked who monitor's the outsourcing facility?

Mr. Edwards stated his understanding is that if you are registered as an outsourcing facility, you have registered with FDA and you would come under their purvue. Does the outsourcing facility have to be a licensed pharmacy in the state it resides in?

The Chair stated it is her understanding that is not required.

The EO stated if you want to require that on a state level, then I'm sure you can.

Mr. Edwards stated if you read the federal definition of wholesale distribution, it talks about compounding. However the question is, if this is for finished dose FDA approved products or products that are not FDA approved?

The EO stated in Chapter 328 it says, wholesalers can only sell prescription drugs, which includes products that are compounded.

Mr. Edwards stated he has always leaned on the other side of the language that says these are policies and procedures for the distribution of FDA approved finished dose products.

The EO stated asked Mr. Edwards to check with his DAG regarding any exemptions pertaining to compounding for wholesale distribution under Chapter 328, and the Committee will continue discussion at their next meeting.

Next Meeting: May 21, 2015
Immediately following the Board meeting
Queen Liliuokalani 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 11:30 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

3/27/15

Minutes approved as is.

Minutes approved with changes; see minutes of _____.