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

MINUTES OF MEETING

Date: Thursday, September 17, 2015

Time: Immediately following Board of Pharmacy meeting

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

Members Present: Kerri Okamura, RPh, Pharmacist
Garrett Lau, RPh, Pharmacist

Members Excused: Mary Jo Keefe, RPh, Committee Chair, Pharmacist

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

Guest: Tiffany Yajima, Ashford & Winston
Kellie Noguchi, Times
Paul Smith, Walgreens
Tina Liu, Walgreens

Call to Order: Mr. Lau called the meeting to order at 10:46 a.m. and excused the Committee Chair from today's meeting.

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

Since the Chair was not present, Mr. Lau asked the audience to introduce themselves

Approval of the Previous Minutes – March 12, 2015 meeting

Mr. Lau called for a motion to the minutes of the March 12, 2015 meeting.

Upon a motion by Mr. Lau, seconded by Ms. Okamura, it was voted on and unanimously carried to approve the minutes of the March 12, 2015 meeting as circulated.

New Business: **Discussion on Limiting Number of Times an Individual Can Take NAPLEX and/or Hawaii MPJE**

The Committee reviewed an email from the National Association of Boards of Pharmacy ("NABP") regarding a candidate that has taken and failed the NAPLEX eight times. In accordance with NABP's testing policy, the Board must provide approval to NABP for requests that exceed NABP's five time testing limit before a candidate is permitted to register again for the examination.

The EO stated at this time since Hawaii does not have a limit on the number of times a candidate can take the exam, she had no choice but to allow the registration.

Ms. Okamura stated we should add something to our rules to align ourselves with NABP.

The EO asked so you would allow them five times?

Ms. Okamura stated or three times.

The DAG stated you could make your own policy. For example you could allow three times and then after the third attempt they have to take a remedial course before they are allowed to test again.

The EO stated you would have to promulgate rules. Then there is also the jurisprudence exam or MPJE. If you are going to put a limit on taking the NAPLEX, do you also want to put a limit on the MPJE?

Ms. Okamura stated yes.

Mr. Lau asked how fast could we get this changed?

The EO stated you would have to promulgate rules.

Ms. Okamura stated she thinks after two attempts there should be some sort of remediation and they have to wait six months before they can test again.

The EO asked what kind of remediation?

Ms. Okamura stated a NAPLEX prep course.

The EO stated you should research what is available. You don't want to implement this and there's nothing available. Would this apply to both MPJE and NAPLEX?

Ms. Okamura stated both.

The EO stated that she does not think you would find an MPJE prep course.

Ms. Okamura stated it should be consistent.

The EO clarified, the suggestion is two attempts, if you fail, you take remediation and wait six months, then you get one more try and if you fail that you're out, and this would be only for applicants applying by examination. For reciprocity applicants this would not apply.

Ms. Okamura stated yes, and asked if this would be for both exams?

The EO stated what is their remediation if they fail the MPJE? Does the Daniel K. Inouye College of Pharmacy offer a remediation course?

Ms. Okamura stated no.

The EO stated then until a laws and rules course becomes available she does not think this would work for the MPJE.

Mr. Lau stated before they take the MPJE they should be reading the laws and rules.

The EO stated yes, they should be. So for now, unless you can come up with remediation for the MPJE, this will only apply to the NAPLEX.

Mr. Lau asked if we need remediation?

The EO asked so your saying for the MPJE, they fail three times and that's it, they can't ever get licensed here?

Ms. Okamura stated yes, and asked the audience in attendance what they thought.

The audience in attendance stated that's too harsh.

Mr. Lau asked if after five times is too harsh?

The EO stated we will do more research on this.

Further discussion was deferred.

Old Business: **Practice of Pharmacy – Collaborative Practice Agreements**

Discussion of March 2015 Draft

The Committee reviewed the working draft from the March 2015 meeting as follows:

§16-95-2 Definitions.

"Collaborative pharmacy practice" is that practice of pharmacy whereby a registered pharmacist and a licensed practitioner voluntarily agree to work collectively to provide patient care services under established policies, procedures, and protocols, in addition to appropriate training, to achieve optimal medication use and desired patient outcomes.

"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:

(1) Printed name and license number of registered pharmacist;
(2) The name, address, and phone number of the pharmacy or place of business of the registered pharmacist;
(3) Signature of the registered pharmacist and date signed
(4) Printed name and license number of the licensed provider;
(5) The name, address, and phone number of the licensed practitioner.
(6) Signature of the licensed provider and date signed
(7) The types of decisions that the registered pharmacist is allowed to make may include, but not limited to, 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.

(8) A provision to allow either party to cancel the agreement by written notification to the other party; and
(9) A specific date the agreement is in effect

The EO stated under §16-95-2 Definitions. "Collaborative pharmacy practice", the "appropriate training" part needs to be clarified.

Ms. Okamura stated we could change it to… "in addition to the registered pharmacist receiving the appropriate training". We should also add (10) An authorized agent of the Board of Pharmacy.

The EO stated she will go through the key elements and other states to see what they have that this Board does not have.

National Alliance of State Pharmacy Associations ("NASPA")– Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority

The Committee will review and compare their proposed rules regarding collaborative practice agreements with the National Alliance of State Pharmacy Association ("NASPA") workgroup recommendations regarding Collaborative practice agreements to see if it matches.

Durable Medical Equipment Providers

The EO stated at the last Board meeting the Board came out with an informal interpretation regarding the licensure of DME Providers. In the meantime the administrative bill deadline has passed, however, the Department of Health bill may resurface in 2016, so we will just monitor that for now.

Compounding Pharmacies

The EO asked if you want to go into specific regulations and requirements for compounding pharmacies?

Ms. Okamura stated we should just follow the federal regulations and requirements.

The EO stated according to the 2015 survey of pharmacy law, the question was… "Does your state issue separate licenses for sterile compounding facilities that are registered with the FDA as outsourcing facilities?"… only 4 states answered "yes". Another question was… "Does your state issue separate licenses for sterile compounding pharmacies that are not registered with the FDA as an outsourcing facility?"…, only 10 answered that they had a license separate from a pharmacy license. Right now at the very least you should probably look at compounding

pharmacies that compound for office use. You could say you have to have a miscellaneous permit and be registered with the FDA as an outsourcing facility. You want to make sure the local pharmacies are not at a disadvantage. The EO stated she will check on the outsourcing facilities requirements and the model act and report back to the Committee.

Further discussion was deferred.

Next Meeting: Mr. Lau announced November 19, 2015 as the next meeting. Mr. Lau stated if he is able to attend they should have a meeting October 22, 2015. He will check his schedule and get back to the EO.

November 19, 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, Mr. Lau adjourned the meeting at 11:27 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

10/1/15

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