# BOARD OF PHARMACY LAWS & RULES COMMITTEE

Professional & Vocational Licensing Division
Department of Commerce and Consumer Affairs
State of Hawaii

#### MINUTES OF MEETING

Date: Thursday, February 13, 2014

Time: Immediately following Board meeting

Place: 677 Ala Moana Blvd., Suite 1025 – New Location

Honolulu, Hawaii 96813

AND

The Daniel K. Inouye College of Pharmacy at the University of Hawaii at Hilo, Classroom I

722 South Aohoku Street

Hilo, Hawaii 96720

Members Present: Todd Inafuku, Pharmacist, Chair

Kerri Okamura, Pharmacist Mary Jo Keefe, Pharmacist

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

Lisa Kalani, Secretary

Guest: Paul Smith, Walgreens

Greg Edwards, Dept. of Health, Food and Drug Branch

Eden Chik, Creighton University Nancy Huang, Walgreens Patrick Adams, Foodland

Carolyn Ma, Pharmacist, Board of Pharmacy

Guests from the UH Hilo Lara Gomez

<u>College of Pharmacy</u> Zack Campbell via webcast: Zack Campbell Christina Method

Arnold Sarvo Thao Le Jake Babbel Jynelle Tangonan

Venus Ho Yen Dao Barnes Chau Dang Tony Huynh Jared Crowther

Camilla Kim Aryn Meguro Thuy-Vi Le Laws & Rules Committee Meeting February 13, 2014 Page 2

Yolette Quach

Andrew Hayashi

Sarah Osellanu

Melissa Monette

Okezie Irondi

Kelsey Chang

Jerilyn Gudoy

Bryce Fukunaga

Christopher Thai

Tina Liu

Thuy-Tien Diep

John Hoang

Blake Johnson

Jane Penho

Katherine Lee

Albert Lee

Mireya Talavera

Joseph Nguyen

Walter Domingo

Eric Sanders

Voc Le

Necole Miyazaki

Jeremy Lozano

**Beth Earles** 

Rachel Ebbett

Keetae Kim

Ornella Fassu

Amber Goodloe

Sisan Spirnay

Raymond Okamura

Carlo Tiano

Andy Wong

George Karvas

Samantha Chang

Alex Guimarues

Kasia Lynn Quintal

Shanon Makanui

Josen Ho

Bert Matsuo

Jairus Mahoe

Jason Perreira

Kimberly Victorine

Jamie Mizusawa

Kim Duong

Minu Thong

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Call to Order: Chair's Report:

The Chair called the meeting to order at 11:03 a.m.

**Announcements and Introductions** 

The Chair asked the audience to introduce themselves

### Approval of the Previous Minutes – January 23, 2014 meeting

The Chair called for a motion for the minutes of the January 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 January 23, 2014 meeting as circulated.

#### Old Business:

### Collaborative Agreement

#### **Immunizations**

The Chair prepared a draft of collaborative agreement section and provided it to the Committee (see attached copy of the draft). Currently, collaborative agreements are limited to emergency contraception. What this would do is reorganize the section and add the definition of what is collaborative pharmacy practice and the definition of a collaborative agreement. The recommendation is to take into consideration subchapter 16 and under 16-95-130, which currently says emergency contraception written collaborative agreement, we're going to change that to collaborative agreements and define what a collaborative agreement is, however maintain and keep the section on emergency contraception written collaborative agreement as section 16-95-131. In the draft, collaborative pharmacy practice means that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more license physician under policies, procedures, or protocols whereby the pharmacist may perform certain patient care functions authorized by the license physician or licensed physicians under certain specific conditions and/or limitations and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols.

The Chair stated in Chapter 461, the practice of pharmacy definition talks about a licensed physician, it does not say practitioner. Therefore, in the draft, the rules make reference to a licensed physician. Also in the draft, collaborative agreement means the written and signed agreement between one or more pharmacist and one or more licensed physician that provides for collaborative pharmacy practice.

The EO asked if licensed physician is defined in Chapter 461.

Guest Greg Edwards stated in Chapter 461 a licensed physician is defined as a physician licensed by the Board of Medical Examiners pursuant to Chapter 453.

The EO asked if this means it will be limited to medical doctors and osteopaths

and not anyone else who has prescriptive authority.

The Chair stated unless the statute is revised we have to go with the current practice definition.

Guest Pat Adams stated in the past when questions were posed to the Board, some things you could act collaboratively with a physician and some things you could act collaboratively with a practitioner. The laws have changed a lot for practitioners, and the progressive thing would be to change everything to practitioners, it would make it cleaner for interpretation for the Board.

The Chair stated because in the current statutes it states licensed physician, that's what he put in the draft.

Ms. Keefe stated section (6) is not necessary, section (7) covers notifying the patient's primary care provider or licensed physician.

Ms. Okamura agreed with Ms. Keefe.

The Chair stated he will strike section (6).

The EO stated in Chapter 461 is states registered pharmacist, therefore it would be pertinent to state registered pharmacist in the draft and not licensed pharmacist.

The Chair agreed with the EO.

Ms. Okamura asked if the pharmacist works at multiple pharmacies, would they have to get an agreement for each pharmacy.

The Chair stated it would be appropriate because you may have an agreement tied to a specific pharmacy or pharmacies.

Guest Greg Edwards asked if the collaborative agreement expires or has to be renewed.

The Chair stated it is in effect until rescinded in writing by either the licensed physician or the pharmacist.

Guest Pat Adams stated collaborative agreements have never been looked at before as written aside from emergency contraception and immunizations. Mr. Adams stated there is a difference between working collaboratively and having a written collaborative agreement. Mr. Adams is concerned if collaborative agreements are so specifically written it may limit pharmacists so much that they are not able to do some things that they are able to do right now. Mr. Adams asked, can we really do a written collaborative agreement for all a pharmacist

does. Mr. Adams suggested adding another section, so you would have one section on written collaborative agreements for specific things that you want to control, and another section for working collaboratively.

The Chair stated he understands Mr. Adams concerns. The Chair stated things we know we need to put in place so when someone does something, like modify drug therapy or provide immunizations, something specific where training is required, that is defined and there is a protocol in place. This section would be for specific situations. If you want to keep the other things general, working collaboratively, that doesn't have to be written.

Guest Paul Smith stated this could be addressed in the definitions. You could put something in the definition of collaborative agreements that says this by no means constrains working collaboratively.

Ms. Okamura stated the intent with coming up with definitions of working collaboratively and collaborative practice agreement is not to hinder the advancement of the practice but to set guidelines on ways that it can be expanded safely.

The EO suggested looking at other state boards of pharmacy to see if their practice act requires them to have collaborative agreements. The EO stated the definition of collaborative agreements is in the National Association of Boards of Pharmacy (NABP) model act so this has been discussed before. The EO asked if some of the students in attendance today could do the legwork in getting information from other state boards.

Dr. Ma stated that could be an assignment. There are 80 students and 50 states, so you could assign two students per state and have them find out what the states practice act says about collaborative agreements.

Guest Lara Gomez (via webcast) stated the students could do some legwork and digging of information and send it to the Board to review. It would be a good assignment, especially for the students who plan on practicing outside of Hawaii.

The EO stated she also wanted to clarify on what Ms. Okamura stated, this is not an expansion of your scope of practice, this is what you can do already, but it's how you go about doing it safely.

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Next Meeting:	March 20, 2014 Immediately following 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 12:10 p.m.	
Taken and reco	rded by:	Reviewed and approved by:
/s/ Lisa Kalar Lisa Kalani, Sed		/s/ Lee Ann Teshima_ Lee Ann Teshima, Executive Officer
3/11/14		
[ x] Minutes approved as is. [ ] Minutes approved with changes; see minutes of		

#### SUBCHAPTER 16

#### [EMERGENCY CONTRACEPTION] COLLABORATIVE AGREEMENTS

#### §16-95-2 Definitions.

"Collaborative pharmacy practice" means that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more licensed physician under policies, procedures, or protocols whereby the pharmacist may perform certain patient care functions authorized by the licensed physician or licensed physicians under certain specific conditions and/or limitations and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols.

"Collaborative agreement" means the written and signed agreement between one or more pharmacist and one or more licensed physician that provides for collaborative pharmacy practice.

## §16-95-130 [Emergency contraception written collaborative agreement.] Collaborative agreements:

- (a) A 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 physician and pursuant to a collaborative agreement. A collaborative agreement shall include, but not be limited to the following:
  - (1) The name, address, and phone number of the licensed pharmacist and pharmacy and the signature of the licensed pharmacist;
  - (2) The name, address, and phone number of the licensed physician and the signature of the licensed physician;
  - (3) The purpose of the collaborative agreement;
  - (4) The description of the nature and scope of the drug therapy management appropriate for the condition or diagnosis, and include specific directions for the use of the drug, specify the dosage regimen, dosage form or route of administration that are authorized;
  - (5) Contain clear criteria and specific directions pharmacists are to follow when implementing and monitoring drug therapy;
  - (6) A provision that the licensed pharmacist shall refer the patient to the patient's primary care provider or licensed physician in the collaborative agreement or any other applicable referral;
  - (7) A provision that the licensed pharmacist when administering a drug to a patient in accordance with the collaborative agreement shall notify the patient's primary care provider or licensed physician in the collaborative agreement or any other applicable agency of an adverse drug event;
  - (8) Any limitation agreed upon by both the licensed pharmacist and the licensed physician including, but not limited to, approved drugs that may not be prescribed to the patient or whether the licensed pharmacist's or the licensed physician's decision shall control in the event of a disagreement on a prescription for a patient;
  - (9) If the collaborative agreement includes the ordering and evaluating of laboratory tests, it shall contain instructions on which tests are to be

- ordered, the criteria for ordering the test, how the test are to be interpreted, and what action the pharmacist shall take dependent upon the test results;
- (10) If the collaborative agreement includes modifying drug therapy, it shall contain instructions as to the criteria dictating a change, specify how the therapy is to be changed, and require that the pharmacist issue written notification to the patient's licensed physician or enter the appropriate information in an electronic patient record system shared by the licensed physician, within twenty-four hours; and
- (11) If the collaborative agreement includes initiation and administration of a vaccine for the purpose of immunization, the pharmacist must successfully complete a pharmacy-based immunization program approved by the Accreditation Council for Pharmacy Education (ACPE), complete a current basic life support for health care providers certification program which must include a live trainer portion, screen each patient for previous adverse reactions, allergies, pregnancy, receipt of blood or antibody products, immune status, and any underlying diseases prior to administration of the vaccine and the collaborative agreement shall contain protocols and procedures for the management, use, reporting, treatment and administration of the appropriate treatment agent including, but not limited, to epinephrine and or diphenhydramine by injection in the case of severe allergic reactions
- (b) By executing the collaborative agreement, both the licensed physician and pharmacist agree and acknowledge that:
  - (1) They accept the responsibility for the dispensing and administration of any drug covered by the collaborative agreement;
  - (2) The licensed pharmacist shall provide the patient with drug information concerning dosage, potential adverse side effects, follow-up care and when administering a vaccine for immunization provide the patient or the patient's agent with the most recent vaccine information statement for each immunization administered; and
  - (3) The collaborative agreement shall be effective unless rescinded in writing by either the licensed physician or the pharmacist, with written notice to the other and the board, or unless the board invalidates the agreement or changes the terms of the agreement.
- (c) The board of pharmacy shall have the authority to reject a collaborative agreement if the board determines that the collaborative agreement is not in compliance with this section or is not in the best interests of the patient.
- §16-95-131 Emergency contraception written collaborative agreement.

  Place emergency contraception section here.