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

MINUTES OF MEETING

Date:	Thursday, December 15, 2016
Time:	9:00 a.m.
Place:	Queen Liliuokalani Conference Room 335 Merchant Street, First Floor King Kalakaua Building Honolulu, HI. 96813
Members Present:	Kerri Okamura, RPh, Chair, Pharmacist Carolyn Ma, PharmD., BCOP, Pharmacist Garrett Lau, RPh, Vice Chair, Pharmacist Marcella Chock, PharmD., Pharmacist Ronald Weinberg, Public Julie Takishima-Lacasa, PhD, Public
Members Excused:	Mary Jo Keefe, RPh, Pharmacist
Staff Present:	Lee Ann Teshima, Executive Officer ("EO") Shari Wong, Deputy Attorney General (“DAG”) Lisa Kalani, Secretary
Guests:	Jacqueline Moore, Foodland Tiffany Yajima, Ashford & Wriston LLP Pat Adams, Foodland Stacy Pi, Kaiser Permanente Albert Lau, Kaiser Permanente Joe Parriott, Walmart Paul Smith, Walgreens Danielle Odenthal, NDSU Samantha Chan, UC San Diego Kellie Noguchi, Times Mike Kido, Ashford & Wriston LLP
Call to Order:	The agenda for this meeting was filed with the Office of the Lieutenant Governor, as required by section 92-7(b), Hawaii Revised Statutes ("HRS"). There being a quorum present, the Chair called the meeting to order at 9:01 a.m.

Chair's Report:

Announcements and Introductions

The Chair asked the audience to introduce themselves.

Approval of the Previous Minutes – November 15, 2016 Meeting

The Chair called for a motion in regards to the minutes of the November 15, 2016 meeting.

There being no discussion, upon a motion by Mr. Weinberg, seconded by Dr. Chock, it was voted on and unanimously carried to approve the minutes for the November 15, 2016 meeting as circulated.

Executive Officer's Report:

Controlled Substance Prescriptions

Pharmacist's Corresponding Responsibility Guidelines – Consideration of Final Draft
The Board reviewed the final draft that included the recommendations discussed at the October and November meetings.

The EO thanked Mr. Weinberg for questioning the source of the information at the last meeting. She did check on the references to that summary of the corresponding responsibility and it did look a little old. So now it just makes reference to the CDC and DEA. So if anyone wants updated statistics or information they are referred directly to them.

There being no further discussion, upon a motion by Mr. Weinberg, seconded by Dr. Ma, it was voted on and unanimously carried to approve the final draft of the Pharmacist's Corresponding Responsibility Guidelines, have it posted on the Board's webpage and distributed to the NED and the PVL Boards that license prescribers.

Professional Development

The Board reviewed information on Professional Development. Some articles of interest were:

- Managing Holiday Stress
- Tips to prevent holiday stress and depression;
- Take control of your holidays, instead of letting the holidays control you;
- Remaining Safe During a Winter Storm

Conferences/Seminars/Meetings

NABP Interactive Member Forum, November 30 – December 1, 2016, Rosemont, Illinois

The Chair reported that the meeting was very worthwhile. There were 47 board members in attendance, including members from three Canadian provinces, Guam and the Virgin Islands. They had a panel of different board members and talked about what is going on. The first thing they talked about was new board members versus the

veteran board member and what to take into consideration. First and foremost the purpose of the board is to ensure public/patient safety. Some things that were suggested the boards think about going forward were:

- New board member orientation prior to their first meeting to explain how the meetings are run and the purpose of the Board;
- Ask questions, get the facts;
- Encourage discussion and stay relevant; and
- Resources available from NABP:
  - Survey of Pharmacy Law
  - Model Pharmacy Practice Act
  - NABP Board Member Manual

Other areas talked about are as follows:

- NABP Multistate Pharmacy Inspection Blueprint (blueprint).

  The blueprint was developed by member boards and allows states to ensure their own inspection forms and processes cover the minimum requirements agreed upon by the majority of state boards. The blueprint largely focuses on general areas of pharmacy and references existing national compounding standards, such as United States Pharmacopeia (USP) Chapters <795> and <797>. The goal is to increase patient safety, provide uniform and standard inspection across states, and to provide peace of mind for board members when looking at applications and making decisions;

- USP <797>

  Some states, like Virginia, fully adopted it into their laws. There are some states that just refer to it and some reference it in their rules.

- Medication Errors

  What Contributes to medication errors?

  1. Interruptions from patients/staff.
  2. Electronic prescriptions - some states require physician entry for e-scripts.
  3. Pharmacist Working Conditions
     - Breaks
     - Staffing
     - Length of shifts
  4. Changes made to ensure patient safety:
     - Limit to number of hours a pharmacist can work.
     - Length of break between shifts.
     - Limit length of shift

- Security in Pharmacies

  In B.C. pharmacies have time delayed safes, and that has decreased the number of robberies. In Missouri, their board is considering funding security cameras/systems for pharmacies.

- Physician Dispensing

  In some states the board of pharmacy regulates physician dispensing, in

other states it's the medical boards.

- Expanded Roles of Pharmacist
  - In Oregon pharmacists have prescriptive authority for oral contraceptives. They say it is successful because they have collaborated with the medical, and nursing boards and the College of OB/GYN to come up with training and requirements. They are now looking to expand the pharmacists prescriptive authority to other forms of birth control, naloxone and "nuisance prescriptions". A nuisance prescription would be for example a maintenance prescription that ran out of refills, so the pharmacist can fill it one time because they know the patient still needs it.
  - In Canada their scope is very progressive. They have a central database linking all prescriptions filled. They are allowed to prescribe maintenance medications for one month (if patient is out of refills). They can make changes on their own to prescriptions like add missing information and change dosage forms. Their pharmacists get paid for medication reconciliation, compliance packaging and MTMs. Starting in 2012 they were allowed to prescribe for minor ailments and that expanded to topic infections and hemorrhoids. They are currently working to add other conditions they can prescribe for like UTIs and other conditions that can be self-diagnosed.
- Oxycodone to Heroin Epidemic
  - In Tennessee they require daily reporting of controlled substances dispensing and zero reporting.
  - Some states have added gabapentin to PMP reporting
  - Some states require anyone with a controlled substance permit to register in the PMP and there is a fine of $100 per day they are not registered.
- Regulating Pharmacy Technicians

  Some things to consider:
  - Pharmacy technician to pharmacist ratio
  - Patient safety
  - Expanded scope of practice
  - Tracking for diversion and performance
- Other Issues
  - Recreational and Medical Marijuana
  - Collaborative practice versus prescriptive authority by protocol agreement between medical board and board of pharmacy
  - When considering prescriptive authority, collaborative practice and protocols, consider the barriers and hurdles. Extra training may be a barrier
  - USP 800

The Chair stated she would like the Rules Committee to take some of these issues into consideration the next time they meet.

DEA Conference "Pharmacy Diversion Awareness Conference, January 22-23, 2017, Honolulu, Hawaii
The EO reported from what she understands it is not a two day conference, it is the same conference repeated on both days. The EO and NED will be doing a joint presentation at the conference at 1:00 p.m. to 1:45 p.m. Mr. Redulla from NED will also be talking about drug theft and robbery. Also, David Thornton, who you all met at the October meeting is no longer the Administrator for NED, Jared Redulla is the Acting Administrator.

Mr. Weinberg asked if it is open to the public?

The EO stated no, you have to register to attend.

The Chair stated this is a continuing education also.

NABP 113th Annual Meeting – May 20-23, 2017, Orlando, Florida
The EO stated Ms. Keefe has already expressed interest in attending and asked if anyone else was interested.

Mr. Weinberg stated he was interested in attending.

2017 Legislative Session

Status Report on Draft of Bill Relating to Pharmacist Provider Status (Requires Insurers, mutual and fraternal benefit societies, and health maintenance organizations to recognize services provided by pharmacists.)
The EO stated there was a conference call scheduled for December 7, 2016 that she was not able to participate in and asked Mr. Adams if he could provide information.

Mr. Adams stated that the call failed. They are still waiting on the final drafts of the bills from the Legislative Reference Bureau.

Status Report on Draft of Bill Relating to Practice of Pharmacy (Expands the scope of practice of pharmacists to include the furnishing of specific drugs and services.)
See discussion under Status Report on Draft of Bill Relating to Pharmacist Provider Status (Requires Insurers, mutual and fraternal benefit societies, and health maintenance organizations to recognize services provided by pharmacists.).

Department of Health, Office of Health Care Assurance – Licensing of Durable Medical Equipment Suppliers Program

The EO reported information regarding this new law, Act 137, and a link to the Department of Health, Office of Health Care Assurance webpage has been posted on the Pharmacy Board's webpage. If you have any questions, you can email them.

Dr. Ma asked if a pharmacy sells durable medical equipment do they have to comply with this?

The EO stated that pharmacies are exempt.

Correspondence: **Can a pharmacy legally require all of their patients to exclusively use their service?**

The Chair asked Dr. Chock to lead the discussion on the following email inquiry:

"*In Hawaii county, a chain of pharmacies has recently taken a hard stance against filling any controlled substance prescriptions for patients that use more than one pharmacy. I know that prescribers cannot steer patients to use a specific pharmacy without justification, but does that same restriction apply to pharmacists? I understand that a patient who consistently splits their regimen among multiple pharmacies will have a less effective DUR, but a single order for a chronic medication does not pose the same level of risk. Can a pharmacy legally require all of their patients to exclusively use their service? Or is his only permissible after a legal or therapeutic concern has been established? I know the burden put on patients to transfer all of the medications for their chronic condition to another pharmacy because their regular pharmacy was out of stock of one medication in a single instance seems unreasonable to me (not to mention the difficulty of getting new Medicare Part B compliant orders as those cannot be transferred at all). Please let me know your thoughts on this practice."*

The EO asked if he is only talking about controlled substances because he mentions "chronic medication"?

Dr. Ma stated in the first sentence of his inquiry he states …"any controlled substance prescriptions…"

The Chair stated it appears the main question is, "can a pharmacy legally require all of their patients to transfer all of their medications to them? - I think it is safer, but it is not addressed in our laws and rules.

The EO stated, so it is not "required", but in the interest of patient safety, patients a re encouraged to get all their medications from one pharmacy. Any questions he has specifically regarding controlled substances, he can check with NED.

The DAG stated they can be encouraged, but cannot be required because it is not in your laws and rules.

Dr. Takishima-Lacasa stated there may be an access issue as well. In the scenario he is describing if there is this one medication that the local pharmacy is out of stock and this patient had to go to another pharmacy to get this one medication, it does not make sense to require the patient to transfer all their prescription just because of this one incidence.

Dr. Ma stated there could also be a situation where your pharmacy closes at a certain time and you have an emergency prescription you have to fill.

The Vice Chair stated another reason this may have come up is because the distributors have limits set on pharmacies as to how much controlled substances they can order, and their ratio of controlled and non-controlled substances they can order could come into play. So you could have a scenario where a patient goes to their regular pharmacy for all their medications, and for one fill their regular pharmacy is out of stock so they are sent to another pharmacy. What happens is when the other pharmacy fills the prescription for a controlled substance, but not for their maintenance medications, it skews their ratio for purchasing by the distributor.

Dr. Chock stated she was not aware that they looked at the ratio for non-controlled substances.

The Vice Chair stated there is an order monitoring program in place, so that may be the background for this inquiry.

There being no further discussion, the Board by consensus determined that the pharmacy laws and rules do not specifically address this issue. Although there is no "requirement" for a patient to transfer all of their prescriptions to one pharmacy, in general, pharmacists using their professional judgment, may prefer a patient transfer their prescriptions, including those for controlled and non-controlled substances, in the interest of the patient's safety, this allows a pharmacists to review all prescription medications for possible drug interactions.

In accordance with Hawaii Administrative Rules section 16-201-90, the above interpretation is for informational and explanatory purposes only. It is not an official opinion or decision and is therefore not binding on the Board.

Drug Compounding – FDA Has Taken Steps to Implement Compounding Laws, but Some States and Stakeholders Reported Challenges

The Chair asked Dr. Ma to report on the following publication:

FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges:
The Government Accountability Office's ("GAO") survey of state pharmacy regulatory bodies found that drugs are compounded in a variety of health care settings, and

some data are collected on the number of entities that compound drugs (drug compounders), but not the volume of compounded drugs. In addition to pharmacies, drug compounding settings include physicians' offices and outsourcing facilities-a new type of facility established by law in 2013, which can compound sterile drugs without patient-specific prescriptions and register with and are inspected by the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS). While FDA and some states collect data on drug compounders, only one state reported collecting data on the number of prescriptions or the volume of compounded drugs. In addition, states GAO surveyed and stakeholders GAO interviewed did not collect data specific to the extent of compounding performed by nonpharmacists, such as physicians.

Nearly all of the states GAO surveyed reported having drug compounding laws, regulations. or policies, though few apply to nonpharmacists, and states conduct inspections and can take actions to enforce them. Less than 20% percent of states reported having laws, regulations, or policies specific to compounding by nonpharmacists (e.g., physicians}, and these state laws varied. To help ensure compliance, most states reported inspecting drug compounders, such as pharmacies and outsourcing facilities, and most states can take several types of actions against pharmacies, including monetary fines, and suspension and revocation of a license or registration.

Most states reported being satisfied with their communication with FDA and other states, although some reported challenges. About three quarters of the states reported participating in FDA-sponsored activities, such as intergovernmental meetings, and obtaining information from FDA's website. Some states reported challenges with this communication, such as getting FDA to respond to requests for information. In terms of communication between states, most survey respondents reported that they are satisfied with this communication, which occurs through conferences and other activities.

FDA has taken steps to implement its regulatory responsibilities to oversee drug compounding, but states and stakeholder organizations have cited challenges and concerns. FDA has issued numerous draft and final guidance documents related to drug compounding, and conducted more than 300 inspections of drug compounders, which resulted in actions such as FDA issuing warning letters and voluntary recalls of potentially contaminated compounded drugs. Some stakeholder organizations said the amount of time it takes FDA to finalize the guidance and other documents, including those required by the 2013 law is challenging. FDA officials noted that reviewing the large number of comments received has contributed to the time the agency has taken to finalize them. States and stakeholder organizations also cited concerns related to access to compounded drugs and differences between states and FDA on the appropriate inspection protocols to use when inspecting drug compounders. In August 2016, FDA changed Its procedures to address concerns about the appropriate protocols to use for these

inspections.

Drug compounding is the process of combining, mixing, or altering ingredients to create a drug tailored to the needs of an individual patient. An outbreak of fungal meningitis in 2012 linked to contaminated compounded drugs raised concerns about state and federal oversight of drug compounding. The Drug Quality and Security Act, enacted in 2013, helped clarify FDA's authority and included a provision for GAO to report on drug compounding.

This report examines (1) the settings in which drugs are compounded, and the extent of drug compounding; (2) state laws and policies governing drug compounding, and how they are enforced; (3) communication between states and FDA, as well as among states, regarding drug compounding, and the associated challenges; and (4) steps FDA has taken to implement its responsibilities to oversee drug compounding, and challenges that have been reported with these efforts.

GAO surveyed state pharmacy regulatory bodies in the 50 states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands (all but 4 completed the survey); reviewed documents and interviewed officials from FDA, 25 stakeholder organizations (including national pharmacy and medical associations), and agencies in 3 states selected for having differing laws and policies; reviewed relevant laws; and examined FDA data on drug compounding inspections and actions taken.

NABP State News Roundup

The Chair reported on the latest NABP State News Roundup that included the following articles:

- Illinois – New Law for Pharmacy Personnel Termination Reporting
  On August 19, 2016 Public Act 199-0863 was signed into law, which amended e Illinois Pharmacy Practice Act to require that a pharmacy or pharmacist-in-charge file a report with the chief pharmacy coordinator of the Illinois Department of Financial and Professional Regulation ("IDFPR") any time a pharmacist, a registered pharmacy technician, or a registered certified pharmacy technician licensed by the IDFPR is terminated for actions that may have threatened patient safety.

- Illinois – Updates on Pharmacy Citation Program
  In February 2016, he IDFPR announced a pilot pharmacy citation program. This program was designed to reduce the amount of resources spent by both the IDFPR and the licensed pharmacists when dealing with minor infractions. During just over six months of this program, more than 80 tickets were issued. Each pharmacy that was

issued a ticket had the option of choosing not to pay the nominal fine of no more than $500. If the pharmacy did this, the infraction would be litigated through the system normally. Out of the tickets issued, no pharmacies chose to fight their fine.

- Ohio – Updates Rules on Pharmacist Consult Agreements with Physicians
  On March 23, 2016 Ohio House Bill 188 went into effect. This law makes the following modifications to pharmacist consult agreements with physicians:
  - Authorizes one or more pharmacists practicing under a consult agreement with one or more physicians to (1) manage a patient's drug therapy for specified diagnosis and (2) order and evaluate blood and urine tests;
  - Creates a single process for establishing a consult agreement, in place of separate processes that were based on whether the patient's drug therapy was being managed within or outside a hospital or long-term care facility;
  - Grants certain immunities from civil liability to pharmacists and physicians practicing under consult agreements.

Executive Session: At 9:46 a.m. upon a motion by Mr. Weinberg, seconded by Dr. Ma, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-5(a)(4), "To consult with the board's attorney on questions and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities".

At 9:51 a.m. upon a motion by the Vice Chair, seconded by Dr. Takishima-Lacasa, it was voted on and unanimously carried to move out of executive session.

Applications: **Ratification List**

Upon a motion by Mr. Weinberg, seconded by Dr. Chock, it was voted on and unanimously carried to approve the attached ratification lists.

Miscellaneous Pharmacy Permits (PMPs)
Upon a motion by the Chair, seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the following:

Emerson Pharmacy Inc., dba Loyola Pharmacy – Nima Rodefshalom-Own, RPH
Allergychoices Pharmacy & Michael Kachel, RPH

Next Meeting: The Chair asked if everyone was available to meet January 24, 2017.

Dr. Chock and Dr. Takishima-Lacasa stated they cannot make it on January 24, 2017.

January 24, 2017 - New Date
9:00 a.m.
Queen Liliuokalani Conference Room
King Kalakaua Building
335 Merchant Street, First Floor
Honolulu, Hawaii 96813

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 10:01 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

12/27/16

[ ] Minutes approved as is.
[X] Minutes approved with changes; see minutes of 1/24/17

BOARD OF PHARMACY
December 15, 2016 Ratification List

Miscellaneous Permits (PMP)

Change of PIC

Coast Quality Pharmacy LLC (PMP-1079)
5710 Hoover Blvd.
Tampa, FL. 33634
New PIC: Denise Foley
Effective: 11/18/16

Pharmamedrx LLC dba Mint Pharmacy and Skin Clinic (PMP-1253)
1201 US Hwy. 1 Ste. 1
North Palm Beach, FL. 33408
New PIC: Lindsey Drescher
Effective: 11/14/16

Sina Drug LLC dba ONCO360 (PMP-526)
225 Community Dr. Ste. 100
Great Neck, NY. 11021
New PIC: Leo Gray
Effective: 8/1/16

Specialty Veterinary Pharmacy (PMP-671)
4159 Bluebonnet Dr.
Stafford, TX. 77477
New PIC: Alexia Westerhausen
Effective: 11/4/16

ImprimisRx CA Inc. dba ImprimisRx (PMP-1030)
9257 Research Dr.
Irvine, CA. 92618
New PIC: Phillip Chung
Effective: 11/21/16

Name/Trade Name Change

Biorx LLC dba Diplomat Specialty Infusion Group (PMP-697)
7167 E Kemper Rd.
Cincinnati, OH. 45249
Effective: 8/29/16

Kroger Specialty Pharmacy FL2 LLC
dba Kroger Specialty Pharmacy FL2 (PMP-740)
6435 Hazetine National Dr. Ste. 140
Orlando, FL. 32822
Effective: 10/19/16

Relocation/Address Change
Arriva Medical LLC dba Arriva Pharmacy (PMP-969)
310 Eagles Landing Drive
Lakeland, FL. 33810
Effective: 9/12/16

Atlantic Medical LLC (PMP-852)
915 Ferncliff Cove Suite 1A
Southaven, MS. 38671
Effective: 10/11/16

Closure/Cancellation
Unicare Pharmacy Inc. dba Medicorx Specialty (PMP-1084)
7039 Valjean Ave.
Van Nuys, CA. 91406
Effective: 11/16/16

Matrix Pharmacy LLC dba Mymatrix Pharmacy (PMP-571)
3111 W Martin Luther King Jr. Blvd. Ste. 800
Tampa, FL. 33607
Effective: 11/23/16

Unicare Pharmacy Inc. dba Medicorx Specialty (PMP-1084)
7039 Valjean Ave.
Van Nuys, CA. 91406
Effective: 11/30/16

Brand Direct Health LLC (PMP-1152)
68397 Tammany Trace Dr.
Mandeville, LA. 70471
Effective: 11/21/16

Pharmacy (PHY)

Change of PIC
Kalihi-Palama Health Center dba KPHC Pharmacy (PHY-797)
89 S King St.
Honolulu, HI. 96813
New PIC: Wayne Awakuni
Effective: 11/30/16

Longs Drug Stores California LLC dba Longs Drugs #9317 (PHY-738)
590 Farrington Hwy. Unit 300
Kapolei, HI. 96707
New PIC: Marisa Nonaka
Effective: 12/4/16

Longs Drug Stores California LLC dba Longs Drugs #9300 (PHY-736
925 California Ave.
Wahiawa, HI. 96786
New PIC: Lauren Daima
Effective: 12/4/16

Longs Drug Stores California LLC dba Longs Drugs #9890 (PHY-734)
95-1249 Meheula Pkwy. #D
Mililani, HI. 96789
New PIC: Brandon Reiss
Effective: 12/4/16

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN ST	BUSN ZIP	BP NAME PART 1
PHY	912	1329 LUSITANA ST #307	HONOLULU	HI	96813	HAWAII CANCER CARE INC

LTYPE	LIC NUM	BP NAME PART 1
PH	4117	CHARLES W <DINGELDEIN<
PH	4118	UOC MINH <LE<
PH	4119	JOYCE C M <RAMANO<
PH	4120	COURTNEE S K <HO<
PH	4121	JIM X <DU<
PH	4122	DEIRDRA D <LORIO<

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN ST	BUSN ZIP	BP NAME PART 1
PWD	185	91-240 KALAELOA BLVD	KAPOLEI	HI	96707	HOSPIRA WORLWIDE LLC