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

MINUTES OF MEETING

Date: Tuesday, October 25, 2016

Time: 9:30 a.m.

Place: King Kalakaua Conference Room
335 Merchant Street, First Floor
King Kalakaua Building
Honolulu, HI. 96813

Members Present: Kerri Okamura, RPh, Chair, Pharmacist
Mary Jo Keefe, RPh, Pharmacist
Marcella Chock, PharmD., Pharmacist
Ronald Weinberg, Public
Julie Takishima-Lacasa, PhD, Public

Members Excused: Carolyn Ma, PharmD., BCOP, Pharmacist
Garrett Lau, RPh, Vice Chair, Pharmacist

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

Guests: Catalina Cross, Times
Tiffany Yajima, Ashford & Wriston LLP
Paul Smith, Walgreens
Albert Lau, Kaiser Permanente
Patrick Uyemoto, Times
Fred Cruz, CVS Caremark
Stacy Pi, Kaiser Permanente
Jeremy Lozano, Times
Amy Este, Walmart
Mihoko Ito, Ashford & Wriston LLP
Lani Ladao, Narcotics Enforcement Division ("NED")
David Thornton, Narcotics Enforcement Division ("NED")
Jared Redulla, Narcotics Enforcement Division ("NED")

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 9:36 a.m. and excused the Vice Chair and Dr. Ma from today's meeting.

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

The Chair asked the audience to introduce themselves.

Additions/Additional Distribution to Agenda

The Chair announced the following agenda items had additional distribution:

Additional Distribution

3. Executive Officer's Report
   a. Department of Public Safety, Narcotics Enforcement Division
      3) Discussion on Controlled Substance Prescriptions – Pharmacist's Corresponding Responsibility - Draft of Pharmacist's Corresponding Responsibility Guidelines
   d. 2017 Legislative Session
      1) Pharmacist Provider Status Bill

4. Correspondence
   b. Implementation of U.S. Pharmacopeia Convention (USP), General Chapter <800>, Hazardous Drugs – Handling in Healthcare Settings

Approval of the Previous Minutes – September 15, 2016 Meeting

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

Executive Officer's Report: **Department of Public Safety, Narcotics Enforcement Division**

Information Presentation of Prescription Drug Monitoring Program
Mr. David L. Thornton, State Narcotics Chief, thanked the Board for inviting the NED to present at today's meeting. He introduced himself and his two top supervisor's Ms. Lani Ladao, and Mr. Jared Redulla. Ms. Ladao will be doing the PDMP presentation and Mr. Redulla will be doing the responses to questions previously presented.

Ms. Ladao began by stating as some of you may know they are transitioning to a new vendor for the Prescription Drug Monitoring Program (PDMP). They have just started the transitioning of data to the new system and she has been told that as long as all the accounts are current they should go over seamlessly to the new system. The new vendor is APPRISS Health and the system is called PMP AWARxE.

Currently the number of physician queries to the PDMP for the last 3 years are as follows:

- 2014 – approximately 20,000;
- 2015 – approximately 40,000; and
- 2016 – approximately 35,000

Currently the number of pharmacist queries to the PDMP for the last 3 years are as follows:

- 2014 – approximately 90,000;
- 2015 – approximately 180,000; and
- 2016 – approximately 140,000

It is obvious that pharmacists utilize the program frequently. Comparing the number of controlled substance prescriptions by county, Honolulu has by far the highest number, and Hydro/ACET is the most prescribed controlled substance. Right now there are 912 pharmacist registered to the PDMP. NED could not get a number of physicians registered. Some of the reasons why NED chose APPRISS Health as the new vendor is that the system is more user friendly, it has an improved admin platform, supports integration of healthcare IT systems, and supports inter-state sharing with 33 other states. Act 218 allows a pharmacist to appoint delegates to the PDMP. NED wants to emphasize that although you may have assigned delegates, the licensed pharmacist is ultimately responsible for the use of the system. For now NED will be allowing 2 delegates per account. The new website address is: https://pmpclearinghouse.net/registrations/new and the target date to go live is the week of December 12th. On November 15, 2016, from 9:00 a.m. to 12:00 p.m. the new vendor APPRISS Health will be on-site at NED headquarters to hold a training session for pharmacy managers. There is a limited number of 40 slots, so please call NED at (808) 837-8470 by November 1, 2016 if you wish to attend. If there is enough people interested, we will try to schedule a second session.

Dr. Chock asked if the training session will also be for prescribers?

Ms. Ladao stated that NED will be addressing that in different venues, but for now it is just for the pharmacists.

Response to Questions Previously Presented

Mr. Redulla stated as you can see from the slides, pharmacists are checking the PDMP more than physicians. The question is why. One of the things that connects to an agenda item coming up later pertaining to pharmacist's corresponding responsibility, is we ask pharmacists to trust that what is going on in the physician's office is what is supposed to happen. What it looks like is people in the pharmacy community are being very diligent, and they are checking, compared to physicians. I am now going to try and answer some of the questions brought to us by the Board. The first couple of question have to do with the new 30 day C2 prescription law. When the 30 day law passed this July 2016, for weeks almost every single phone call into the NED office was about this new law.

When Act 218 was passed, it changed part of the controlled substance act by saying, "no schedule 2 *narcotic* controlled substance can be prescribed or dispensed for greater than the 30 day supply, and there are 2 exceptions. One exception is where the single dose package exceeded the 30 day supply, and the other is when the doctor has certified the patient as terminally ill. When we take the law apart, the first thing you see is "no schedule 2 **narcotic** controlled substance can be prescribed or dispensed for greater than the 30 day supply"... When you look up the definition of what a narcotic drug is, they are drugs that are made out of opium or coca. So if it is a schedule 2 drug, but does not have opium or coca in it, then Act 218 does not apply to it. Now for those narcotic drugs that do apply, the pharmacist cannot dispense more than a 30 day supply, with the 2 exceptions. What it does **not** say is that you have to wait 30 calendar days in between. Now if you dispense a 30 day supply today and then tomorrow another 30 day supply, that will raise a red flag. So the question now becomes one of professional judgement. There could be a valid reason why the prescription is being filled before the 30 days is up. Another question was, in the controlled substance act were there changes made to what kind of identification (ID) information you have to capture. The answer is no. You are supposed to collect and report information captured from the individual who obtains the controlled substance. Not necessarily the patient, but from the person who picks up the drug. The law refers to proper ID, and proper ID is a government issued ID card, with a photograph, printed name, ID number and the signature of the person. On the PDMP reporting screen right now, there is an option for "other ID qualifiers", there are no other ID qualifiers, do not use it. Another question was, how NED notifies pharmacists if a physician is under investigation or if the physician's registrations are revoked, suspended, or expired. When someone is under investigation, unfortunately NED cannot acknowledge the existence of that investigation, even if it is reported in the public arena. So if you call us and ask about it, we will not acknowledge the existence of an investigation. A person is presumed innocent, until proven guilty. As such, when NED is working a case, we have to make sure we avoid any indication of bias or prejudice. For example, if a doctor gets arrested for prescription offenses, and there are a lot of questions in the pharmacy community, as long as that doctor's registrations and licenses are intact, we are going to say that they can practice as usual until you hear otherwise. The last question was how can you check an NED registration. You can check online at: dps.hawaii.gov on the home page there is a link to the Narcotics Enforcement Division, and on NED's page there is a link to check registrations. If you have questions, you can call NED's office during business hours at: (808) 837-8470. One of the great controversies that happened over that last month was about Suboxone and if it could be prescribed. Looking at the current Suboxone law, there are at least three places where it says it cannot be prescribed, at least that is what it looks like in the simple reading of this law. Basically, this Suboxone controversy went to the Attorney General for an opinion and the Attorney General quickly opined that in fact Suboxone can be prescribed. The practice of physicians prescribing Suboxone can continue.

Chapter 329 is a difficult read, and can be interpreted in many different ways. So when we first read this Suboxone law, we said it could not be prescribed, but the Attorney General said it can be prescribed. The issue for pharmacist is that it is very difficult to legislate and enforce laws for every conceivable event or situation.

Dr. Chock asked regarding the Suboxone law, is it for all the same types of drugs in that particular class?

Mr. Redulla stated it is narcotic drugs used for detox treatment and maintenance treatment. The major consideration is when we try to answer your questions, we are sometimes looking at very antiquated laws and trying to apply it to the modern practice of pharmacy, and sometimes those concepts clash. We have to rely on common sense, reasonableness and discretion. If you need to reach NED during business hours, please call the number provided, however if it is for a narcotics enforcement law issue after hours, there is a 24 hour pager number you can call, (808) 363-0576, and either Ms. Ladao or myself will call you back.

Ms. Keefe asked how big is NED's staff?

Mr. Redulla stated they have an office of fifteen which includes office staff, support staff, and agents. Right now there are about ten sworn law enforcement officers that includes both the supervisors and the chief. Our primary responsibility is to enforce Chapter 329, and state statute also commands us to investigate illicit criminal drugs under the penal code. That is half of what we do, the other half is to provide narcotics investigation support to the states executive agencies. For example prison contraband cases, people who are smuggling in our airports, and sometimes we get calls about people selling drugs on Hawaiian homelands. It is a very busy office and at any given time agents can have active caseloads numbering about 100 each.

Dr. Chock asked regarding the new PDMP vendor, does it also address partial fills?

Ms. Ladao stated she is not sure, but she will make a note to check on that.

Ms. Keefe asked if NED has seen a decrease in the number of prescriptions filled in the last few years?

Mr. Redulle stated no, there has actually been an increase.

Mr. Weinberg asked if given the choice, what laws would you like to see amended?

Mr. Redulla stated one of the things the Attorney General said is this Suboxone law is in dire need of re-construction. So our office is now looking at what parts of the law need to be made more clear and we will be recommending for the next legislative session very clear language. As you may also know every year we are required under statute to make recommendations for changes in the controlled substance act, we have to make recommendations to add certain substances to the scheduled list.

Although we are not there yet, we are looking to add a new drug called "Kratom".

Mr. Weinberg asked if we know how we are doing in comparison to other states?

Mr. Redulla stated that is difficult to gauge. Our agents go to an organization called the National Association for Controlled Substances Administrators. What that organization does is it looks at our controlled substances laws and tries to make recommendations to make them clearer or better, or to address community issues like the opioid epidemic.

The Chair asked regarding the delegates for the PDMP, do we have to submit written authorization to NED on who your delegates are?

Ms. Ladao stated she has not seen the format yet, but hopefully it will be done all online.

The Chair stated the limit of two delegates per user might be difficult. For example in a retail pharmacy setting you will have different technicians working at different times. So it may be hard to only delegate two technicians.

Chief Thornton stated that is something they can look at, but the biggest issue is controlling the PDMP.

The EO stated the only problem is we do not regulate pharmacy technicians. Some states have moved toward that and they warned us that we have to be prepared when we start regulating them for all the diversion cases. We did a survey a couple of years ago and it did not come out one way or the other, so right now we feel we don't need to regulate technicians.

Ms. Keefe clarified, you said two delegates per account, is an account a person?

Ms. Ladao replied yes, an account is a person.

Ms. Pi asked regarding the ID requirement, she understands that the person picking up the drug has to show ID, but for the purposes of submitting to the PDMP, the submission is for the patient?

Mr. Redulla stated yes, it is the patient's information. There is a question if you have to ID everyone, and the answer is no. You are only obligated to ID a person you do not know. Your company policy may state differently, but under the law, if this is a customer you have known for say the last five years, you do not need to ID them.

Ms. Pi clarified, that is only for the pick-up of the drug.

Mr. Redulla replied yes. In your computer profile you should have information on the patient and that is what you are reporting. At the time you dispense you are charged with getting a government issued ID, but when you report, you are reporting however you established the patient in your computer system.

So when you set up a new patient in your system, you're going to have to ask for their ID. Once they are established, if someone else picks up for them, you are still going to ask for their ID, but you will already have the patient information and that is what you will be reporting.

Ms. Ladao stated she does not recall seeing patient's information with another person's ID number attached to it, so it would appear it's currently being reported properly.

Discussion on Controlled Substance Prescriptions – Pharmacist's Corresponding Responsibility – Draft of Pharmacist's Corresponding Responsibility Guidelines
The Board reviewed a Draft of Pharmacist's Corresponding Responsibility Guidelines with comments from Mr. Redulla.

The EO asked if anyone had additional comments or corrections to the draft? Once it is finalized, it will be posted on the Board's webpage, as well as sent to the Boards of Nursing, Dental and Medical, so they know what pharmacists will be looking for.

Ms. Keefe stated on page two, under the "Checklist" to ensure that the prescription is filled for legitimate purposes, the following should be added:

- The name, strength, quantity, and specific instructions for the drug to be dispensed.

The EO stated she will create a final draft and send to NED for their review before posting it online and sharing with the other boards.

Upon a motion by Ms. Keefe, seconded by Mr. Weinberg, it was voted on and unanimously carried to finalize the draft of the Pharmacist's Corresponding Responsibility Guidelines and once final, post on the Board's webpage and distribute to the Boards of Nursing, Dental, and Medical.

The EO and the Board thanked the NED for coming today to answer questions and for providing very important and useful information to the Board.

Professional Development – Working Solutions

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

- Maintaining Wellness Under High-Stress;
- Stress Management: Discover Your "Flow";
- Soft Skills to Know: Conflict Resolution;
- How to Deal With a Bully at Work; and
- Listening Tips for Difficult Situations.

Conferences/Seminars/Meetings

2016 NABP/AACP Districts VI, VII & VIII Joint Meeting, September 11-14, 2016, Portland, Oregon

Dr. Chock reported Hawaii is part of District VIII, which also includes Arizona, California, Colorado, Guam, Nevada, New Mexico, New Zealand and Utah. It was a two day meeting, some of it was on business, and a lot of it was on continuing education (CE). There were two resolutions that passed for District VIII. The first one had to do with dispensing veterinary medications, and the resolution to NABP was for clarification and guidance to help some of the state boards to recognize the differences between dispensing for humans versus animals. The second resolution that is being submitted to NABP was asking for support and guidance for pharmacists having prescriptive authority, and a lot of that discussion was around reimbursement. In some of the other states in District VIII, there are pharmacist that are prescribing under the umbrella of a prescriber, so when it comes to billing, the prescriber is getting billed but not the pharmacist.

Food and Drug Administration – Inter-Governmental Working Meeting, September 20-21, 2016, Silver Spring, Maryland

Ms. Keefe reported that she and Kris Kimoto from RICO attended this meeting. The meningitis outbreak caused by the unsanitary conditions at New England Compounding Center (NECC) which resulted in several deaths, many more long term side effects, and the closing of the pharmacy, and charges being bought against the owners and pharmacists of the facility resulted in action being taken by the FDA to oversee compounding. Compounding has traditionally been the responsibility of the states and Boards of Pharmacy. So the FDA came up with 503b which relates to outsourcing facilities. The intent of the law is to prevent manufacturing under the guise of compounding. These facilities are not traditional pharmacies (although they could be). Outsourcing facilities are not required to be licensed as pharmacies, but compounding must be by or under the direct supervision of a licensed pharmacist. They are not required to have patient specific prescriptions, they are not required to follow the guidelines outlined in 797 or 795 and are exempt from track and trace requirements. Outsourcing facilities are engaged in the compounding of sterile drugs and have elected to register as an outsourcing facility and all that entails which includes, inspections, fees, current good manufacturing practices (CGMP), reporting of adverse advents and lists of drugs that the facility compounds. You have regular pharmacies, those are 503a and your outsourcing facilities, and those are 503b. Patient specific prescriptions are required for 503a, but not for 503b. Compounding oversight is 797 and 795 for 503a and CGMP for 503b. For inspections, the states inspect 503a, and the federal inspects 503b, and neither facility is exempt from "insanitary conditions". The issue here is how do we register a 503b, as a manufacturer, pharmacy, special license or as an outsourcer, which is what the FDA recommends. You must be a 503b pharmacy to compound without a patient specific prescription. Some states already allow this, but we here in Hawaii do not. Would we rely on home state practices, laws and rules to oversee a 503b? How would we inspect for CGMP? Hawaii does not have pharmacy inspectors. So 503a pharmacies do not obtain approval of their compounded drugs. They get a patient specific prescription, they make it.

They do not comply with CGMP, they follow 797 and 795. They do not report adverse effects to the FDA, and they do not label compounded drugs with warnings or adequate directions for use, and they do not register with FDA, they register with their boards of pharmacy. Interestingly enough since October of 2012 there have been over 100 recalling events involving compounded drugs, many due to the lack of sterility and insanitary conditions.

The EO asked if Hawaii is the only state that does not have pharmacy inspectors?

Ms. Keefe stated she is not sure, but she thinks so.

The EO stated even if we try to regulate compounding pharmacies or outsourcing facilities, we would not be in compliance with any kind of inspection requirement.

NABP Interactive Executive Officer Forum, October 4-5, 2016, Rosemont, Illinois
The EO stated she will provide a written report to the Board at the next meeting. Some of the issues discussed at the meeting that she will be reporting on are:

- ✓ New vendor for PDMP/PMP - APPRISS Health; and
- ✓ Regulation of pharmacy technicians;

NABP Interactive Member Forum, November 30 – December 1, 2016, Rosemont, Illinois
The EO reported that the Chair will be attending.

2017 Legislative Session

Pharmacist Provider Status Bill
The EO reported there recently was a working group conference call and Pat Adams submitted information on a California Bill, Medi-Cal, pharmacist services. California had this bill to amend their Medicaid program to recognize pharmacists performing specific activities for reimbursement. This allows a form of prescriptive authority for pharmacist to prescribe and dispense specific drugs. During the conference call Mr. Adams did comment on how the group should also look at amending the pharmacist scope of practice to include prescriptive authority for specific drugs. The EO did mention that last legislative session there was a bill introduced by the women's caucus pertaining to oral contraceptives that mirrored Oregon, Washington and California's law, that would have allowed prescriptive authority for pharmacist to prescribe and dispense specific drugs and devices. It was moving through, but for some reason it died at the end. Nationally this appears to be the trend. The EO told the working group that they should not put in a provider bill and include scope of practice issue in that same bill. Because if someone has a problem, the entire bill will die. She suggested if they want to go for a pharmacist provider bill for reimbursement, submit that bill. If you want to change your scope of practice that is another matter. She also cautioned about submitting two bills at the same time, one for providership and one opening the scope of practice. They will also be meeting with Representative Cindy Evans regarding this matter as Pat Adams got her to write this bill and introduce it.

Collaborative Practice Agreement ("CPA") – Draft of Collaborative Practice Agreement for Naloxone

The EO stated that the last recommendation from the Board was to come up with criteria and a list of things that should be included in the collaborative agreement specifically for naloxone. She will have a draft ready for review at the November meeting.

Correspondence:

Pharmacist "Adding" Information on the Prescription/Label – Response from DOH

The Board received an email asking the following question:

"Is there anything in state law in regards to what a pharmacist can add to the directions of a prescription so it will appear on the Rx label without having to call the prescriber? Can we add a diagnosis if a facility/care home/patient provides it and wants it on the label but the Rx from MD doesn't include it? Can we add standardized additional instructions for administration such as "do not crush", "take with 4-8 oz. of liquid", etc. if MD doesn't include it on the Rx?"

As there is no language in Chapters 95 and 461 that pertain to a pharmacist "adding" additional information on the prescription, and the inquiry refers to the Rx or prescription label, the email was referred to the Department of Health, Sanitation/Food and Drug Branch, as labeling requirements come under Chapter 328 Food Drugs and Cosmetics. Their response was as follows:

"We do not have any law that prohibits additional information on the prescription. You may offer the consumer the option of having the symptom or condition for which the drug is prescribed on the label ONLY with their consent. The patient can refuse to have the symptom or condition listed on the label. You may add standardized additional instructions as long as it does not conflict with or confuse the original instructions given by the practitioner."

The EO stated any inquiries regarding Chapter 328 now go to Peter Oshiro (808) 586-8020 or email at: peter.oshiro@doh.hawaii.gov ,he is the Environmental Health Program Manager for the Department of Health, Sanitation Food and Drug Branch. Greg Edwards is no longer the contact person.

Implementation of U.S. Pharmacopeia Convention (USP), General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings

The Board reviewed a joint letter from the following organizations:

- American Pharmacists Association (APhA);
- American Society of Consultant Pharmacists (ASCP);
- College of Psychiatric and Neurologic Pharmacists (CPNP);
- International Academy of Compounding Pharmacists (IACP);
- National Alliance of State Pharmacy Associations (NASPA);
- National Association of Chain Drug Stores (NACDS); and

- National Community Pharmacists Association (NCPA).

The letter is regarding a new general chapter from U.S. Pharmacopeial Convention (USP), General Chapter <800>, Harzardous Drugs-Handling in Healthcare Settings. Chapter <800> will apply to all healthcare personnel who handle hazardous drug preparations, including members of our organizations. Also impacted will be nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians and the entities where they practice. General Chapter <800> was published February 1, 2016. In recognizing that it will take facilities time to conform to the new requirements, USP extended the official implementation date until July 1, 2018. However, given such highly complex, resource intensive, and time consuming compliance requirements, we respectfully request that the Hawaii State Board of Pharmacy carefully consider any actions related to pharmacy compliance with the standards. The organizations listed are asking for a delay in enforcement of USP <800> to allow healthcare organizations sufficient time to plan and gradually implement changes and if the Hawaii State Board of Pharmacy (Board) agrees that a graduated approach to implementing General Chapter <800> is consistent with its mission and goals, they respectfully request that the Board grant a five year delay in enforcement of General Chapter <800> until July 1, 2021. They believe that this grace period allows state-licensed practitioners to assess and plan for the significant operational and structural changes needed as well as budget and obtain the necessary resources in an already strained financial environment.

The Board will take the letter under advisement.

Inquiry Regarding Pharmacy Technician Duties

The Board reviewed an email inquiry about pharmacy technician duties in a hospital pharmacy. The following are questions asked in the email and the Board's responses:

1. Can the night pharmacist leave the pharmacy with only a technician on duty in the event of hospital emergencies requiring their physical presence at bedside?

   Yes, pursuant to the following sections: ***(emphasis added)***
   §16-95-79 Supervision by a registered pharmacist. (a) A registered pharmacist shall immediately supervise all activities and operations of a pharmacy, and ***immediately supervise the functions and activities of*** *pharmacy interns and* ***pharmacy technicians*** *to ensure that all functions and activities are performed in accordance with laws and rules governing the practice of pharmacy.*
   (b) ***A pharmacist either employed within an institutional facility or providing services to an institutional facility shall be responsible for ensuring that the institutional facility establishes, maintains, and operates in accordance with written policies and procedures as outlined in section 16-95-80****.*
   §16-95-80 Physical presence of a registered pharmacist. (a) A registered pharmacist shall be ***physically present during the hours of operation of a prescription area****.*

(b) ***At any time a registered pharmacist is not in the prescription area, (except in cases of emergencies), the entire stock of prescription drugs shall be secured from access to unauthorized persons and the means of access shall only be in the control of the pharmacist.***

(c) A pharmacist in an institutional pharmacy shall ensure that written policies and procedures have been established by the institutional facility for providing drugs to the medical staff and other authorized personnel of the institutional facility by use of night cabinets, and access to the institutional pharmacy and emergency kits when the pharmacist is not in the area. A "night cabinet" is a cabinet, room, or any other enclosure not located within the prescription area. The written policies and procedures shall provide that a pharmacist shall be "on call" during those periods when night cabinets are utilized and shall provide policies and procedures regarding the following:

(1) Security of the night cabinet to ensure that the night cabinet is sufficiently secured to deny access to unauthorized persons by force or otherwise;

(2) The development and maintenance of an inventory listing of all drugs included in the cabinet and the requirement that the pharmacist ensures, at a minimum, that:

(A) Drugs available therein are properly labeled;

(B) Only prepackaged drugs are available therein in amounts sufficient for immediate therapeutic requirements; and

(C) An appropriate practitioner's prescription regarding the dispensing of drugs exists;

(3) Access to the pharmacy. In the event a drug is not available from floor supplies or night cabinets and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the institutional pharmacy in accordance with this subsection. Authorized personnel may remove drugs therefrom provided:

(A) The authorized personnel are designated, in writing, by the institutional facility;

(B) The authorized personnel have been instructed by the pharmacist of the proper methods of access, and the records and procedures regarding removal of the drugs; and

(C) The authorized personnel are required to complete a form which shall include the patient's name and room number, the name of drug, drug strength, dosage, quantity of drug removed, date, time, and the signature of the authorized personnel; and

(4) The prompt detection, removal, disposal, handling, and replacement, if possible, of a drug that has been recalled by the U.S. Food and Drug Administration or the manufacturer to ensure that recalled drugs are removed from the pharmacy's inventory, emergency kit, night cabinet, remote dispensing machine, or from the patient if deemed necessary according to the federal and manufacturer's guidelines.

"Immediate supervision" means that a registered pharmacist is physically present in the area or location where a pharmacy intern or pharmacy technician is working and ***oversees the correctness and accuracy of the prescription's ingredients, quantity, and label****.*

2. Can the night technician attend codes instead of the pharmacist?

   No, based on the above sections, the pharmacy technician may attend codes if accompanied by the pharmacist. The pharmacist is required to oversee the correctness and accuracy of the prescription's ingredients, quantity and label.

3. And if #2 is a yes, then in what capacity are they allowed to assist? *n/a*

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

Pharmacies Offering Prescription Drug Disposal

The EO received an inquiry about a pharmacy offering to take back prescriptions. When looking at §16-95-87 Return or exchange of drugs prohibited, it says, No prescription drug shall be accepted for return or exchange after the drug has been taken from the premises where dispensed or sold by prescription. The section specifically refers to "return" or "exchange" but it does not talk about for "disposal". Some pros/cons for allowing pharmacists to take back drugs for "disposal" are:

- How can the Board ensure that pharmacies are not diverting drugs;
- How can the Board ensure that pharmacies are not redispensing the drugs; and
- What is the positive impact if pharmacies are allowed to take back drugs for disposal if not to protect consumers/environment.

If the Board wants allow a pharmacy to take back drugs for disposal, can they informally opine that based on the above mentioned section, a pharmacy may take back or participate in take back for disposal programs as long as there are written policies and procedures in place that include, but is not limited to the following:

- How/who entity disposing of drugs. If reverse distributor, not allowed, as this is strictly for disposal;
- Drugs returned for disposal only, redistribution of returned drugs is strictly prohibited;
- Pharmacist supervision is required; and
- Diversion of any drugs that are obtained by the pharmacy for disposal is strictly prohibited.

The EO stated NED currently works with the AG's office for a Federal take-back program, but it is technically not the pharmacy that is taking back the drugs, it is NED.

Ms. Ladao stated the NED works with the DEA twice a year on a take back program. In between those events the NED works with the AG's office on smaller community take-backs. Right now state law does not allow for the pharmacy to take-back, and one of the reasons is because drugs were being returned and put back into stock. We are currently working with the AG's office to establish some kind of pilot program.

The EO asked if during the DEA take backs, do you get a lot back?

Ms. Ladao stated yes, the last event they received about 2,600 pounds. You would think the number would go down, but since they started doing this in 2010, the numbers have only gone up. During the smaller community events, they take in about 400 pounds.

The EO asked what is done with the drugs?

Ms. Ladao stated they have worked out an agreement with Covanta H Power. They are one of eleven high temperature incinerators within the nation. She does know of a mailer program to return drugs, but the patient has to pay for that.

Ms. Keefe asked if there is a distinction between controlled and non-controlled drugs?

Ms. Ladao stated there is no distinction, we just ask they not turn in syringes and things like that.

Mr. Weinberg asked if the expiration date of the drug has any influence?

Ms. Ladao stated no, because we can't exchange it or there is no drug bank. We do get the question, if drugs can be donated and we are currently in talks with non-profits that will take donated drugs.

The EO stated she will work on drafting a proposed amendment to §16-95-87 to allow the take back of drugs for disposal.

"Pharmacy shutdowns: Independent businesses being swallowed up by falling reimbursements" – Article from Hawaii Tribune

The Board was provided with an article from the Hawaii Tribune titled "Pharmacy shutdowns: Independent businesses being swallowed up by falling reimbursements" for their information. The article talks about insurance reimbursements and how sometimes pharmacies do not get paid enough to buy the drug to fill the prescription.

Nevada State Board of Pharmacy Newsletter

The Board was provided with a copy of the Nevada State Board of Pharmacy Newsletter for their information. Some articles of interest in the newsletter were:

- Fatigue and Your Practice;
- Improper and Unsafe Vaccine Storage;

- FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians; and
- Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

Rx Ipsa Loquitur Newsletter

The Board was provided with a copy of Rx Ipsa Loquitur Newsletter for their information, which is an official publication of the American Society for Pharmacy Law. Specifically to read the article titled "Pharmacy-Based Naloxone Access" by Martha M. Rumore.

Executive Session: At 11:27 a.m. upon a motion by Mr. Weinberg, seconded by Dr. Chock, 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 11:34 a.m. upon a motion by Ms. Keefe, seconded by Dr. Chock, 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. Takishima-Lacasa, 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:

PetMed Express, Inc.
Right Value Drug Stores, Inc., dba Carie Boyd's Prescription Shop

Next Meeting: The Chair announced the next Board meeting as November 17, 2016 and asked if everyone was available.

Dr. Chock stated she will not be available the entire month of November.

The EO asked if the Board meeting date and time can be changed to November 15, 2016 at 1:30 p.m. so the neighbor island Board members can attend the NED presentation.

November 15, 2016 – New date - Tentative
1:30 p.m. – New time
Queen Liliuokalani Conference Room – New 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 11:37 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

11/4/16

[ ] Minutes approved as is.
[X] Minutes approved with changes; see minutes of 11/15/16

BOARD OF PHARMACY
October 25, 2016 Ratification List

Miscellaneous Permits (PMP)

Change of PIC

Mission Specialty Pharmacy LL dba Mission Pharmacy (PMP-1169)
3267 Roosevelt Ave.
San Antonio, TX. 78214
New PIC: Dudley Klatt
Effective: 9/1/16

Pharmaceutical Technologies Inc. dba Integrated HMO Pharmacy (PMP-556)
13660 California St.
Omaha, NE. 68154
New PIC: Aaron Fredricks
Effective: 9/14/16

Ameripharm Inc. dba Medvantx Specialty Pharmacy (PMP-1022)
1860 Outer Loop Ste. 348
Louisville, KY. 40219
New PIC: Sean Harms
Effective: 9/9/16

LMC Medical Supplies Inc. dba LMC Pharmacy (PMP-910)
1090 Holland Drive Suite 3
Boca Raton, FL. 33487
New PIC: Ira Schulman
Effective: 9/21/16

Martinsville Family Pharmacy (PMP-1104)
1049-A Brookdale St.
Martinsville, VA. 24112
New PIC: Paul Alexander
Effective: 10/3/16

ImprimisRx PA Inc. dba ImprimisRx (PMP-729)
780 Primos Ave. Unit E
Folcroft, PA. 19032
New PIC: Akash Patel
Effective: 8/26/16

Avella of Deer Valley (PMP-600)
23620 N 20th Dr. #12
Phoenix, AZ. 85085
New PIC: Christopher Griffee
Effective: 9/1/16

Magellan Rx Pharmacy LLC (PMP-560)
6870 Shadowrise Dr. Ste. 111
Orlando, FL. 32812
New PIC: Isaac McGee
Effective: 9/1/16

Caremark Therapeutic Services (PMP-415)
1127 Bryn Mawr Ave. #A
Redlands, CA. 92374
New PIC: Rabeah Elbanna
Effective: 9/26/16

ARJ Infusion Services Inc. (PMP-1139)
10049 Lakeview Ave.
Lenexa, KS. 66219
New PIC: Scott Cleland
Effective: 9/6/16

Enclara Pharmacia Inc. (PMP-1247)
1601 Cherry St. Ste. 1800
Philadelphia, PA. 19102
New PIC: Walter Valentine
Effective: 9/22/16

Trinity Compounding Pharmacy Inc. dba Broadway Apothecary (PMP-792)
1515 Oak St.
Eugene, OR. 97401
New PIC: Anne Elizabeth Harthman
Effective: 10/16/16

Name/Trade Name Change
Wedgwood Village Pharmacy LLC (PMP-407)
405 Heron Dr. #200
Swedesboro, NJ. 08085
Effective: 9/20/16

Closure/Cancellation
Prescription Dispensing Laboratories Inc. (PMP-480)
19230 Stone Oak Pkwy. #200
San Antonio, TX. 78258
Effective: 3/31/16

Precision Rx Compounding LLC (PMP-1148)
10323 A Cross Creek Blvd.
Tampa, FL. 33647
Effective: 6/3/16

My Health South Pharmacy Inc. dba Biopharmaceuticals (PMP-1239)
11948 Miramar Parkway
Miramar, FL. 33025
Effective: 9/30/16

Express Plus Pharmacy LLC (PMP-913)
6692 Stirling Rd.
Davie, FL. 33024
Effective: 9/26/16

Southwestern Regional Medical Center Inc. dba Brightwell Health (PMP-1230)
10153 E 79th St. Ste. 102
Tulsa, OK. 74133
Effective: 9/23/16

Pharmacy (PHY)

Change of PIC
QSI Inc. dba Times Pharmacy (PHY-831)
3350 Lwr Honoapiilani Hwy.
Lahaina, HI. 96761
New PIC: Ryan Wilkin
Effective: 8/24/16

Longs Drug Stores California LLC dba Longs Drugs #7098 (PHY-790)
15-1454 Kahakai Blvd.
Pahoa, HI. 96778
New PIC: Mariko Yano
Effective: 9/11/16

Queen's Development Corporation dba Queen's POB II Pharmacy (PHY-465)
1329 Lusitana St. Ste. 101
Honolulu, HI. 96813
New PIC: Lisa K. Asato
Effective: 9/19/16

Wal-Mart Stores Inc. (PHY-653)
700 Keeaumoku St.
Honolulu, HI. 96814
New PIC: Sean Nobuhiro Chu
Effective: 9/7/16

Safeway Inc. dba Safeway Pharmacy #1501 (PHY-864)
75-1027 Henry St.
Kailua Kona, HI. 96740
New PIC: Melissa Bumgardner
Effective: 9/17/16

5 Minute Pharmacy LTC LLC dba 5 Minute Pharmacy Long Term Care (PHY-805)
94-216 Farrington Hwy. #B1-102B
Waipahu, HI. 96797
New PIC: Roxane Bajet
Effective: 10/3/16

Kmart Corporation dba Kmart Pharmacy #9430 (PHY-611)
500 Kamokila Blvd.
Kapolei, HI. 96707
New PIC: Gracie Brooks
Effective: 10/10/16

LTYPE	LIC NUM	BP NAME PART 1
PH	4080	BARBARA <JONES<
PH	4081	MARGARET L <MCMAHON<
PH	4082	ANDY J <TAKAHATA<
PH	4083	JERILYN R <GUDOY<
PH	4084	MELISSA K <HASHIMOTO<
PH	4085	JANICE <ROSE<
PH	4086	BRYCE T P <FUKUNAGA<
PH	4087	MAMI <SHINDO<
PH	4088	JAMIE F <MIZUSAWA<
PH	4089	YOLETTE C <QUACH<
PH	4090	COURTNEY N <MCKAY<
PH	4091	SHANNON W P <MAKANUI<
PH	4092	MONICA R <REINEKE<
PH	4093	CHAU M <DANG<
PH	4094	DAVID K H <LEE<
PH	4095	DAVID T W <LEE<
PH	4096	VICTOR G <SPEARMAN<
PH	4097	KATRINA I E <SPINOLA<
PH	4098	ARYN S <YOU<
PH	4099	FRED <STAFF<
PH	4100	CHRISTOPHER L <KLOCKAU<
PH	4101	VINCE E <DEGUZMAN<
PH	4102	URVASHI <GARIB-SOHAN<
PH	4103	JEFFREY A <KEIMACH<
PH	4104	CARY T <NINOKAWA<

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN ST	BUSN ZIP	BP NAME PART 1
PHY	910	1130 N NIMITZ HWY #A153	HONOLULU	HI	96818	OPEN DOOR PHARMACY LLC
PHY	911	P O BOX 526	HANAPEPE	HI	96716	BRIAN A CARTER INC

LTYPE	LIC NUM	BUSN ADDR 1	BUSN CITY	BUSN ST	BUSN ZIP	BP NAME PART 1
PMP	1313	1600 HIGHLAND DR #A	AMORY	MS	38821	PRIORITY CARE PHARMACY SERVICES LLC
PMP	1314	2416 LAKE ORANGE DR #190	ORLANDO	FL	32837	PERFORMSPECIALTY LLC
PMP	1315	2950 THOUSAND OAKS DR #25	SAN ANTONIO	TX	78247	R & R COMPOUNDING LLC
PMP	1316	17255 NO. 82ND ST #130	SCOTTSDALE	AZ	85255	FSHS ENTERPRISES INC
PMP	1317	2050 S FINLEY RD #20	LOMBARD	IL	60148	OPTION CARE ENTERPRISES INC
PMP	1318	P O BOX 2269	ROCKVILLE	MD	20847	CGS PHARMACY LLC
PMP	1319	2626 S LOOP WEST #555	HOUSTON	TX	77054	NANOBOTS HEALTHCARE LLC
PMP	1320	4142 COMMERCIAL WAY	SPRING HILL	FL	34606	ALPHA OMEGA PHARMACY LLC
PMP	1321	5758 S MARYLAND AVE MC0010	CHICAGO	IL	60637	THE UNIVERSITY OF CHICAGO MEDICAL CENTER
PMP	1322	1620 W NORTHWEST HWY #100	GRAPEVINE	TX	96051	RECEPT PHARMACY LP
PMP	1323	1110 E COLLINS BLVD #100	RICHARDSON	TX	75081	U & ME PHARMACY LLC
PMP	1324	202 W JACKSON ST #200	RIDGELAND	MS	39157	J-M WARD ENTERPRISES LLC
PMP	1325	425 WESTPARK WAY STE 2	EULESS	TX	76040	SOUTHLAKE PHARMACY GROUP LLC
PMP	1326	440 S HINDRY AVE STE F	INGLEWOOD	CA	90301	INSURE NUTRITION INC
PMP	1327	6560 FRESH MEADOWS LN	FRESH MEADOWS	NY	11365	SPECIALTY CHEMIST CORP
PMP	1328	C/O TOM JORDAK	CHARLOTTE	NC	28277	ACRO PHARMACEUTICAL SERVICES LLC