

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

MINUTES OF MEETING

Date: Thursday, January 18, 2018

Time: 9:00 a.m.

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

Members Present: Kerri Okamura, RPh, Chair, Pharmacist
Julie Takishima-Lacasa, PhD, Vice Chair, Public
Marcella Chock, PharmD., Pharmacist
Mary Jo Keefe, RPh, Pharmacist
Ronald Weinberg, Public
Carolyn Ma, PharmD., BCOP, Pharmacist
Kenneth VandenBussche, RPh, BCACP, Pharmacist

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

Guests: Alanna Isobe, Safeway
Paul Smith, Walgreens
Kellie Noguchi, Kaiser Permanente
Catalina Cross, Times
Jonathan Villarreal, Dept. of Public Safety Narcotics Enforcement Division
Dean Yamamoto, Dept. of Public Safety Narcotics Enforcement Division
Amy Este, Walmart
Fred Cruz, CVS Caremark
Kelli Goo, University of Hawaii at Hilo, DKICP
Stacy Pi, Kaiser Permanente
Patrick Uyemoto, Times
Mihoko Ito, SanHI Govt Strategies
Trangle, Touro Pharm

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 9:08 a.m.

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

The Chair asked the audience to introduce themselves.

Approval of the Previous Minutes – November 16, 2017 Meeting

The Chair called for a motion in regard to the minutes of the November 16, 2017 meeting.

There being no discussion, upon a motion by Dr. Ma, seconded by the Vice Chair, it was voted on and unanimously carried to approve the minutes for the November 16, 2017 meeting as circulated.

Vice Chair's Report: No report.

Executive Officer's Report: **2018 Legislation**

Draft of Bill Relating to Opioid Antagonist – To amend the scope of practice of the pharmacist to authorize pharmacists to prescribe and dispense an opioid antagonist to patients, family members and caregivers of opioid patients.

The EO explained that this bill was drafted as a result of the Statewide Opioid Task Force recommendation.

Ms. Keefe expressed concerns for the language in the bill that requires the pharmacy to maintain a signed acknowledgment form with the prescription record.

The EO explained that this bill is very similar to the women's contraceptive bill that allows pharmacists to prescribe and dispense women's hormonal contraceptives that passed last year.

The Chair also expressed concerns with the acknowledgment form and the language that states that a pharmacist who prescribes an opioid antagonist shall not require the individual to schedule an appointment. She stated that if a pharmacy wanted to require an appointment to prescribe and dispense an opioid antagonist, then they should be allowed to do.

The EO asked what the justification was for removing the language pertaining to the signed acknowledgement.

Ms. Keefe asked how would a pharmacy maintain that record?

Mr. Uyemoto asked to address the Board about the acknowledgement form. He stated it could be addressed the same way a pharmacy requires a signature for controlled substances and recommended that a pharmacy maintain the opioid antagonist acknowledgment form with the prescription the same they would maintain records for a controlled substance.

The EO stated that if a pharmacy was not able to maintain the acknowledgment then pharmacists at that pharmacy would not be able to prescribe and dispense opioid antagonist.

The Chair stated that that may prevent a pharmacy from providing this service.

After further discussion, it was the consensus of the Board to support the intent of the bill with amendments to delete the acknowledgment form maintenance requirement and reference to not requiring an appointment.

Draft of Bill Relating to Health Profession Preceptor Tax Credits – To allow advanced practice registered nurses, physicians, dentists, and pharmacists to receive tax credits for volunteer-based supervised clinical training rotations provided to eligible students to enable the student to obtain and eligible healthcare professional degree or certificate.

The EO explained that this bill would allow preceptors for pharmacy interns to apply for a preceptor tax credit for up to \$5,000 a year.

After some discussion, it was the consensus of the Board to support this measure.

HCR 164, SD1 – Requesting that the Director of Health Establish and Convene a Medication Synchronization Working Group to Explore and Propose Legislation

The Board reviewed the Report to the Legislature that recommended legislation to allow prescribers and pharmacists to adjust the drug dispensed for purposes of “synchronizing” the patient’s chronic drug medications. The bill also proposes to amend the insurance code to allow for health insurance plans to apply prorated daily cost-sharing rates for prescriptions dispensed for less than a 30-day supply for the purpose of synchronizing medications.

After further discussion, it was the consensus of the Board to support the intent of the measure with a recommendation to change “narcotic” to “opioid” under section 3, §432:1(d).

Executive Session:

At 9:52 a.m., upon a motion by Dr. Chock, seconded by Mr. Weinberg, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-5(a)(1), “To consult with the Board’s attorney on questions and issues pertaining to the Board’s powers, duties, privileges, immunities, and liabilities;”.

At 10:20 a.m. upon a motion by the Dr. Chock, seconded by Dr. Ma, it was voted on and unanimously carried to move out of executive session.

Naloxone Collaborative Practice/Standing Order – Discussion on Latest Draft from Department of Health

The Board was distributed the latest draft of the standing order.

The EO explained that there were concerns with the draft regarding collaborative practice vs. standing order.

The Board deferred any comments or action at this time.

DME Suppliers- Continuation of Discussion from November 2017 meeting

The EO explained she needs one more clarification on this issue. Act 137, SLH 2016 included in the definition of “durable medical equipment”, **Does not contain any prescription drug**. But the Board’s previous informal interpretation is that *only pharmacies may dispense a “prescription” device with the exception that the device does not contain or is used in the delivery of a prescription drug*. So, if a non-pharmacy sells/dispenses a prescription device that does not contain or is used in the delivery of a prescription drug, they may be licensed as a DME supplier under the Department of Health. However, that is not the case since the new law only refers to device that do not contact any prescription drug and does not address devices used in the delivery of a prescription drug.

After some discussion, it was the consensus of the Board to informally opine that based on Act 137, SLH 2016, only a licensed/permitted pharmacy shall dispense a “prescription” device with the **exception** that the device does not contain any prescription drug and is an equipment that is considered a selected product under the Centers for Medicare and Medicaid Services durable medical equipment such as prosthetics, orthotics, and supplies competitive bidding program that can stand repeated use; is primarily and customarily used to serve a medical purpose; is used in the home and is not considered to be a specialty item, equipment, or service, then the device may be sold/dispensed by a DOH licensed DME supplier.

In accordance with HAR §16-201-90, the above interpretation is for informational and explanatory purposes only and based solely on the information provided. It is not an official opinion or decision and therefore not binding upon the Board.

Revisions to Pharmacist's Corresponding Responsibility Guidance Statement

The Chair reported that she and Valerie Matsunaga, have been participating in a working group that includes representatives from the Office of the Attorney General, law enforcement from Oahu and neighbor islands and others on revisions to the Pharmacist's Corresponding Responsibility Guidance Statement to include opioids.

The Board was provided a draft of the proposed revisions.

The EO recommended that the "title" of the guidance document be amended to include "opioids" but not delete "Controlled Substances" since the information in the guidance document still pertained to corresponding responsibility for all controlled substances. The Board was also provided a copy of the DOH "Informed Consent for Opioid Prescribed Pills" between a patient and a provider.

There being no further recommendations, it was the consensus of the Board to accept the EO's recommendations and to include information on the DOH "Informed Consent for Opioid Prescribed Pills" between a patient and a provider.

Self Help Articles

4 Stupidly Simple Habit Changes to Lower Your Work Stress This Year

The EO reported this article included recommendations on 4 things you can do to lower one's stress, one is deleting an app you use at least once daily, an app, especially a game app can suck your time without adding value; another recommendation was to set a "get ready for bed" alarm...lost of sleep is a huge drain on productivity and a big cause of work-related stress; the third recommendation was to keep water nearby...upping your water intake can improve how you function at work; and the fourth recommendation was to sit less at work...self-explanatory, but may not apply to pharmacists who maybe on their feet all day.

November 2017 Working Solutions

Articles in the November 2017 issue included "Don't be a bystander to workplace harassment"; "Workplace safety: just don't fall"; "4 A's of stress management (avoid, alter, adapt and accept)"; "Dignify differences in others"; "Take steps to overcome worry, fear, and chronic stress"; "To do list"; and "Breast cancer awareness".

2017 Alliance Work Partners

The article in this edition was "Learn to be more attentive and psychological safety at work".

Business Insider Article "Chocolate is on track to go extinct in 40 years"

The EO reported that she came across this article and wanted to share with the Board members.

Correspondence: **National Association of Boards of Pharmacy**

MPJE Item Development Workshop, March 6-8, 2018, Mount Prospect, Illinois – 2 Attendees

The EO reported that Mr. VandenBussche and Mark Brown will be attending.

USP General Chapter <800> Implementation Delay

The Chair stated that the new implementation date for USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings is December 1, 2019. According to the USP, the reason for the delay is to align the official date of this chapter with the official date of the next revision to General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.

NABP State News Roundup

The Chair shared the following updates regarding the different states:

- November 2017 – Illinois renews and extends PPA until 1/1/2020 (among other amendments: creation of a collaborative pharmaceutical task force charged with discussing and making recommendations for how to further advance the practice of pharmacy; adds additional disciplinary grounds for “willful failure to report suspected abuse under the APSA and for being named as an abuser in a verified report by the Dept. of Aging and upon proof by clear and convincing evidence that the PH violated the APSA) and issues a new SO and updates Naloxone Standardized Procedures;

Ohio rule expands administration of injections by PHs and reclassifies license types for manufacturers and distributors of dangerous drugs, outsourcing facilities, repackagers of dangerous drugs and 3rd party logistics providers;

Oregon updates rules on Naloxone (allows PHs to prescribe Naloxone w/out special training), hormonal contraception (allows PHs to prescribe and administer injectable hormonal contraceptives and prescribe and dispense self-administered hormonal contraceptives) and advisory committee (establishes the Public Health and Pharmacy Formulary Advisory Committee that would recommend a formulary of post-diagnostic drugs or devices for the OR BOP to adopt by rule and recommend specific statewide protocols);

Virginia amends laws affecting the practice of pharmacy (allows PHs to dispense Naloxone pursuant to a SO, in accordance with protocols developed by the BOP in consultation with the MB and DOH and without charge or compensation, also allows PHs to “administer” Naloxone; eff. 7/1/2020 requires electronic prescribing for any CS containing an opiate; authorizes pharmaceutical processor, under the supervision of a PH, to cultivate cannabis...).

- December 2017 – Idaho provides PHs rx authority for tobacco cessation medications;
Kansas – adopts regulations on nonresident pharmacies, drug repackaging;
Montana – Intern licenses/requirements (allows issuance of intern license after 1 day of class...what?) and Naloxone access (statewide SO and authorizes emergency use of opioid antagonists in a school setting, medication disposal (distribution of Detera bags to be distributed to medical offices and pharmacies who can provide bags to patients) and opioid strategic planning.

Scope of Practice Questions

Inquiry from Harold Horowitz, M.D. and Eunah Cheon, PharmD, both from New York Presbyterian Brooklyn Methodist Hospita- Can pharmacist in Hawaii perform Penicillin Skin Allergy Testing in a Hospital Setting if the Pharmacist has Received the Appropriate Training?

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

The Board discussed the following email inquiries:

Is it within the scope of practice for pharmacists in Hawaii to do penicillin skin allergy skin testing in the hospital setting if appropriately trained?

Thank you

*Harold Horowitz, M.D.
Chief of Service, Infectious Diseases
New York-Presbyterian Brooklyn Methodist Hospital*

Is it within the scope of practice for pharmacists in Hawaii to do Penicillin Skin Allergy Testing in the hospital setting if appropriately trained? I would appreciate any information on this if possible. Thank you.

*Regards,
Eunah Cheon*

Dr. Chock stated that normally there is an injection kit for these tests that includes a prescription drug, so although the pharmacists may administer drugs and “perform routine drug therapy related patient assessment procedures”, in order to perform this activity, the pharmacist needs to have a prescription, the appropriate training, and a collaborative practice agreement, pursuant to the definition of “Practice of pharmacy” under HRS §461-1.

Dr. Ma stated that this is not a CLIA-waived test as it is not in a clinical setting.

The EO stated that the practice of pharmacy does not distinguish between retail or hospital or other pharmacy settings.

After some discussion, it was the consensus of the Board that a pharmacist who has: received the appropriate training; collaborative practice agreement; and a valid prescription may administer the drug test.

Henry Delu, PIC, Farma Pharmaceuticals- Clarification of "Fill Date" vs "Dispense Date"

The Chair asked Mr. VandenBussche to lead the discussion on the following inquiry:

"I have several questions that relate to the fill date for a prescription.

1. What is the definition of a fill date for a prescription?
2. If a patient brings a prescription dated on Friday December 8th 2017 and it is not in stock and you have to order it and it arrives on Monday December 11th does that mean the fill date is December 11th or December 8th?
3. Is it fine to bill the insurance on Dec 8th while the medication is on order and then dispense it on Dec 11th once you have the product? I thought there is a 10-14 day window for the patient to pick up the medication once you bill it. Please clarify for me.
4. Is the fill date and dispense date the same in this situation?
5. The written date is the date the MD signs and dates the prescription. The patient may hold on to the prescription for several days and then bring it to the pharmacy. The fill date is the date the product is filled when it arrives or is it the date you bill. Please clarify by defining dispense date and fill date."

During the discussion, the Board referred to Hawaii Administrative Rules §16-95-82 Valid prescriptions and §16-95-87 Return or exchange of drugs prohibited.

After some discussion, it was the consensus of the Board to refer Mr. Delu to HAR §§ 16-95-82 and 16-95-87 and that the pharmacy practice act does not address billing matters.

Eric Murray, M.D.- Prescription requirements for Methadone

The Chair lead the discussion on the following inquiry:

"I'm a physician on the Big Island. I was told today by a pharmacy that they will not accept a prescription for methadone without the words "for pain" written in the sig.

The prescriptions from our electronic medical record prints prescriptions with the indication for the medication written immediately after the prescription. Here is an example

Sig: Methadone 5 mg po bid
Indications: Chronic back pain

The pharmacy informed me that this was not adequate and refused to fill the prescription until I put "for pain" on the sign line as well. The prescription actually had the word "pain" written in 3 separate areas but they would not fill it until I wrote it a 4th time. The patient had to drive an hour to get a new prescription to bring back to the pharmacy.

Unfortunately, our clinic does not have the funds to purchase the e-prescribing module for controlled substances yet.

Who at your department might be able to settle this question since reprinting prescriptions is a time consuming step and this strict interpretation of the rule does nothing for patient safety."

Mr. Yamamoto from the Department of Public Safety, Narcotics Enforcement Division was present and referred to HRS §329-38(i)(1)(B) that states:

- (i) Prescriptions for controlled substances shall be issued only as follows:
 - (1) All prescriptions for controlled substances shall originate from within the State and be dated as of, and signed on, the day when the prescriptions were issued and shall contain:
 - (A) The first and last name and address of the patient; and
 - (B) The drug name, strength, dosage form, quantity prescribed, and directions for use. *Where a prescription is for gamma hydroxybutyric acid, methadone, or buprenorphine, the practitioner shall record as part of the directions for use, the medical need of the patient for the prescription.*

Mr. Yamamoto stated that based on how it is written in the law it has to be written on the script. Therefore, they would side with the Pharmacist because they are going by what the law says. Therefore, it the responsibility by the medical facility to abide by the laws. A computer software incapability is not an excuse for not abiding by the law.

Cindy Khamphaphanh, P4 Pharmacy Student- Requirements for Pharmacy Infusion Center

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

"I am a P4 pharmacy student on rotation at Pali Momi and the pharmacy would like to inquire about licensure for their new Cancer Center. Pali Momi is currently working to open their Cancer Center's Infusion Center. The infusion center themselves will be making IV's for their patients. The center is still a department of PMMC and staff will be from PMMC. However, it is located in a different building directly across PMMC (the old ROSS).

Does the Infusion Center require a NEW and SEPARATE pharmacy license despite still being a part of PMMC, just in a different location?"

During the discussion, the Board members referred to the definition of "Pharmacy" in HRS §461-1, and HAR §16-95-26 Pharmacy permit.

After some discussion, it was the consensus of the Board to inform Ms. Khamphaphanh that a separate pharmacy permit would be required for the separate location.

Gregg Smith, Transition Pharmacy- Patient Portal

The Board discussed the following email inquiry:

"Please be advised that Transition Pharmacy is developing a patient portal website to better service our patients. We would like to provide notice and to inquire if there is anything Transition Pharmacy would need to do prior to launching the site to ensure we are compliant with pharmacy rules and regulations. The site name will be my.transitionrx.com for informational purposes at this time.

Below is a brief overview of the scope and features of this new portal:

Secure Registration

- Patients use their RX Number and DOB to register
- ID challenge questions are presented to verify their identity.

Prescriptions

- View your prescriptions
- Request a refill
- Request to be on autofill

Notifications

- Email messages when something new happens in your account

Orders

- View all your orders for a prescription and get shipping details, tracking and cost information
- Filter by order dates
- Print Statement for sending to FSAs or Medicare

Reminders (coming soon)

- Set daily Text message, IVR, or email reminders for your medications.

Education

- View educational content that correlates with the drugs in your account.

Support

- Technical Support contact info
- Pharmacy Operations contact info

After some discussion, it was the consensus of the Board to inform Mr. Smith that there is no pharmacy law or rule that specifically prohibits this type of activity that they had some HIPAA concerns and that he should consult with the appropriate authority for HIPAA compliance issues.

Joint Accreditation Interprofessional Continuing Education

The Board discussed a letter from Joint Accreditation, Interprofessional Continuing Education regarding continuing education.

The Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Pharmacy Education (ACPE), and American Nurses Credentialing Center (ANCC) have jointly developed the “Interprofessional continuing education” (IPCE) credit for learning and change identify continuing education activities designed by and for the healthcare team.

Key points listed in the letter include:

- IPCE credits for learning and change can only be awarded by CE providers that are jointly accredited by the ACCME, ACPE, ANCC. Jointly accredited CE providers must meet rigorous standards for educational quality and independence.
- The IPCE credit designation is only used for activities that have been planned by and for the healthcare team. IPCE is when members from two or more professions learn with, from, and about each other to enable effective collaboration and improve health outcomes.
- IPCE credits identify team-based CE activities – they do not replace education or credits for individual professions. Activities that offer IPCE credits may also offer credits for individual professions.
- The IPCE credit is intended to complement other healthcare credit and metric systems.

The EO asked if CEs from this organization would meet the definition in HRS 461-1 for “Continuing education” defined as “course approved by the Accreditation Council for Pharmacy Education.”

The Board determined that if the IPCE credits are ACPE accredited then they would meet the requirement. It is the responsibility of the person enrolling in the course to confirm with IPCE that the course they have selected is in fact ACPE accredited.

At 11:12 a.m., the Vice Chair was excused.

Compounded and Repackaged Medications for Office Use

The Chair called on Mr. VandenBussche to lead the discussion on a letter from 45 pharmacy associations from various states.

The letter dated November 6, 2017 letter included the following points:

- Pharmacists' ability to provide compounded medications for a physician's administration to or treatment of a patient within their practice should left to the States
- Office use compounding was not to include "dispensing"
- Repackaging office-use products
- A compounding pharmacist or physician may not dispense compounded medications for office-use, but rather, must obtain or issue a patient specific prescription
- The actions by the FDA to prohibit all office-use compounding has resulted in drastically reducing patient access to vital medications

Mr. VandenBussche cited the definition of "prescription drug" under HRS 461-1 as: "Prescription drug" means any drug dispensed, distributed, or sold pursuant to a practitioner's order." and under HRS 328 as: "Prescription drug" means: (1) Any drug required by federal or state statutes, regulations, or rules to be dispensed only upon a prescription, including finished dosage forms and active ingredients subject to section 328-16 or section 503(b) of the Federal Act; or (2) Any drug product compounded or prepared pursuant to a practitioner's order."

Executive Session: At 11:17 a.m. upon a motion by Mr. Weinberg, seconded by Ms. Keefe, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-4 and §92-5(a)(1) and (4), "To consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities and liabilities;," and "To discuss applications and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities".

At 11:25 a.m. upon a motion by Ms. Chock, seconded by Mr. Weinberg, it was voted on and unanimously carried to move out of executive session.

Chapter 91, HRS, Adjudicatory Matters: The Chair called for a recess from the meeting at 11:25 a.m. to discuss and deliberate on the following adjudicatory matter(s) pursuant to Chapter 91, HRS:

In the Matter of the Wholesale Prescription Drug Distributor Licenses of **Airgas USA, LLC; PHA 2017-90-L; PHA 2017-91-L; PHA 2017-92-L; PHA 2017-93-L; PHA 2017-94-L; PHA 2017-95-L; PHA 2017-96-L; and PHA 2017-97-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Boards Final Order; Exhibits "1" through "3"

Upon a motion by Dr. Chock, seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the Board's Final Order.

In the Matter of the Miscellaneous Permit of **Specialty Veterinary Pharmacy; PHA 2017-78-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit ""

Upon a motion by Mr. Weinberg, seconded by Dr. Ma, it was voted on and unanimously carried to approve the Board's Final Order.

Following the Board's review, deliberation, and decisions in this matter, pursuant to Chapter 91, HRS, the Chair announced that the Board was reconvening its scheduled meeting at 11:27 p.m.

Applications:

Ratification List

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

Applications

Miscellaneous Pharmacy Permits

Upon a motion by the Chair, seconded by Mr. Weinberg, it was voted on and unanimously carried to deny the following application based on HRS 436B-19(13):

Creative Compounds Inc. (Michael Can Hua, PIC and VP)

Next Meeting:

The Chair announced that the next Board meeting is scheduled:

Thursday, February 8, 2018
9:00 a.m.
Daniel K. Inouye College of Pharmacy
722 South A'ohoku Place
Joseph M. Long Pavilion #2 (LPLH2)
Hilo, Hawaii 96720

AND

Daniel K. Inouye College of Pharmacy
677 Ala Moana Blvd., Suite 1025
Honolulu, Hawaii 96813

Ms. Keefe, Mr. VandenBussche and the Chair stated they are not able to attend the March 8, 2018 meeting. The EO said the Board can decide to change the meeting for the March meeting if there is no quorum.

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 11:30 a.m.

Taken and recorded by:

Reviewed and approved by:

/s/ Nohelani Jackson
Nohelani Jackson, Secretary

/s/ Lee Ann Teshima
Lee Ann Teshima, Executive Officer

2/1/18

[X] Minutes approved as is.

[] Minutes approved with changes; see minutes of _____