BOARD OF PHARMACY

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

MINUTES OF MEETING

<u>Date</u> :	Thursday, July 19, 2018
<u>Time</u> :	9:00 a.m.
<u>Place</u> :	King Kalakaua Building 335 Merchant Street Queen Liliuokalani Conference Room First Floor Honolulu, Hawaii 96813
<u>Members Present</u> :	Julie Takishima-Lacasa, PhD, Vice Chair, Public Alanna Isobe, Pharmacist Mary Jo Keefe, RPh, Pharmacist Carolyn Ma, Pharmacist Ronald Weinberg, Public Member
Members Excused:	Kerri Okamura, RPh, Chair, Pharmacist Kenneth VandenBussche, RPh, BCACP, Pharmacist
Staff Present:	Lee Ann Teshima, Executive Officer ("EO") Shari Wong, Deputy Attorney General ("DAG")
<u>Guests:</u>	Athena Borhauer, UH Hilo DKICOP Paul Smith, Walgreens Ann McCloud, Walgreens Student Yushuan Huang, Walgreens Student Reece Uyeno, Pharmacare Kevin Lei, Pharmacare Intern Lauren Glover Alejad, UH Hilo DKICOP Stacy Ly, UH Hilo DKICOP Fred Cruz, CVS Stacy Pi, Kaiser Permanente Wes Sumida, UH Hilo DKICOP Preston Ho, UH Hilo DKICOP Patrick Uyemoto, Times/HPhA Sabine Sonomura, UH Hilo DKICOP Tiffany Yajima, Ashford & Wriston Kellie Noguchi, Kaiser Permanente

<u>Call to Order:</u> 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, the Vice Chair called the meeting to order at 9:00 a.m.

Vice Chair's Report: Announcements and Introductions

The Vice Chair welcomed new member Alanna Isobe.

The Vice Chair excused the Chair and Mr. VandenBussche and asked the audience to introduce themselves.

The Vice Chair announced that the following agenda items had additional distribution:

3. Executive Officer's Report

- b. 2018 Legislation
 - 1) Act 154, SLH 2018
 - 3) Act 151, SLH 2018
 - 5) Act 153, SLH 2018
 - 6) Act 152, SLH 2018

6. Applications

b. Applications

Conferences/Seminars/Meetings

- 1) Miscellaneous Permit
 - i. Mailmyprescriptions.com Pharmacy Corporation

Approval of the Previous Minutes – June 21, 2018 Meeting

The Chair called for a motion in regards to the minutes of the June 21, 2018 meeting.

There being no substantive amendments, upon a motion by Mr. Weinberg, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the minutes for the June 21, 2018 meeting as circulated.

Executive Officer's Report:

NABP/AACP Districts VI, VII & VII (Annual Meeting, October 14, 17, 2018, Kansas City, Missouri

The EO announced that Ms. Keefe will be attending the NABP/AACP district meeting to be held in Kansas City, Missouri, October.14-17, 2018

2018 MPJE State Specific Review and Pre-test Item Selection, September 6-7, 2018, Mount Prospect, Illinois

The EO stated that after discussing with the Chair, the Board will conduct their review remotely whereas the questions will be divided up among the following Board members: The Chair, Ms. Keefe, Mr. VandenBussche and Ms. Isobe.

Ms. Keefe asked if former Board member Mark Brown would be included.

The EO stated that if Mr. Brown wants to assist the Board in reviewing and if the NABP allows it, then it would be okay.

2018 Legislation

The EO reported on the status of the following bills:

<u>SB 2247, SD1, HD2, CD1</u> Relating to Opioid Antagonists – Authorizes pharmacists to prescribe, dispense, and provide related education on opioid antagonists to individuals at risk of opioid overdose and to family members and caregivers of individuals at risk of opioid overdose without the need for a written, approved collaborative agreement; subject to certain conditions. (CD1) Governor approved on 7/9/2018, Act 154, SLH 2018.

<u>HB 2145, HD1, SD1, CD1</u> Relating to Medication Synchronization - Allows the synchronization of plan participants' medications. Requires plans, policies, contracts, or agreements that are offered by health insurers, mutual benefit societies, and health maintenance organizations and provide prescription drug benefits, to apply prorated daily cost-sharing rates for prescriptions dispensed by network pharmacies for less than a thirty-day supply. (HB2145 CD1) Governor on 7/10/2018, Act 197, SLH 2018

<u>HB 1602, HD2, SD1, CD1</u> Relating to Opioids - Requires the inclusion of a label warning of the risks of addiction and death on the packaging of any opioid drug dispensed by a health care professional or pharmacist. (HB1602 CD1) Governor approved on 7/9/2018, Act 151, SLH 2018

<u>HB 2739, HD1</u> – Relating to Health - Establishes a regulated process under which an adult resident of the State with a medically confirmed terminal disease and less than six months to live may choose to obtain a prescription for medication to end the patient's life. Imposes criminal sanctions for tampering with a patient's request for a prescription or coercing a patient to request a prescription. (HB2739 HD1) – Act 2, SLH 2018

<u>SB 2646, SD1, HD3, CD1</u> – Relating to Prescription Drugs - Requires prescribers of certain controlled substances to consult the State's Electronic Prescription Accountability System before issuing a prescription for the controlled substance, under certain circumstances. Provides that a violation by a prescriber shall not be subject to criminal penalty provisions but that a violation may be grounds for professional discipline. Repeals on 6/30/2023. (CD1) – Governor approved on 7/9/2018, Act 153, SLH 2018.

<u>HB 2384, HD1, SD1</u> – Relating to the Uniform Controlled Substance Act - Updates Uniform Controlled Substances Act for consistency with federal law. Allows prescription of drugs to patients undergoing medically managed withdrawal, also known as detoxification treatment and maintenance treatment, by practitioners who are properly registered. Governor approved 7/9/2018. Act 152, SLH 2018

Revisions to Pharmacist's Corresponding Responsibility Guidance Statement - Draft

The EO reported that she is working with the Chair on revisions that will also include reference to the new laws recently enacted by the Governor.

Pharmacists Continuing Education Audit – Report

The EO reported that there are still a few pharmacists who did not respond and a few more that are deficient. She will try to finalize by the next Board meeting.

Working Conditions Survey

The EO reported that she is checking if the working conditions survey can be placed on the Board's web page.

State Board of Pharmacy ACPE CPE Activity

The EO reported that she is still considering this as an option to provide a laws and rules update online course.

<u>Correspondence:</u> National Association of Boards of Pharmacy ("NABP")

News Roundup

The Vice Chair asked Dr. Ma to summarize the following articles in the June 2018 New Roundup:

Dr. Ma summarized the following:

District of Columbia Launches Death With Dignity Program

In 2017 the District of Columbia passed the "Death with Dignity Act of 2016" (D.C. Official Code §7-661-01 et seq), which provides for District of Columbia residents, qualified with a terminal disease, to die in a humane and peaceful manner through the voluntary use of prescribed medications. The District of Columbia Death with Dignity Program is currently operational and accepting patients.

DC Health is responsible for the implementation and regulation of the Death with Dignity Program and has launched a <u>website</u> with instructions and forms for terminally ill patients, physicians, and pharmacists who wish to participate in the program. Physicians who choose to participate in the Death with Dignity Program must be licensed in the District of Columbia, sign up via the physician portal on the Death with Dignity Program website, and are encouraged to complete a <u>physician training module</u>. Patients who wish to participate must show proof of current residency in the District of Columbia, have a terminal illness that is expected to result in death within six months, and are encouraged to complete a <u>patient training module</u>.

Idaho Passes Bills on Therapeutic Substitution, CS Scheduling, Licensure and Registration, PMP Reporting

The following pharmacy-related bills were passed by the Idaho Legislature and signed into law by Governor Butch Otter with an effective date of July 1, 2018. For details on the bills listed below, see the Idaho State Board of Pharmacy's <u>June 2018 Newsletter</u>. **House Bill (HB) 339** enables therapeutic substitution within the same therapeutic class (excluding narrow therapeutic drugs and biological products) in any practice setting if three things occur as specified in the bill. If all three occur and a pharmacist makes a therapeutic substitution, he or she must also modify the prescriber's directions to allow for an equivalent amount of drug to be dispensed as prescribed and notify the original prescriber of the substitution within five business days.

HB 340 provides housekeeping to the Uniform Controlled Substances Act. Of note, the bill places acetyl fentanyl in Schedule I and removes dronabinol in oral solution from Schedule I consistent with Drug Enforcement Administration's scheduling of the product (Schedule II).

HB 351 updates and modernizes provisions of the Idaho Pharmacy Practice Act related to licensure and registration. The bill specifically eliminates two categories of registration: non-pharmacy retail outlets (eg, retail outlets that sell nonprescription drugs) and certain veterinary drug outlets. Elimination of these registration categories does not mean these activities cannot occur; it simply removes the need for registration prior to engaging in these activities. The bill also updates the annual renewal dates for licenses and registrations. Most individual licenses will renew by the end of the licensee's birth month, and facilities will renew by December 31 annually.

HB 354 requires all controlled substances (CS) and opioid antagonists as defined in Section 54-1733B of the Idaho Code to be reported to the Idaho Prescription Monitoring Program (PMP). This requirement includes all naloxone dispensed in or into Idaho.

Electronic Prescriptions to Become Mandatory in Iowa

The lowa Legislature passed a bill during its 2018 session related to the opioid epidemic, House File 2377, referred to as the "opioid bill." The bill contains several new requirements, including requirements affecting electronic prescriptions in Iowa. Beginning January 1, 2020, every prescription issued must be electronically transmitted to a pharmacy. There are certain exceptions identified in the bill – such as for patients residing in inpatient hospice care, long-term residential facilities, or correctional facilities – and exemptions for licensed veterinarians or practitioners who are unable to timely comply (with Iowa Board of Pharmacy approval). A pharmacist who receives a written, oral, or facsimile prescription after January 1, 2020, will not be required to verify that a prescription is subject to an exception and may still dispense the medication. However, a pharmacist must exercise professional judgment in identifying and reporting suspected violations to the Board or to the appropriate professional licensing board.

Kansas PDMP Debuts New Website and Data Integration Process

K-TRACS, the Kansas prescription drug monitoring program (PDMP), has a new website: <u>http://ktracs.ks.gov</u>. The PDMP also has a new <u>poster</u> that can be downloaded and used in the pharmacy for customer notification or other promotional material. The Kansas State Board of Pharmacy is accepting requests for <u>INTEGRx8</u>, the statewide integration of K-TRACS data into pharmacy management systems.

> The Board also recently amended <u>Kansas Administrative Regulation 68-21-7</u> to include any product, compound, mixture, or preparation containing gabapentin as a drug of concern in Kansas. This regulation will take effect and require reporting to K-TRACS beginning July 25, 2018.

> Additionally, in conjunction with the Kansas Department of Health and Environment and the Centers for Disease Control and Prevention Data-Driven Prevention Initiative, a new public dashboard was created using K-TRACS and other data to shine a light on prescription opioids and other epidemiological data in Kansas. More information is available at <u>www.preventoverdoseks.com</u>.

Kentucky Legislation Addresses MAT, Safe Medication Disposal, PBMs

The following pharmacy-related bills were passed by the 2018 Kentucky Legislature and have become law.

Pilot Project for Pharmacist-Led Medication-Assisted Treatment Therapy (HB 246) will allow pharmacies to participate in a pilot project for pharmacist-led medicationassisted treatment (MAT) for opioid use disorder. This bill builds on the Board-authorized protocol regulation approved by the Kentucky Board of Pharmacy.

Safe Medication Disposal (Senate Bill (SB) 6) allows a pharmacist to make safe disposal mechanisms available and requires pharmacists to inform patients about safe disposal of medications. The legislation also allows information to be provided to patients in writing, verbally, or by posting a sign.

Anti-Gag Order Legislation (HB 463) ensures that patients are not paying too much for prescriptions. The bill prohibits insurance companies or pharmacy benefit managers (PBMs) from prohibiting pharmacists from telling patients that they can get a prescription cheaper than their copay if they pay cash.

Kentucky Board Partners With NABP on Compounding Inspections

The Board's inspection staff have agreed to participate in the NABP Multistate Pharmacy Inspection Blueprint Program. NABP is attempting to standardize an inspection process for pharmacies that dispense compounded preparations across state lines. This allows participating states to eliminate the need to perform their own inspections of out-of-state pharmacies. Both the Blueprint Program and Kentucky inspections are performed to the standards of United States Pharmacopeia Chapters 795 and 797. For more information about the Blueprint Program, visit the <u>Member Services section</u> on the NABP website under Inspection Tools and Services.

North Dakota Offers Free Prescription Opioid Bag Stuffers for Distribution to Patients The North Dakota State Board of Pharmacy has partnered with the North Dakota Department of Human Services and the North Dakota Pharmacists Association to develop and distribute free bag stuffers that can be utilized when dispensing opioid prescriptions. This bag stuffer is meant to be a tool for pharmacists to utilize in their practice. The Department of Human Services is able to ship the bag stuffers to North Dakota pharmacies upon request at no cost. For more information, visit the North Dakota Prevention Resource & Media Center website at www.prevention.nd.gov.

<u>Virginia Passes Bills Affecting Drug Disposal, CBD and THC-A Oil Use, PMP Reporting,</u> <u>Drug Donations</u>

The following is a summary of select pieces of legislation passed by the 2018 Virginia General Assembly affecting the profession of pharmacy. For details and requirements on the bills listed below, see the Virginia Board of Pharmacy's <u>June 2018 Newsletter</u>. **HB 501: Home hospice programs; disposal of drugs** requires every hospice to develop policies and procedures for the disposal of drugs dispensed as part of the hospice plan of care for a patient, which shall include specific requirements for such disposal.

HB 1251/SB 726: CBD oil and THC-A oil; certification for use, dispensing and SB 330: THC-A oil; dispensing, tetrahydrocannabinol levels set requirements regarding the use and dispensing of cannabidiol (CBD) oil or tetrahydrocannabinolic acid (THC-A) oil and made amendments to the current law. Among the changes enacted include an increase in the supply of CBD oil or THC-A oil that a pharmaceutical processor may dispense from a 30-day supply to a 90-day supply and the addition of CBD oil or THC-A oil to the list of covered substances the dispensing of which must be reported to the Virginia PMP.

HB 1177/SB 933: Health insurance; contracts with pharmacies and pharmacists, etc, prohibit certain provisions in provider contracts between a health carrier or its PBM and a pharmacy or its contracting agent and also require specific provisions in such contracts as stated in the bills. This measure applies to provider contracts entered into, amended, extended, or renewed on or after January 1, 2019.

SB 226: Prescription Monitoring Program; veterinarians requires veterinarians who dispense CS to report certain information about the animal and the owner to the PMP. **SB 544: Prescription drugs; donation of used medicines** clarifies that prescription drug donation programs may accept eligible prescription drugs from individuals and facilities listed in the bill. Such donations of eligible drugs may be redispensed to indigent patients in compliance with Regulations 18VAC110-20-740 through 18VAC110-20-800.

Wyoming Revises Statutes on Biological Products, PDMP Reporting, and Marijuana; Creates Opioid Task Force

The following pharmacy-related bills were passed by the 2018 Wyoming Legislature and have become law.

Senate File (SF) 0075 – Biological products-pharmacies revised the Wyoming Pharmacy Act to provide a definition for "substitute," authorizes pharmacists to dispense interchangeable biological products as such products are defined by Food and Drug Administration (FDA), and specifies record-keeping requirements relating to biological products, effective July 1, 2018.

SF 0083 – Controlled substance prescription tracking changed Wyoming Statute (W.S.) 35-7-1025 to require mandatory registration in the state's PDMP, the Wyoming Online Prescription Database (WORx), for practitioners in Wyoming dispensing Schedule II-V CS. The bill also requires reporting of all Schedule V CS dispensed to WORx. This bill became effective March 14, 2018.

SF 0078 – Opioid addiction task force created a temporary task force to consider such issues as PDMPs and electronic prescribing systems; the availability and use of naloxone; the quality of treatment for opioid addiction and overdoses; strategies to reduce the administration of opioids; and any other matter relating to opioids determined to be relevant. The task force will submit a report on or before October 1, 2019, to legislative committees and the governor and will terminate on December 31, 2019. **HB 0099 – Prescription and possession of FDA approved drugs** revised the Controlled Substances Act in W.S. 35-7-1031 to specify that no prescription or practitioner's order for marijuana, THC, or synthetic equivalents of marijuana or THC shall be valid unless the prescription is for a drug that has received final approval from FDA, including dronabinol, effective July 1, 2018.

Is there a limit to the number of times an original, unfilled prescription can be transferred?

The Vice Chair asked Mr. Keefe to lead the discussion on the following email inquiry:

"Does Hawaii limit the number of times an original, unfilled prescription can be transferred?

My research shows that Haw. Code R. § 16-95-84 & Meeting Minutes from the Hawaii Board of Pharmacy (Feb. 2014), *available at* <u>http://cca.hawaii.gov/pvl/files/2014/09/140213-min.doc.pdf</u> allow unfilled transfers, but do not discuss how many times they may be transferred."

Ms. Keefe stated that her review of HAR §16-95-84 did not indicate any limitations.

The Board reviewed HAR §16-95-84 as follows, and after careful consideration, confirmed that the HAR cited does not discuss how many times an unfilled prescription may be transferred:

§16-95-84 Transfer of prescriptions. (a) Transfers of prescription information for the purpose of initial fill or refill dispensing is permissible between pharmacies provided the pharmacist transferring the prescription provides all information necessary for a valid prescription, and records on the prescription, the name and location of the pharmacy receiving the prescription, the name of the pharmacist receiving the prescription information, the date of transfer, and the name of the pharmacist transferring the prescription, or notes the pharmacist's name on the electronic files, and records that the prescription is inactivated or made void for future refills at the location from which it is being transferred.

(b) The pharmacist receiving the transferred prescription information shall indicate the name of the pharmacist transferring the prescription as well as the transferring pharmacist's or pharmacy name, the transferring pharmacy's name, location, and original prescription number, the original date the prescription was written, the number of refills or quantity remaining on the prescription, and the last date the prescription was filled.

(c) All records of transferred prescriptions shall be maintained for a period of five years from the date of filling or refilling. [

<u>Chapter 91, HRS</u> At 9:25 a.m., the Vice Chair called for recess pursuant to Chapter 91, HRS to discuss and deliberate on the following adjudicatory matter:

In the Matter of the Miscellaneous Permit of **Wellness Pharmacy, Inc., aka Wellness Health & Pharmaceuticals, Inc.; PHA 2017-86-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final order; Exhibits "1" through "3"

Upon a motion by Mr. Weinberg, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the Board Final Order for PHA 2017-86-L

Following the Board's review, deliberation, and decision in these matters, pursuant to Chapter 91, HRS, the Vice Chair announced that the Board was reconvening its scheduled meeting at 9:28 a.m.

Executive Session: At 9:28 a.m., upon a motion by Dr. Ma, seconded by Mr. Weinberg, it was voted on and unanimously carried to move into executive session pursuant to §92-4 and §92-5(a)(1) and (4), HRS, "To consider and evaluate personal information relating to individuals applying for professional or vocational licenses cited in section 26-9 or both;" and "To consult with the Board's attorney on questions and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities".

At 9:58 a.m., upon a motion by Mr. Weinberg, seconded by Ms. Keefe, it was voted on and unanimously carried to move out of executive session.

Applications:

Ratification Lists

Upon a motion by Mr. Weinberg, seconded by Dr. Ma, it was voted on with the Vice Chair, Dr. Ma, Mr. Weinberg and Ms. Isobe voting yes to approve the attached ratification list(s).

Applications

Miscellaneous Permit

Upon a motion by Mr. Weinberg, seconded by Dr. Ma, it was voted on to approve the following miscellaneous permit application(s):

Mailmyprescriptions.com Pharmacy Corporation EntirelyPets Pharmacy

Upon a motion by Mr. Weinberg, seconded by Ms. Isobe, it was voted on and unanimously carried to defer the following application for additional information (signed statement). Upon receipt of the requested document, the Board delegates the EO to approve and continue processing the application:

SterlingRx, Inc., dba Sterling Specialty Pharmacy, Daniel B. Astrup, Owner

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<u>Pharmacist(s)</u> The Board deferred the following application for additional information:

Mark K. Miles

<u>Next Meeting:</u> Thursday, August 16, 2018 9:00 a.m. Queen Liliuokalani Conference Room, First Floor 335 Merchant Street Honolulu, Hawaii 96813 The Vice Chair asked if everyone could attend.

Dr. Ma said she is unable to attend.

Adjournment: With no further business to discuss, the Vice Chair adjourned the meeting at 10:05 a.m.

Taken and recorded by:

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

7/22/18

[X] Minutes approved as is.

[] Minutes approved with changes; see minutes of _____