BOARD OF PHARMACY

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

MINUTES OF MEETING

<u>Date</u> :	Thursday, March 15, 2018
<u>Time</u> :	9:00 a.m.
<u>Place</u> :	King Kalakaua Building 335 Merchant Street Exam Conference Room Third Floor Honolulu, Hawaii 96813
<u>Members Present</u> :	Kerri Okamura, RPh, Chair, Pharmacist Mary Jo Keefe, RPh, Pharmacist Ronald Weinberg, Public Carolyn Ma, PharmD., BCOP, Pharmacist
Members Excused:	Julie Takishima-Lacasa, PhD, Vice Chair, Public Marcella Chock, PharmD., Pharmacist Kenneth VandenBussche, RPh, BCACP, Pharmacist
Staff Present:	Lee Ann Teshima, Executive Officer ("EO") Shari Wong, Deputy Attorney General ("DAG") Nohelani Jackson, Secretary
<u>Guests:</u>	Alanna Isobe, Safeway Paul Smith, Walgreens Kellie Noguchi, Kaiser Permanente Dean Yamamoto, Dept. of Public Safety Narcotics Enforcement Division Matt Tsujimura, Walgreens Fred Cruz, CVS Caremark Ashok Kota, Foodland
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 9:05 a.m.

<u>Chair's Report</u> :	Announcements and Introductions
	The Chair excused the Vice Chair, Dr. Chock and Mr. VandenBussche and asked the audience to introduce themselves.
	Approval of the Previous Minutes – February 8, 2018 Meeting
	The Chair called for a motion in regards to the minutes of the February 8, 2018 meeting.
	Mr. Weinberg moved to accept the minutes as circulated. There was no second, the motion died.
	Dr. Ma recommended the following "correction" on page 7:
	"Dr. Ma stated that there is no evidence that making the font size bigger <u>labeling the</u> <u>bottle w</u> ill deter the patient from taking the drug or from becoming addicted."
	The Chair also recommended that on page 6, reference to HRS "416-14" should be amended to HRS "461-14".
	There being no further amendments, upon a motion by Mr. Weinberg, seconded by Dr. Ma, it was voted on and unanimously carried to approve the minutes for the February 8, 2018 meeting as amended.
Executive Officer's Report:	Conferences/Seminars/Meetings MPJE Item Development Workshop March 6-8, 2018 Mr. VandenBussche to report on attendance - Deferred to April 19th meeting
	<u>NABP Annual Meeting, May 5-8, 2018</u> The EO reported that she needs to submit the registration/delegate appointment and although Mr. VandenBussche indicated that he was interested in attending and would let her know upon his return, she doesn't want to miss the opportunity to apply for the grant and therefore, will be registering Ms. Keefe to attend the annual meeting in Denver, Colorado.
	Department of Public Safety, Narcotics Enforcement Division Agent Yamamoto did a presentation on Controlled Substance Prescriptions, Misfills and Fraudulent Prescriptions.
	2018 Legislation <u>HB 1950, HD2 Relating to the Practice of Pharmacy</u> - Amends the definition of "practice of pharmacy" to expand the scope of services and specific medications that pharmacists may furnish. Establishes a working group to review the scope of practice of pharmacists and continuing competency requirements for pharmacists. (HB1950 HD2)

The EO reported that this bill crossed over to the Senate and was referred to the Committee on Commerce, Consumer Protection, and Health ("CPH"). She also reported that yesterday she was informed that there was a senate and house concurrent resolution establishing a working group, similar to the working group in HB 1950, HD2.

The Board discussed their preference of establishing a working group over the amendments being proposed in HB 1950, HD2.

After some discussion, it was the consensus of the Board to support SCR 135 in lieu of HB 1950, HD2.

<u>SB 2247, SD1 Relating to Opioid Antagonists</u> – 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. Takes effect on 7/1/2050. (SD1)

The EO reported that this bill was heard by the House Health and Human Services (HHS) Committee yesterday and that the Committee was going to pass it out with an HD1 with recommendations from the Board, Kaiser and Walgreens and will note in the Committee report concerns expressed by HMSA. She also reported that she has been working with Kaiser, Walgreens and the Hawaii Pharmacists Association and that the group came to a consensus to recommend amendments for clarification.

It was the consensus of the Board to continue their support of this measure.

<u>SB 2339, SD1 Relating to Prescription Drugs</u> – Authorizes pharmacies to accept for disposal the return of any unused, remaining, or expired prescription drugs, excluding opioids, that the pharmacy previously dispensed, via collection receptacles or mail-back programs. (SD1)

The EO reported that this bill was heard by HHS on Tuesday and was passed out with amendments proposed by the Department of Public Safety, Narcotics Enforcement Division and that opioids will be included. The bill was previously amended to prohibit the return of opioids back (it was previously removed by the Senate CPH).

The Board discussed concerns that the bill still specified that the drugs may only be returned to the pharmacy that sold or dispensed it and not to any other pharmacy.

After further discussion, it was the consensus of the Board to support the intent but to continue to express their concerns with the lack of logistics in the bill and that should the bill pass, the Board will have to promulgate administrative rules in order to implement this statute.

The Board reviewed HAR §16-95-87 that prohibits the return or exchange of drugs by a pharmacy and also a list of states that have laws/regulations on the disposal of medications.

<u>HB 2145, HD1 Relating to Medication Synchronization</u> - Requires health insurance and hospital and medical service plans that provide prescription drug benefits to apply prorated daily cost-sharing rates for prescriptions dispensed by pharmacies. (HB2145 HD1)

The EO reported that this bill crossed over to the Senate and was referred to CPH and WAM.

It was the consensus of the Board to continue their support of this measure as long as they are able to be reimbursed for partially filling a prescription for the purpose of medication synchronization.

<u>SB 2656, SD2 Relating to Medication Synchronization</u> – 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 organization 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. Repeals 7/1/2023. Effective 7/1/2050. (SD2)

The EO reported that this bill crossed over to the House.

It was the consensus of the Board to continue their support of this measure as long as they are able to be reimbursed for partially filling a prescription for the purpose of medication synchronization.

<u>SB 2298, SD2 Relating to Healthcare Preceptor Tax Credits</u> – Allows advanced practice registered nurses, pharmacists, and physicians to receive income tax credits for acting as preceptors in volunteer-based supervised clinical training rotations provided to eligible students that enable the students to obtain an eligible healthcare professional degree or certificate. Applies to taxable years beginning after 12/31/2018. (SD2)

The EO reported that this bill was heard by the House HHS Committee on Tuesday, March 13, 2018 and was passed out with amendments to include the other professions indicated in HB 1967, HD2.

It was the consensus of the Board to continue to support this measure as it pertains to pharmacists students/preceptors.

> HB 2347, HD1/SB 2774, SD1 Relating to Insurance – Amends various portions of the Hawaii Insurance Code by adopting NAIC model language for corporate governance annual disclosures, establishing a procedure for changes in trade name or an assumed name, and clarifying reimbursement to health insurance providers. Clarifies requirements for reporting and recordkeeping for vehicle protection product warrantors and service contract providers. Makes various housekeeping amendments. (HB2347 HD1)/ Updates various areas of the State's insurance laws to: adopt the NAIC's Corporate Governance Annual Disclosure Model Act beginning on 1/1/2020; allow the department of commerce and consumer affairs and the insurance commissioner to determine whether a request to add or change a trade name or assumed name satisfies certain requirements; clarify certain provider reimbursement requirements; adopt revisions to the Insurance Holding Company System Regulatory Act beginning on 1/1/2020; provide the insurance commissioner with additional regulatory authority to supervise or liquidate a captive insurer; enable the insurance division to create stopgap measures, until 12/31/2020, to implement the Network Adequacy Model Act; change notice requirements and recordkeeping obligations for vehicle protection product warrantors and service contract providers; and make various housekeeping amendments to clarify existing language and avoid ambiguities. (SD1)

The EO reported that the Senate bill was heard yesterday by the House Consumer Protection and Commerce Committee and was passed out with amendments recommended by the Insurance Commissioner. She said that she will review the testimony submitted by the Insurance Commissioner to ensure that the definition of "health care provider" would still authorize insurance reimbursement for pharmacists practicing within their scope of practice.

<u>HB 1602, HD2 Relating to Opioids</u> - Permits 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 HD2)

The EO reported that this bill no longer requires the 14 pt font and that it crossed over to the Senate.

Status on other pharmacy related bills

The EO reported on the status' of following bills that she is tracking on behalf of the Board:

- HB2631, HD1 Relating to the Electronic Prescription Accountability System (Prescription Drug Monitoring Program);
- SB 2275 Relating to Mandatory Reporting Requirements;
- HB 1631, HD1/SB2358 SD1 Relating to Workers' Compensation Prescription Drug Reimbursement;
- HB 1603, HD2 Relating to Health Insurance;
- SB 3072 Relating to Pharmacy Benefit Managers;
- HB 2644/SB 3104, SD2 Relating to Pharmacy Benefit Managers
- SB 2727 Relating to Health
- HB 2622/SB 3061 Relating to Informed Consent for Vaccinations

	Revisions to Pharmacist's Corresponding Responsibility Guidance Statement - Draft
	The Chair went through some of the amendments to the guidance statement recommended through a collaborative working group with the Police Chiefs of Hawaii Association.
	The DAG expressed concerns with some of the information contained in the guidance statement.
	The Chair reported she will work on another draft for the Board's consideration.
Recess:	The Chair called for a recess of the meeting at 10:38 a.m.
	The Chair announced that the Board was reconvening its scheduled meeting at 10:45 a.m.
	Pharmacists Continuing Education Audit – Report
	The EO reported that approximately 150 audit letters were sent to pharmacists and that she would like to remind everyone that we will accept the CPE monitor transcript that list the CE courses taken between January 1, 2017 through December 31, 2018 in lieu of the actual completion certificates.
Correspondence:	National Association of Boards of Pharmacy
	The Chair briefly reported on the following initiatives in other states:
	 February 2018 State News Roundup Illinois Public Act 100-0497 created a Collaborative Pharmaceutical Task Force to discuss and make recommendations on how to further advance the practice of pharmacy in a manner that recognizes the needs of the health care system, patients, pharmacies, pharmacists, and pharmacy technicians in Illinois.
	 The task force is to include eight voting members and three nonvoting members. The task force will meet at least once per month or more frequently if deemed necessary by the task force chair. Now that all pharmacies licensed by the Massachusetts Board of Registration in Pharmacy must maintain a naloxone standing order and a sufficient supply to meet the needs of the community, naloxone may be dispensed in Massachusetts to any person at risk for an opioid-related overdose or to family members,

friends, or others in a position to assist a person at risk for an opioid-related overdose. Patient-specific prescriptions from practitioners may still be honored.

> As of January 1, 2018, Minnesota statutes require all individuals seeking to be licensed as a pharmacist for initial licensure, licensure by transfer (reciprocity), or license reinstatement to complete a fingerprint-based criminal background check (CBC) (Minnesota Statute §214.075). At this time, pharmacists with existing licenses do not have to complete a CBC. However, it is possible that the Minnesota Legislature will amend the statutes to require licensees to have a one-time CBC in the future, in conjunction with license renewal. Because pharmacist-interns and pharmacy technicians are registered, not licensed, they will not have to undergo a CBC.

The requirement to have a CBC applies to all professionals licensed by Minnesota's Health Licensing Boards (HLBs). The HLBs have cooperatively established a Criminal Background Check Program to help applicants efficiently complete the mandatory background check.

- Effective December 29, 2017, Ohio Administrative Code Rule 4729-5-30 requires a diagnosis/procedure code for all opioid prescriptions. This rule requires prescribers (except for veterinarians) to indicate the first four alphanumeric characters of The International Classification of Diseases, Tenth Revision, Clinical Modification medical diagnosis code (eg, M16.5) or the Code on Dental Procedures and Nomenclature on all opioid analgesic prescriptions. The requirements for all other controlled substances go into effect on June 1, 2018. The Ohio Automated Rx Reporting System (OARRS) has been updated to include advanced analytics and reporting through NarxCare, a comprehensive tool that provides a Narx Score (a three-digit risk score for the prescribing of narcotics, sedatives, and stimulants), predictive risk scores, red flags, a prescription graph, and access to resources in a single, easy-to-use interface. NarxCare is currently available using the OARRS web interface. The State of Ohio Board of Pharmacy is working with vendors to ensure NarxCare will be available through currently integrated systems (ie, those that provide OARRS data within the clinical workflow) over the next few months.
- The Ohio Board has posted its annual online Jurisprudence Quiz, available at <u>www.pharmacy.ohio.gov/quiz</u>, which provides one hour of free continuing education credit to its licensees. The questions in the quiz relate to topics covered in the February, May, August, and November 2017 issues of the Board's *Newsletters*, available on the Board's <u>website</u> under the Publications tab. As in past years, the test is taken online and graded as soon as the test is submitted.

USP <795> and <797> - USP Accepting Written Comments

The Chair reported that the United States Pharmacopeia is allowing for written comments on USP <795> and <797>. The intent is to provide a unified approach to qualify compounding by aligning the timing and content of General Chapters <795>, <797> and <800>.

Talking Points for Pew Report on Pharmacy Compounding Regulations

A copy of the Report on Pharmacy Compounding Regulations was made available for the Board members.

Scope of Practice Questions

<u>Hormonal Contraception Age Requirements</u> The Chair asked Ms. Keefe to lead the discussion on the following email:

I called earlier regarding the age requirements for prescribing oral contraception. Under HRS 461, there is no mention of a minimum age so just wanted to clarify before advertising services to everyone.

Ms. Keefe stated that pharmacists should use their professional judgment since the pharmacy practice act does not indicate a minimum age for the prescribing and dispensing of women's hormonal contraceptives.

The EO asked about the training course and if that includes any information on the age restriction?

Ms. Isobe stated that the training includes a screening checklist that the pharmacist utilizes when determining whether or not the patient can be a recipient of women's hormonal contraceptives.

It was the consensus of the Board that although the age of the patient is not specified in the pharmacy practice act, using the screening checklist provided through the women's hormonal contraceptive training, a pharmacist, using their professional judgement, could prescribe and dispense women's hormonal contraceptives.

Approval of Collaborative Practice Agreement for Kaiser

The Chair asked Dr. Ma to lead the discussion on a request for approval of a Collaborative Practice Agreement from Kaiser Permanente, to allow their pharmacists to initiate a prescription for an opioid antagonist pursuant to the following language under the definition of "Practice of pharmacy" in HRS 461-1:

(I) Dispensing an opioid antagonist in accordance with a written collaborative agreement approved by the board, between a licensed physician and a pharmacist who has received appropriate training that includes programs approved by the ACPE, curriculum-based programs from an ACPE- accredited college of pharmacy, state or local health department programs, or programs recognized by the board;

After some discussion, upon a motion by Dr. Ma, seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the Collaborative Practice Agreement submitted by Kaiser pursuant to HRS 461-1, under the definition of "Practice of pharmacy", (I).

<u>Follow-up/Status from Department of Health on Immunization Registry</u> The Chair reported that the DOH immunization registry is working now.

Warning Caps for Schedule II Drugs

The Chair asked Ms. Keefe to lead the discussion on the following information received from C. Roy Shipp, Director of Business Development, Trade Relations for Tri State Distribution, Inc.:

"The subject of Opioid and Schedule II prescriptions is certainly at the forefront of discussions throughout our country. From Washington, D.C. to the States, and even to the municipalities, steps are being taken to address this major healthcare crisis. As a means of protecting their citizens, some States have taken action to introduce Bills and Proposals related to this urgent concern. Some of the steps being taken involve reinforcing the need for caution in the packaging, storage and protection of Schedule II prescription drugs.

As one of the nation's largest "Made in the USA" manufacturers and suppliers of prescription packaging, Tri State Distribution has already developed a number of innovative products which fulfil these needs. These products are currently in stock, ready to ship, and very cost-effective.

I have attached a one page product listing that shows both pictures and descriptions, along with case quantities of these products. Certainly contact me, by email or phone, if you have any questions, or call our Customer Service number provided at the bottom of the attached product listing. We want to be of assistance in improving the dispensing of prescription drugs and the effective management of our nation's healthcare."

The EO stated that in light of all the legislation pertaining to the opioid epidemic including the destruction/disposal of and special labeling requirements for controlled substances, she thought that this was pertinent as it does include a warning on the top of the "red" cap.

National Transportation Safety Board – Safety Recommendation: Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment – NTSB's Dissatisfaction with Department's Reponses

The EO reported that in a March 6, 2018 letter to Governor Ige, Robert L. Sumwalt, III, Chairman of the National Transportation Safety Board (NTSB) expressed his dissatisfaction with the Board's previous initiative to disseminate NTSB's recommendations and an article.

For history purposes, sometime in 2014, NTSB supposedly sent recommendations as a result of their safety study *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment.*"

	In November 2015, the NTSB submitted a letter to Governor Ige regarding NTSB's previous notification of their recommendations and expressing interests in knowing whether and how their "recommendations" would be implemented, also including a statement that they "expect" actions to address their recommendations be completed within 3-5 years.
	At that time, the NTSB's 2015 was to the Hawaii Medical Board, Board of Nursing and Board of Pharmacy.
	As a result, in March 2016, the EO initiated a memorandum summarizing the NTSB's recommendations and the memo was and still is posted on the Board's web page under "Important Announcements".
	The NTSB is now requesting that we post or publish their sample article on all the board's web pages including the Board of Dental Examiners.
	At this point, the Director's Office is drafting a response on behalf of all the boards affected and requesting a copy of the "article".
	The EO stated that she would keep the Board apprised of this matter.
Executive Session:	At 11:09 a.m., upon a motion by Dr. Ma, seconded by Ms. Keefe, 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 11:42 a.m., upon a motion by Mr. Weinberg, seconded by Dr. Ma, 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 and unanimously carried to approve the attached ratification lists.
	Applications
	Miscellaneous Pharmacy Permits

Upon a motion by the Chair, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the following applications for miscellaneous permit as an out-of-state pharmacy:

Katy Pharmacy, Inc. One Way Drug, LLC, dba Partell Specialty Pharmacy Nubratori, Inc.

Upon a motion by the Chair, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the following miscellaneous permit as an out-of-state pharmacy with conditions: RxC Acquisition Company, dba RxCrossroads Louisville, KY - The approval does not include pharmacists David Walters; Paul Koenig and Raymond De Piero pursuant to HRS § 436B-19(13). It was the consensus of the Board to defer decision making on the following application for additional information: MailMyPrescriptions.com Pharmacy Corp., dba MailMyPrescriptions.com Next Meeting: Thursday, April 19, 2018 9:00 a.m. Queen Liliuokalani Conference Room, First Floor 335 Merchant Street Honolulu, Hawaii 96813 The Chair stated she is not able to be at the April meeting. With no further business to discuss, the Chair adjourned the meeting at 11:45 a.m. Adjournment:

Taken and recorded by:

Reviewed and approved by:

<u>/s/ Nohelani Jackson</u> Nohelani Jackson, Secretary /s/ Lee Ann Teshima Lee Ann Teshima, Executive Officer

3/19/18

[X] Minutes approved as is.

[] Minutes approved with changes; see minutes of _____