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

MINUTES OF MEETING

Date: Thursday, September 19, 2019

Time: 9:00 a.m.

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

Members Present: Alanna Isobe, Chair
Julie Takishima-Lacasa, PhD, Public Member – Vice Chair
Catalina Cross, Public Member
Mary Jo Keefe, RPh, Pharmacist
Sheri Tokumaru, Pharmacist
Kenneth VandenBussche, RPh, BCACP, Pharmacist

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

Guests: Kellie Noguchi, Kaiser Permanente
Tiffany Yajima, SanHI Government Strategies
Katya Blissard, DEA
Alex Nikoloudakis, DEA
Greg Edwards, Department of Health, Food and Drug Branch
Reece Uyeno, Pharmacare
Patrick Uyemoto, Times
Carolyn Ma, UH Hilo, DKICP
Tanya Demattia, CVS Health
John Garibaldi, Watanabe Ing

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, the Chair called the meeting to order at 9:06 a.m.

Chair's Report **Announcements and Introductions**

The Chair asked the audience to introduce themselves.

Approval of the Previous Minutes – August 15, 2019 Meeting

The Chair called for a motion for the minutes of the August 15, 2019 meeting.

There being no amendments, upon a motion by Ms. Keefe, seconded by Mr. VandenBussche, it was voted on and unanimously carried to approve the minutes for the August 15, 2019 meeting as circulated.

Executive Officer's Report:

Conferences/Seminars/Meetings

Boards and Commissions Member Orientation, October 11, 2019, 8:30 – 12:00, State Capitol Auditorium
The EO stated that the Chair, Ms. Cross and Ms. Tokumaru will be attending this orientation.

2020 Legislation

The EO reported that at the August 15, 2019 Pharmacy Working Group meeting, the discussion was focused on two possible legislation. The first was to require mandatory e-prescribing for controlled substance prescriptions and the second pertains to amending the labeling requirements under HRS Chapter 328.

She stated that at that time, the positions from the Narcotics Enforcement Division and the Department of Health was not known.

Board Approved Pilot Projects

The EO reported that the if the Board approves the application form today, we can have the form posted on the Board's web page under Important Announcements and Applications.

It was the consensus of the Board to approve the application form for Pilot Projects.

Pharmacy FAQs

The EO stated that she is still working on the FAQs.

Compounding for "Office Use"/ Outsourcing Facilities

The EO reported that she has not had an opportunity to discuss with Ms. Keefe.

Upcoming Renewal

The EO stated that as reported at the last meeting, pharmacy renewals go "live" on November 4, 2019.

Working Solutions

Board members were distributed a copy of the September 2019 Working Solutions issue.

Phone Scam Calls Targeting Licensed Professionals Reported

The EO reported that several licensed professionals, including a pharmacist was contacted by an individual claiming to be a state official and informing the licensee that they were under investigation. She stated that if anyone receives a suspicious phone call to report it immediately to the Board. More information is posted on the DCCA's web page.

Hawaii Department of Health Announces New School Immunization Requirements to Begin July 1, 2020

The EO reported that beginning in the 2020-2021 school year, additional immunizations required for students entering preschool, kindergarten through grade 12, and colleges/universities in Hawaii. In addition, before the first day of school year 2020-2021, all seventh grade students must provide documentation of having received the following immunizations/vaccinations:

- Tdap;
- HPV; and
- MCV

Although all states require children to be vaccinated against certain infectious diseases as a condition for school and childcare attendance, Hawaii continues to recognize exemptions to the immunization requirements for medical and religious reasons. Philosophical or personal belief exemptions are not allowed in Hawaii.

For a complete list of required vaccinations, you can go to DOH's web page.

She stated that since pharmacists who have received the appropriate education and training can administer vaccines to persons between 14 and 17 and the HPV, Tdap, meningococcal and influenza vaccines to persons between 11-17 pursuant to a valid prescription she reminded anyone who is administering to minors to review the requirements and procedures under HRS §461-11.

Opioids:

Revisions to Pharmacist's Corresponding Responsibility Guidance Statement

The Chair reported that the Board is still working on it.

Hawaii Opioid Initiative – Hawaii Naloxone Dispensing Guidance Document

The Chair stated that the Board did receive a copy of the Guidance Document prepared by Mr. Uyemoto. She addressed Mr. Uyemoto to see if there was anything he wanted to add.

Mr. Uyemoto stated that he wanted the Board to review the document and if there were any comments or feedback to let him know before they finalize the document.

The EO stated that once the document is finalized, she will post a link to the Hawaii Opioid website where the document can be found.

Email from Richard A. "Red" Lawhern, PhD – Prescribing

An email from Dr. Lawhern regarding his opinion about the opioid crisis was shared with the Board. The Chair stated that the article was for informational purposes only as Dr. Lawhern did not ask for a response from the Board.

Correspondence:

NABP – State News Roundup
The Board reviewed the following State News Roundups:

- 9/4/2019

Alabama Legislation Addresses Collaborative Practice, Prescription Signatures
According to the Alabama State Board of Pharmacy, one of the most monumental bills that passed the legislative session was related to collaborative practice. **House Bill (HB) 35,** known as the collaborative practice bill, received unanimous support in both the Alabama State House of Representatives (96-0) and the Alabama Senate (27-0), and was signed by Governor Kay Ivey on June 4, 2019. Now known as Alabama Act 2019-368, this legislation requires the Alabama State Board of Pharmacy and the Alabama Board of Medical Examiners to complete the rule writing procedure before Alabama Act 2019-368's effective date of October 1, 2019. Prior to the bill being passed, Alabama was one of only two states that did not have collaborative practice legislation.

HB 69, which addresses signature line requirements, also passed during the 2019 legislative session and became Alabama Act 2019-441. This legislation removes the requirement for an electronic, verbal, or e-fax prescription to contain two signature lines. This legislation also allows for a therapeutically equivalent product to be dispensed unless otherwise communicated by the prescribing physician.

Massachusetts to Only Accept Electronic Prescriptions for CS
In Massachusetts, beginning January 1, 2020, only electronic prescriptions will be accepted at pharmacies for all controlled substances (CS) in Schedules II through VI. The Massachusetts Board of Registration in Pharmacy noted that the change was implemented in order to help combat the opioid epidemic via paper-based prescriptions.

Exceptions to the new law include veterinary prescriptions, out-of-state prescriptions, instances where electronic prescribing is not available due to temporary technological or electrical failure, emergency prescriptions as defined by the commissioner of the Massachusetts Department of Public Health, and in cases where the prescriber has been issued a temporary waiver.

Ohio Board Resolution Permits Licensed TDDD to Store Naloxone at Off-Site Location

At the June 2019 State of Ohio Board of Pharmacy meeting, the Board issued a resolution to facilitate greater access to naloxone. The resolution permits a licensed terminal distributor of dangerous drugs (TDDD) to store naloxone off site for the purposes of personally furnishing the medication. For example, a local health department licensed as a TDDD can maintain a supply of naloxone at a community center to personally furnish it without the community center having to be licensed as a TDDD.

Ohio Requires Pharmacy Technicians to Obtain Criminal Background Check

All pharmacy technician applicants in Ohio are required to obtain a criminal record check by submitting fingerprints to the Ohio Bureau of Criminal Identification and Investigation and the Federal Bureau of Investigation via a WebCheck provider located in Ohio. The new rule went into effect on April 6, 2019.

More information about criminal background checks for pharmacy technicians can be found by viewing the Board's criminal records check document for pharmacy technicians.

New Legislation in Oregon Impacts the Practice of Pharmacy

The 2019 regular session of the Oregon Legislature has concluded with the passage of several bills that will affect pharmacists, pharmacy technicians, interns, and drug outlets. The following are brief summaries of selected bills that will affect Oregon State Board of Pharmacy licensees and require Board rulemaking.

- Senate Bill (SB) 9 allows pharmacists to prescribe and dispense emergency refills of insulin and insulin-related devices and supplies.
- SB 71 allows the use of sedative and analgesic medications when euthanizing animals.
- SB 698 directs the Board to adopt rules to require that prescription drugs be labeled in English and another language, upon the request of the practitioner, patient, or patient representative.
- SB 910 requires a retail or hospital pharmacy to provide written notice in a conspicuous manner of the availability of naloxone at the pharmacy.
- HB 2011 requires specified professional regulatory boards (including the Oregon State Board of Pharmacy) to require persons authorized to practice professions regulated by the boards to complete cultural competency continuing education.
- HB 2935 requires pharmacies to notify patients to whom prescription drugs are dispensed that prescription readers are available.

The Oregon State Board of Pharmacy noted that it will begin prioritizing the required responses for these statutes and other new statutes immediately. Rulemaking procedures require a public notice of proposed rulemaking, a public hearing, other stakeholder input, and final adoption by the Board.

South Carolina Updates Rules Related to Authorized Prescription Refills
On May 13, 2019, South Carolina Governor Henry McMaster signed S.463 into law. The bill states that "[u]nless a prescriber has specified on a prescription that dispensing the prescription for a maintenance medication in an initial amount followed by periodic refills is medically necessary, a pharmacist may exercise his professional judgment, in consultation with the patient, to dispense up to a ninety-day supply of medication per refill up to the total number of dosage units as authorized by the prescriber on the original prescription."

The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy notes that this law does not apply to scheduled medications, psychotherapeutic drugs, or medications that are required to be reported to the prescription monitoring program.

In addition, in consulting with the patient, the pharmacist must use readily available, existing mechanisms, such as online claim adjudication, and inform the patient of any cost changes of the proposed dispensing change. Also, if the pharmacist is presenting the patient with an option to not use an available benefit plan, then the pharmacist must inform the patient that any amounts paid would potentially not apply to the deductibles or other out-of-pocket calculations of his or her benefit plan.

This section shall not be construed to supersede or invalidate any third-party payer agreement, in whole or in part, between a third-party payer and a retail pharmacy.

At its June 2019 meeting, the Board interpreted "psychotherapeutic drugs" to be antipsychotic medications.

Virginia Updates Processes for Issuances of Licenses, Registrations, and Permits
The Virginia Board of Pharmacy is implementing a process to cease mailing out on an annual basis the hard copy licenses, registrations, and permits that bear an expiration date. A final hard copy will be issued that contains no expiration date. Licensees must still continue to renew their licenses annually or as required, submit payment, and attest to compliance with obtaining any required continuing education. More information is available at www.dhp.virginia.gov/pharmacy/newsletters/2019/PhamacyNews06262019.pdf.

Virginia Legislative Updates Address Gabapentin, Naloxone, and Other Changes Impacting the Practice of Pharmacy
The following bills, effective July 1, 2019, were passed during the 2019 Virginia General Assembly Session that impact the practice of pharmacy. For more details on these updates, see the Virginia Board of Pharmacy's August 2019 Newsletter.

Gabapentin

- House Bill (HB) 2557 classifies gabapentin as a Schedule V controlled substance (CS). More information is available at www.dhp.virginia.gov/pharmacy/newsletters/2019/PhamacyNews06072019.pdf.

Pharmaceutical Processors

- HB 1841 allows pharmaceutical processors to employ or permit to act as an agent of the pharmaceutical processor, individuals who have been convicted of certain drug and drug paraphernalia misdemeanors, except in cases where such a conviction occurred within the last five years. The bill also requires that pharmaceutical processors adopt policies for pre-employment drug screenings and regular, ongoing, and random drug screenings of employees.

Naloxone

- HB 2158 expands the list of individuals who may dispense naloxone, pursuant to a standing order, to include health care providers who provide services in hospital emergency departments and emergency medical services personnel. The bill eliminates certain requirements and establishes requirements for dispensing naloxone in an injectable formulation with a hypodermic needle or syringe.
- HB 2318 adds school nurses, local health department employees assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services to the list of individuals who may possess and administer naloxone or another opioid antagonist, provided that they have completed a training program.

Electronic Prescriptions

- HB 2559 provides certain exceptions, effective July 1, 2020, to the requirement that any prescription for a CS that contains an opioid be issued as an electronic prescription. The bill requires the licensing health regulatory board of a prescriber to grant such prescriber a waiver of the electronic prescription requirement for a period not to exceed one year. The waiver may be granted due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or under exceptional circumstances demonstrated by the prescriber. The bill provides that a dispenser is not required to verify whether one of the exceptions applies when he or she receives a non-electronic prescription for a CS containing an opioid.

Virginia Reports Updates Related to CBD and THC-A Products

The following bills were passed during the 2019 Virginia General Assembly Session related to the regulation of cannabidiol (CBD) and tetrahydrocannabinolic acid (THC-A) products. For more details on these updates, see the Virginia Board of Pharmacy's August 2019 Newsletter.

- HB 1839 contains several provisions, including a provision to conform Virginia law to the 2018 United States Farm Bill by amending the definitions of CBD oil, marijuana, and tetrahydrocannabinol (THC) to exclude industrial hemp in the possession of a registered person, hemp products, or an oil containing no more than 0.3% THC. This bill became effective on March 21, 2019.
- SB 1557 authorizes licensed physician assistants and licensed nurse practitioners to issue a written certification for use of CBD oil and THC-A oil. The bill requires the Board to promulgate regulations establishing dosage limitations, which shall require that each dispensed dose of CBD oil or THC-A oil not exceed 10 milligrams of THC. This bill became effective on July 1, 2019.

- SB 1632 provides that no school nurse employed by a local school board, person employed by a local health department who is assigned to the public school pursuant to an agreement between the local health department and the school board, or other person employed by or contracted with a local school board to deliver health-related services shall be prosecuted for possession or distribution of CBD oil or THC-A oil for storing, dispensing, or administering CBD oil or THC-A oil, in accordance with a policy adopted by the local school board, to a student who has been issued a valid written certification for the use of CBD oil or THC-A oil. The bill also provides that the Virginia Department of Health Professions, in coordination with the Virginia Department of Education, shall develop and make available to school boards, a standardized form that is to be completed by the practitioner who issues a written certification and the pharmaceutical processor that dispenses the CBD oil or THC-A oil to a student. The bill also provides that no school board shall be required to suspend or expel any student who holds a valid written certification for the use of CBD oil or THC-A oil issued by a practitioner for the possession or use of such oil in accordance with the student's individualized health plan and in compliance with a policy adopted by the school board. This bill is identical to HB 1720 and became effective on July 1, 2019.
- SB 1719 authorizes a patient, or if such patient is a minor or an incapacitated adult, such patient's parent or legal guardian, to designate an individual to act as his or her registered agent for the purposes of receiving CBD oil or THC-A oil pursuant to a valid written certification. Such a designated individual is required to register with the Board. The bill authorizes the Board to set a limit on the number of patients for whom any individual is authorized to act as a registered agent. The bill directs the Board to promulgate regulations regarding the wholesale distribution and transfer of CBD oil or THC-A oil between pharmaceutical processors. This bill also removes a requirement that a pharmaceutical processor may only dispense CBD oil or THC-A oil that is cultivated and produced on site.

Washington Board Requires Nonresident Pharmacies to Submit Inspection Reports With Substantially Equivalent Standards

During the 2019 Washington Legislative Session, the legislature passed HB 1412, an act relating to nonresident pharmacies. HB 1412 amends Revised Code of Washington (RCW) 18.64.360 to require a nonresident pharmacy to submit a copy of an inspection report that has substantially equivalent standards to those of the Washington State Pharmacy Quality Assurance Commission and was issued within the last two years of application for or renewal of a license. This change in law aligns Washington's standards for nonresident pharmacies with those of resident pharmacies, continuing the Commission's efforts to ensure patient safety.

If a state does not qualify, a pharmacy can get an inspection report done through an approved third-party inspection program. This law is effective as of July 28, 2019.

Washington's New Opioid Bill Impacts the Practice of Pharmacy

Governor Jay Inslee proposed a bill aimed at addressing many of the issues that involve the ongoing opioid epidemic. While the bill has many aspects, a couple of them will

directly or indirectly affect the practice of pharmacy in Washington.
A new section is added to RCW Chapter 18.64 to allow the partial fill of opioid prescriptions. The law expands the ability of a pharmacist to dispense an opioid overdose reversal medication pursuant to a collaborative drug therapy agreement (CDTA), standing order, or protocol. The law requires pharmacists to provide written instructions at the time of dispensing on the proper response to an overdose, including instructions for seeking immediate medical attention. It also amends RCW 70.41.480 to permit practitioners to use their professional judgment to dispense prepackaged emergency opioid overdose reversal medication to patients at risk of an opioid overdose from an emergency department. The prepackaged emergency overdose reversal medication is exempt from the labeling requirements of RCW 18.64.246 and RCW 69.41.050.
In addition, the law removes the requirement for the Washington State Pharmacy Quality Assurance Commission to approve electronic prescription communication systems. All systems must comply with state and federal laws and rules.
There are many other aspects of the law aimed at addressing and preventing opioid misuse and overdose, including a requirement that the prescriber notify the patient of the risks associated with opiates; and expanded medication-assisted treatments, education, and treatment. All parts of the law are effective as of July 28, 2019, except the one mandating electronic prescribing for all controlled substances (CS), which begins January 1, 2021. This date aligns with the federal requirement of electronic prescribing for CS prescriptions covered by Medicare Part D.

Washington to Conduct Generic Drug Feasibility Study
The Washington Department of Health (DOH) 2020-2022 biennial budget included funding for DOH to conduct a feasibility study on the ability of Washington State to manufacture generic drugs, with a focus on insulin. Washington State Pharmacy Quality Assurance Commission staff members are working with the DOH's Office of the Secretary of Health to develop this report.

USP GC <795> Nonsterile Compounding and Flavoring

The Chair asked Ms. Keefe to lead the discussion on this agenda item.

Ms. Keefe stated that the Board received a letter from Ned Milenkovich, PharmD, JD, legal representative of FLAVORx, a company that supplies custom-flavoring systems to pharmacies across the U.S. Mr. Milenkovich expressed his concern that a recent change by USP regarding nonsterile compounding, will impact the practice of pharmacy and pediatric healthcare in Hawaii. According to his letter, the USP recently indicated that they intent to classify all flavoring of conventionally manufacture medications as nonsterile compounding that would effectively eliminate flavoring as an adherence boosting service for patients and how that affects medication adherence.

She stated that Mr. Milenkovich states that 14 state boards of pharmacy have language excluding flavoring from the definition of compounding and that he recommends that the Board implement a regulation excepting the safe administration of flavoring from the definition of compounding.

Ms. Keefe stated that the pharmacy laws and rules do not define "compounding" but there are references to "compounding" throughout the practice act and that the following section may require pharmacists adhere to the USP nonsterile compounding regulations should it become effective:

§16-95-110 Grounds for revocation, suspension, refusal to renew or restore, denial, or conditioning of license or permit. (a) In addition to any other acts or conditions provided by law, the board may revoke, suspend, refuse to renew or restore, deny, or condition a license or permit for any one or more of the following acts or omissions:

(17) Failure to comply with the pharmaceutical compounding requirements found in chapters 795 (nonsterile preparations) and 797 (sterile preparations) of the United States Pharmacopeia National Formulary, as amended;

Mr. VandenBussche stated that pharmacists should adhere to USP standards.

It was the consensus of the Board that pharmacists should comply with the 795 and 797 USP standards in order to ensure quality compounded preparations and minimize harm to patients.

Vaccination of Adults by Pharmacists

The Chair asked Ms. Keefe to lead the discussion on the following email inquiry on adult vaccinations administered by pharmacists.
It was the consensus of the Board to respond to the questions as follows:

"Per HRS §461-11.4, a pharmacist may administer certain vaccines to persons aged 11 through 17 years pursuant to a valid prescription from their medical home.

Regarding vaccination of **adults** by pharmacists:
1) Are pharmacists able to prescribe vaccines for persons aged 18 years and older? **No**
2) If no, does a pharmacist administering vaccines to persons aged 18 years and older need a valid prescription? **Yes, if the drug requires a prescription**
3) Would standing orders from a physician working collaboratively with a pharmacy be acceptable in lieu of a prescription? **Yes, but a "prescription record" pursuant to HRS §461-13 shall be maintained by the pharmacy and pursuant to the following definition under HRS 461-1:**

"Practice of pharmacy" means:
(2) Performing the following procedures or functions as part of the care provided by and in concurrence with a "health care facility" and "health care service" as defined in section 323D-2, or a "pharmacy" or a licensed physician or a licensed advanced practice registered nurse with prescriptive authority, or a

"managed care plan" as defined in section 432E-1, in accordance with policies, procedures, or protocols developed collaboratively by health professionals, including physicians and surgeons, pharmacists, and registered nurses, and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols:

(E) Administering: (i) Immunizations orally, by injection, or by intranasal delivery, to persons eighteen years of age or older by a pharmacist having 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 of pharmacy;

4) Would you be able to provide the appropriate HRS/HAR references pertaining to the questions above?" **Yes, see above.**

Prescription refill Consolidation

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

"I am a pharmacist that receives HI prescriptions and had a question about your state's specific regulations. If an rx is received written for #30, 2 refills, is filling all #90 at one time allowable? Are there any exemptions/stipulations to this? (non-control, maintenance med, etc)"

Ms. Keefe said that the pharmacist should only dispense 30 but can check with the prescriber if okay to dispense all 90 pills.

The EO stated that this issue was previously discussed by the Board and at that time the Board determined that it was okay as long as it was covered by the insurance or paid for out-of-pocket.

Mr. VandenBussche stated that some insurance carriers will audit and may not pay for more than 30 even if the prescription was written for 30 and 2 refills.

After further discussion, it was the consensus of the Board that in this scenario, dispensing a total of 90 pills if the prescription was written for 30 with 2 refills, is not prohibited in the pharmacy laws or rules.

The Board further clarified that this does not apply to prescriptions for controlled substances and also referred this matter to the Pharmacy Working Group.

Closed Door Pharmacy – Waiver of Requirements, i.e. refrigerator, sink, balances, etc.

The Chair asked Ms. Tokumaru to lead the discussion on the following email inquiry:

"Are there any waivers or variances from requirements available to pharmacies that are not open to the public and only provide products in their original, sealed packaging? For example, our pharmacy will not mix or compound, will not store anything refrigerated, will not measure any medications, nor distribute controlled substances.
We would have no use for:

- Refrigerator
- Sink
- Balances
- Bottles or vials
- Graduates
- Sewage drain

Please advise if there is a process to follow to request waivers of these requirements upon application."

Ms. Tokumaru referred to HAR §16-95-26(a) Pharmacy permit, and that this section does not authorize the Board to waive any of the requirements or allow for variances. This section requirements including a list the technical equipment and supplies that a pharmacy shall possess as:

(b) The application shall include:

(1) A floor plan of the prescription area which shall diagram the space and location of fixtures such as counters, tables, drawers, shelves, storage cabinets including a locked cabinet, library, sink with hot and cold water, proper sewage outlet, and refrigeration storage equipment;

(7) An attestation that, at a minimum, the pharmacy possesses the following technical equipment and supplies: (A) Class A prescription balance or a balance of greater sensitivity and appropriate weights;
(B) Mortar and pestle (glass or porcelain);
(C) Refrigerator;
(D) Bottles and vials of assorted sizes;
(E) Graduates or other similar measuring device; and
(F) Prescription labels.

Ms. Keefe said that she is open to allowing for variances.

Mr. VandenBussche said he would not waive any requirements.

After further discussion, it was the consensus of the Board that they do not have the authority to waive any of the requirements that a pharmacy shall possess pursuant to HAR §16-95-26. The Board also referred this matter to the Pharmacy Working Group for further discussion.

Remote Pharmacy Data Entry and Pharmacist Services

The Chair Ms. Tokumaru to lead the discussion on the following email inquiry:

"We would like to inquire about providing remote pharmacy data entry and remote pharmacist services in your state. We are based in Texas and would like to know what licensure requirements you would need for us to be able to help independent pharmacies in your state."

The EO followed up with a question: Who and what would be the activity and from where?

Their response: We would be performing **processing only** from our pharmacy in Texas and medications would be dispensed by a pharmacy in Hawaii.

Ms. Tokumaru said that if they are performing "processing" prescriptions in an out-of-state pharmacy, then they would be required to obtain a Hawaii miscellaneous permit as an out-of-stat pharmacy.

The EO asked if the pharmacists working in the out-of-state pharmacy had to be licensed as a pharmacist in Hawaii because that is what the Board previously determined, because the pharmacists is performing activity under the definition of "Practice of pharmacy", although not dispensing any drugs into this State, the pharmacists would have to be licensed as well. She also stated that the Board also previously determined that if an out-of-state pharmacist was performing remote order entry for a Hawaii facility from a location other than a licensed/permitted pharmacy, i.e. office or from home, then the pharmacist would only be required to be licensed as a Hawaii pharmacist.
Ms. Cross referred to HAR 16-95-79 Supervision by a registered pharmacist., and had concerns with oversight of the pharmacist in that scenario.

After further discussion, the Board was unable to come to a consensus and wanted more time to research this issue.

This agenda item was deferred to the Pharmacy Working Group.

Consumer Notifications on Safety Labeling Changes

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

"I represent a consumer-focused nonprofit formed to make the medication experience safer for consumers living in America.

The purpose of my email is to confirm with you, or a member of your team, the process for alerting Hawaii pharmacy customers of new safety labeling changes that are regularly released on the FDA's website (https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/).

After recently contacting the FDA about this, the representatives from their Center for Drug Evaluation and Research (CDER) redirected me to contact individual state boards of Pharmacy and Medicine who, according to CDER, regulate the practice of consumer notifications pertaining to drug safety labeling updates.

Please share details on this consumer notification process."

Mr. VandenBussche referred to sections in HRS Chapter 328, under the Department of Health regarding recalls of drugs and adulterated and impure drugs in HRS §328-17.5 and §328-22 but stated that there is no mandate to notify a consumer of any labeling changes.

The Board agreed with Mr. VandenBussche.

The Board also referred this topic for discussion to the to the Pharmacy Working Group.

License Requirements for Biologics License Holder and Affiliate Companies

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

"I have a nonresident facility that holds a Biologics License from the FDA and a manufacturing license in their home state. They receive patient-specific blood cells, genetically re-engineer them to allow them to recognize and kill cancer cells, and the therapy is then drop-shipped by the manufacturer to the patient's health care team for infusion. This therapy is intended for use in a clinical setting.

Additionally, the manufacturer's parent company will maintain ownership of the product. The parent company may also drop-ship the product into your state to the patient's health care team.

- How should the manufacturer be licensed in your state?
- How should the parent company be licensed if they take ownership of the product and drop-ship it into your state?
- How should the parent company be licensed if they take ownership of the product but do not drop-ship it into your state?"

Mr. VandenBussche stated that based on the email, it doesn't appear that they are dispensing directly to the patient but acting more like a distributor and that Hawaii's laws and rules only require an in-state wholesale distributor to be licensed.

The Board agreed with Mr. VandenBussche.

Applications: **Ratification Lists**

Upon a motion by the Vice Chair, seconded by Mr. VandenBussche, it was voted on and unanimously carried to approve the ratification list(s).

Executive Session: At 10:25 a.m., upon a motion by Mr. VandenBussche, 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(1) and (4), ""To consider and evaluate personal information relating to individuals applying for licensure;" and "To consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities;", Board will vote in Open Meeting.)

At 10:27 a.m., upon a motion by Mr. VandenBussche, seconded by Ms. Keefe, it was voted on and unanimously carried to move out of executive session.

RICO Pharmacy Advisory Committee: Upon a motion by Ms. Keefe seconded by Mr. VandenBussche, it was voted on and unanimously carried to approve the additions and deletions made to the RICO Pharmacy Advisory Committee lists.

Next Meeting: The Chair announced the next Board meeting and asked if everyone was able to attend.

Thursday, October 17, 2019
9:00 a.m.
Queen Liliuokalani Conference Room, First Floor
King Kalakaua Building
335 Merchant Street
Honolulu, Hawaii 96813

Ms. Tokumaru and Mr. VandenBussche asked to be excused.

Adjournment: There being no further business to discuss, the meeting was adjourned at 10:29 a.m.

Taken and recorded by:

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

9/20/19

[X] Minutes approved as is.

[ ] Minutes approved with changes; see minutes of _____

Board of Pharmacy Ratification List for September 19, 2019

Pharmacist (PH)

PH	4452	MELISSA M S KUSAKA
PH	4453	JEFFREY M CRAMER
PH	4455	KRISTIN A OKAMURA
PH	4456	STEPHANIE M SEKIMURA
PH	4457	HEATHER A KAM
PH	4458	AMBER S MASULIT
PH	4459	HALLIE G SKORDALLOS
PH	4460	JACQUELYN GOLDBERG
PH	4461	KEVIN LEI
PH	4462	SABINE C SONOMURA
PH	4463	KELSEY L NOETZELMANN
PH	4464	HOLLY S MORITA
PH	4465	FAITH E R HICKS
PH	4466	JOHNNY R GARCIA JR
PH	4467	BRADLEY S WEAVER

Pharmacy (PHY)

PHY	930	98-1247 KAAHUMANU ST	AIEA	HI	96701	5 MINUTE PHARMACY PEARL CITY, LLC

Miscellaneous Permit (PMP)

PMP	1631	1451 CENTER CROSSING RD	LAS VEGAS	NV	89144	CENTRAL RX SERVICES, LLC
PMP	1632	12 MOUNTFORT ST UNIT 2	PORTLAND	ME	4101	VFC PHARMACY #101, LLC
PMP	1633	4300 N UNIVERSITY DR C101	LAUDERHILL	FL	33351	PATHEMA RX LLC
PMP	1634	991 AVIATION PKWY	MORRISVILLE	NC	57560	SENDERRA RX PARTNERS, LLC
PMP	1636	3057 KOAPAKA ST	HONOLULU	HI	96819	R.C.P.S INC

Whole Sale Distributors (PWD)

PWD	189	694 KOMOHANA ST	KAPOLEI	HI	96707	HAWAII TRANSFER CO, LTD