

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

MINUTES OF MEETING

Date: Thursday, March 18, 2021

Time: 9:00 a.m.

Place: Virtual Videoconference Meeting – Zoom Webinar

Members Present: Alanna Isobe, Chair
Patrick Adams, Pharmacist
Catalina Cross, Public Member
Mary Jo Keefe, RPh, Pharmacist
Sheri Tokumaru, Pharmacist
Kenneth VandenBussche, RPh, BCACP, Pharmacist

Members Excused: Julie Takishima-Lacasa, PhD, Public Member – Vice Chair

Staff Present: Lee Ann Teshima, Executive Officer ("EO")
James Skizewski, Executive Officer
Shari Wong, Deputy Attorney General ("DAG")
Rochelle Araki, Secretary
Stephanie Karger, Tech Support Staff
Christine V. Dela Cruz, Tech Support Staff

Guests: Kellie Noguchi
Lauren Paul
Stacy Pi
Wendy Iwasaki
Gary Hadley
Greg Edwards
Tiffany Yajima
Jerry Hashimoto
Jessica Adams
Diane Straub
Pua Akana
Gail Elliott
Cherylynn Cheng
Scott
Reece

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").

A short video regarding virtual meetings was played for the attendees and the Chair provided information on internet and phone access for today's virtual meeting.

The Chair then took roll call to establish quorum.

The Chair excused the Vice Chair from today's meeting and called the meeting to order at 9:04.

All motions requiring a vote were conducted by roll call.

Chair's Report:

Announcements

The Chair reported she had no announcements.

Approval of Minutes of the January 21, 2021 Meeting

The Chair asked if there were any corrections or discussion of the January 21, 2021 meeting minutes.

There being no corrections/amendments, upon a motion by Ms. Cross, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the minutes as circulated.

Executive Officer's Report:

2021 Legislative Session

The EO provided a brief status report on the following bills:

- HB 306, HD1/SB 976, SD2 – Relating to Health;
- SB 1191, SD1 – Relating to Electronic Prescription Accountability System;
- SB 1192, SD1 – Relating to Electronic Prescription Accountability System;
- SB 602, SD2 – Relating to Pharmacy Benefit Managers; and
- SB 975, SD1 – Relating to Pharmacy Audits

The EO asked if the members had any questions.

There were none.

The Chair asked if anyone attending wanted to address the Board to raise their hand.

Staff reported that no one raised their hand.

COVID-19 Vaccine

The EO reported that the Department of Health requested a list of Hawaii pharmacies so that they could reach out to them in regard to the COVID vaccine. She also mentioned that pharmacies/pharmacist can visit the DOH web site for the latest in the efforts by the State regarding the COVID vaccine.

The Chair reported that the immunization registry may be up and running and that pharmacists who administer vaccines to minors should double check as it was previously not in service.

Correspondence:

FDA's Compounding MOU – Concerns from the Alliance for Natural Health

The Chair reported that the Board's office received an email from the Alliance for Natural Health expressing concerns with the FDA's compounding MOU.

Concerns raised by the ANH:

- FDA will gain oversight of certain aspects of traditional dispensing, which has long been the purview of state boards of pharmacy, NOT a federal agency;
- FDA seriously underestimated the administrative burden on state boards that sign the MOU – the costs of staffing, reporting, etc. required of states in order to comply. The MOU creates, in effect, an unfunded mandate on states that sign; and
- For states that don't sign, compounding pharmacies will be limited to shipping NO MORE THAN 5% of compounded preparations out of state. For many, many compounders, that 5% cap will impede countless patients from getting their medications. It could well put some compounders out of business and result in lost jobs (and tax revenue) in your state.

What happens if FDA is unwilling to make changes? I'll be asking you to sign the MOU because that 5% cap on out-of-state shipments that will be imposed if you don't sign will be the death knell for many compounders. I do understand your role as a regulatory agency is to protect consumers. But when pharmacies can't stay in business, patients in-state and out-of-state can't access the medications they need.

The ANH is a nonprofit organization representing 1 million consumers and healthcare practitioners in the U.S. and protects the right of natural health practitioners to practice and the right of consumers to choose the healthcare options and treatment modalities.

The Chair asked if there was anyone attending wishing to address the Board on this agenda item.

Staff reported that no one raised their hand.

Allowable Quantity to be Dispensed for Controlled and Non-controlled Substances

The Chair reported that the Board received two inquiries in regard to dispensing, one is for non-controlled substances and the other is for controlled substances.

"I have a question about the quantity that can be dispensed for a non-controlled medication. If we get a prescription for Losartan 50mg #30 with 1+5 refills (it may be a new or ePrescribed Rx), are we allowed to dispense #90 tablets at a time with 1 refill of #90? Do we need to have the patient or prescriber approval to change the quantity?"

The Chair stated that in her research, in September 2019, the Board had a similar inquiry and determined that HRS 461 did not allow nor prohibit a pharmacy from dispensing the prescribed amount and refills at once and that she recalls how PBMs were questioning the dispensed amount that included the refills claiming that it was illegal since the pharmacy laws and rules did not specifically allow it.

Mr. Adams also recalled that the Board had this discussion 10 years ago and determined that this practice of filling a prescription, including all refills at once was illegal and also stated that PBMs should not be dictating pharmacy practice as this is an insurance restriction but the Board's concern should be access to care for the patient.

Ms. Cross stated that from a consumer's point of view, her concern was with the impact on the patient not having access to their medications.

The EO clarified so if a pharmacist is presented with a prescription for 30 pills with 2 refills, the pharmacist may dispense 90 pills as long as the pharmacist gets authorization from the prescriber?

Mr. Adams said that there are instances when he did just that and received pushback from the prescriber as to why he/she was being asked this when the prescription was written for a total of 90 pills.

The Chair stated that there are some instances, depending on the drug, for which she would not dispense the prescribed amount and refills at once.

Mr. VandenBussche stated that since it is not specifically addressed in the pharmacy laws and rules then it is okay to dispense the full amount.

The Chair asked if there was anyone attending wishing to address the Board on this agenda item.

Staff reported that Greg Edwards raised his hand. Mr. Edwards was promoted to a panelist.

Mr. Edwards wanted to note that HRS 328 does include a section regarding a "valid" prescription and refills but does not recall if it specifically allows or prohibits a pharmacist from dispensing the drug prescribed including refills. He did caution that this could also apply to instances where a pharmacy may not have enough in stock to fill a 30-day prescription.

There being no further discussion, the Chair asked for a motion.

Upon a motion by Mr. Adams, seconded by Ms. Keefe it was voted on and unanimously carried to inform the inquirer that the Board's laws and rules do not specifically address, allow nor prohibit, a pharmacist to dispense more than one or multiple refills at one time.

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 on the Board.

The Chair announced that the second part to this similar request was in regard to refills for a controlled substance.

The EO reported that she did not see anyone attending from the Narcotics Enforcement Division ("NED") and asked the Board if she could refer this inquiry to the NED.

The Board agreed.

The Chair announced that the next agenda item under Correspondence is regarding miscellaneous permits for an out-of-state pharmacy providing medication therapy management and asked if there was anyone attending wishing to address the Board on this agenda item.

Staff reported that no one raised their hand.

Miscellaneous Permit Required for Out-of-state Pharmacy Providing Medication Therapy Management

The Chair reported that the Board received an inquiry from an out-of-state pharmacy inquiring if a non-dispensing pharmacy must obtain a non-dispensing pharmacy license in Minnesota that is a "limited service" pharmacy license that would permit the pharmacy to provide medication therapy management services to Minnesota patients and wanted to know if Hawaii would issue a nonresident pharmacy license to pharmacies that only provide medication therapy management services to patients in our State.

She stated that in the past the Board would require a miscellaneous permit for the pharmacy and require that the pharmacist hold a Hawaii pharmacist license.

Mr. Adams said that he acknowledges the Board's previous determination but does not agree with the requirements for a miscellaneous permit as an out-of-state pharmacy to be allowed to dispense drugs into this State and that all that is required is a license verification.

Mr. Adam's position was duly noted by the EO that this may be something the Board will have to consider that will require a law change.

The EO also stated that if the Board is going to require that this out-of-state pharmacy, who may have or will be applying for a restricted or limited pharmacy license in their home state to only provide medication therapy management and not dispense any drugs, would this entity meet the requirements for a miscellaneous permit and how would we monitor.

Ms. Keefe said that perhaps a miscellaneous permit is not required in this case, but that the pharmacist(s) performing the medication therapy management must hold a Hawaii pharmacist license.

The Chair agreed adding that in the past, there were inquiries for an out-of-state pharmacist to provide remote order entry from a place other than the pharmacy and the Board required that the pharmacist obtain a Hawaii pharmacist license.

There being no further discussion, upon a motion by Ms. Keefe, seconded by Mr. VandenBussche, it was voted on and unanimously carried to inform the inquirer that a Hawaii miscellaneous permit may not be required if not dispensing drugs into this State but that the out-of-state pharmacist must obtain a Hawaii pharmacist license so that he/she is familiar with Hawaii drugs laws, in order to perform medication therapy management for patients residing in this State.

The Chair announced that the next agenda item under correspondence was pharmacy remote locations for dispensing via telehealth and asked if anyone attending wanted to address the Board on this agenda item.

Staff reported that Scott raised his hand. Scott Kim was elevated to panelist status.

Pharmacy Remote Locations for Dispensing via Telehealth

Mr. Kim thanked the Board and explained that they specialize in behavior health, but due to COVID and tele-psychiatry, patients do not want to leave their home to come to the pharmacy to receive their shots. He mentioned that 5-Minute pharmacy has a mobile pharmacy/pharmacist, but it is not feasible for them to hire a nurse or hire a pharmacist.

The EO asked for clarification as to what he was asking the Board.

Mr. Kim responded that they want the drugs to be administered to the patient at the patient's home.

The Chair clarified that in the email inquiry, they referred to pharmacy technicians and asked if he was asking if a pharmacy technician could go to the patient's home to administer the drug.

Mr. Kim said yes.

The Chair informed Scott that pharmacy technicians cannot administer drugs and that their scope of practice is defined in HAR Chapter 95 and that they require supervision.

The EO stated that the HHS Prep Act allows pharmacy technicians to administer vaccines.

The Chair stated that these drugs are not "vaccines".

Mr. Kim asked if a nurse could administer the drugs to the patient at their home.

The EO asked how that would work because once the drug leaves the pharmacy it is considered dispensed and asked would the nurse work for the pharmacy.

Mr. Kim stated that the nurse works for a case management company, would pick up the drug from the pharmacy, take to the patient's home and administer the drug.

The EO stated that as the EO for the Board of Nursing, she is familiar with the nurse's scope of practice and said that a nurse can administer drugs as part of their scope of practice and carryout the orders of the licensed healthcare professional.

The Chair clarified that a nurse can administer the drug to the patient at their home but a pharmacy technician cannot.

Mr. Kim acknowledged the Chair summation.

The EO also wanted to clarify that the "nurse" is a Registered Nurse or Licensed Practical Nurse.

Mr. Kim said RN.

The Chair asked if there was any further discussion on this agenda item.

There being none, she announced that next agenda item is applications and asked if anyone attending wishes to address the Board on this agenda item.

Staff reported that no one raised their hand.

The Chair called for a motion to move into executive session.

Executive Session:

At 9:57 a.m., upon a motion by Ms. Keefe, seconded by Mr. Adams, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-5(a) (1) and (4), "To consider and evaluate personal information relating to individuals applying for pharmacy licensure," and, "To consult with the board's attorney on questions and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities".

At 10:04 a.m., the Board moved out of executive session.

Applications:

Ratification Lists

The Chair moved to approve the ratification list(s) for pharmacists, pharmacies, miscellaneous permits and pharmacy/miscellaneous closures, change of PIC and relocations. It was seconded by Mr. Adams, voted on and unanimously carried.

Applications

Pharmacist

Joe Y. Vuong

The Chair asked for a motion in regard to the application for pharmacist license for Joe Y. Vuong.

Ms. Keefe moved to approve the application. It was seconded by Mr. Adams, voted on and unanimously carried.

Miscellaneous Permit

Caremark Florida Specialty Pharmacy, LLC, dba CVS/Specialty

The Chair asked for a motion in regard to the application for Caremark Florida Specialty Pharmacy, LLC, dba CVS/Specialty.

Mr. Adams moved to approve the application. It was seconded by Ms. Keefe, voted on and unanimously carried.

The Chair announced that she will recess the meeting pursuant to Chapter 91, HRS to discuss adjudicatory matter(s) and asked if anyone attending wanted to provide testimony on any of the adjudicatory matters.

Staff reported that no raised their hand.

Chapter 91, HRS
Adjudicatory Matters:

At 10:08 a.m., the Chair called for a recess of the meeting to discuss and deliberate on the following adjudicatory matters.

Upon a motion by Mr. Adams, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the following Board's Final Order:

In the Matter of the Pharmacist's License of **Robert Andonian, PHA-2020-69-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1";

Following the Board's review, deliberation, and decision, in these matters, pursuant to Chapter 91, HRS, the Chair announced that the Board was reconvening its scheduled meeting at 10:21 a.m.

Next Meeting:

The Chair announced that the next meeting is as follows and asked if the members are able to attend. Ms. Cross said she will not be able to attend.

April 15, 2021
9:00 a.m.
Virtual

Adjournment:

There being no further business to discuss, the Chair adjourned the meeting at 10:22 a.m.

Taken by:

/s/ Lee Ann Teshima
Lee Ann Teshima
Executive Officer

☒ Minutes approved as is.

☐ Minutes approved with changes; see minutes of _____