

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

MINUTES OF MEETING

Date: Thursday, January 21, 2021

Time: 9:00 a.m.

Place: Virtual Videoconference Meeting – Zoom Webinar

Members Present: Alanna Isobe, Chair
Catalina Cross, Public Member
Mary Jo Keefe, RPh, Pharmacist
Sheri Tokumaru, Pharmacist

Members Excused: Julie Takishima-Lacasa, PhD, Public Member – Vice Chair
Patrick Adams, Pharmacist
Kenneth VandenBussche, RPh, BCACP, Pharmacist

Staff Present: Lee Ann Teshima, Executive Officer ("EO")
Shari Wong, Deputy Attorney General ("DAG")
Rochelle Araki, Secretary
Rise Doi, Executive Officer, Tech Support Staff
Faith Nishimura, Secretary, Tech Support Staff

Guests: Jared Redulla
Brenda Fletcher
Tiffany Yajima
Cherylynn Cheng
Amy Este
Gavin Sanjume
Pua Akana
Mike Hartsock
Kellie Noguchi
Erik Abe
Chelsea Tadena
Cory Lehano
Carolyn Ma
Lauren Paul
Jessica Adams
Lorri Walmsley
Jessica Adams (Regulatory Affairs)
Wendy Iwasaki
Cindy Figuerres
Brande Ribillia

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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 Vice Chair, Mr. Adams and Mr. VandenBussche were excused, four members being present, quorum was established and the Chair called the meeting to order at 9:05 a.m.

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 December 17, 2020 Meeting

The Chair asked if there were any corrections or discussion of the December 17, 2020 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

Draft of Bill – Telepharmacy; medically underserved areas – Erik Abe, Public Affairs and Policy Director, Hawaii Primary Care Association

The EO stated that before she goes through the proposed bill for telepharmacy, the next agenda item regarding the pilot project application has to do with telepharmacy.

She asked if there was any discussion by the Board.

There was no further discussion on this agenda item. This agenda item is related to the legislation and would prefer that the Board discuss the proposed pilot project before discussing the proposed legislation.

Pilot Project Application

Telepharmacy for Lanai Community Health Center (LCHC)

The Chair asked if there was anyone in attendance wishing to address the Board/testify on this agenda item.

Staff reported that Mr. Abe raised his hand.

The Chair allowed Mr. Abe to address the Board.

Mr. Abe thanked the Board for this opportunity and explained that LCHC, a federally funded facility applying for a pharmacy permit is requesting a pilot project; to allow a pharmacist on a neighbor island to be the pharmacist overseeing the pharmacy activities at the LCHC via telepharmacy.

He explained that this would be a 340B pharmacy that would allow residents of Lanai to obtain their prescription drugs more timely. Currently, residents are obtaining their prescription drugs from a neighbor island pharmacy that can take up to 1-3 days; and that although there is one pharmacy on Lanai, that pharmacy is not a participating 340B pharmacy.

Currently, because there is no pharmacist on site at LCHC, they are not able to seek insurance reimbursement for the medications that are dispensed. He also stated that physician dispensed drugs only cover a few days. With this practice, LCHC is not able to sustain the other health care services that they are providing for the residents of Lanai.

Ms. Keefe asked why it is only 6 months for the pilot project.

The EO explained that if the Board approves this pilot project, LCHC will be providing a report of the project to see if prescription drugs could be dispensed safely via telepharmacy and report back to the Board around July or August which will allow time for discussion to determine if legislation should be introduced for the 2022 session to amend the pharmacy practice act to allow for telepharmacy.

Staff stated that Cory Lehano raised his hand and the Chair allowed him to address the Board.

Mr. Lehano introduced himself as the pharmacist on Maui who will be the pharmacist for LCHC.

He reiterated the same sentiments as Mr. Abe as for why he signed on to the project – a more timely delivery of medications, the ability to interface with the patients for more adherence.

The EO asked Mr. Lehano who will be responsible at the LCHC in dispensing the medications and what kind of oversight will be utilized.

Mr. Lehano explained that they are still working on the logistics, but should the Board approve, there would be training as well as technology, i.e. video to allow the technician and patients to consult with the pharmacist.

After further discussion, upon a motion by Ms. Keefe, seconded by Ms. Cross, it was voted on and unanimously carried to approve the proposed pilot project for LCHC.

The EO asked Mr. Abe if they would still be moving forward with the proposed legislation for telepharmacy.

Mr. Abe replied that he feels that this legislation is premature and will be requesting the legislators withdraw this legislation for the 2021 session. He also thanked the Board for this opportunity as well as Mr. Redulla, Administrator for the Narcotics Enforcement Division, Department of Public Safety for his assistance in clarifying the controlled substances aspect and Mr. Kim, Department of Health.

COVID-19 Vaccine

The EO reported that for the following agenda items, they are being provided as information only and all the information is available online at the CDC or State of Hawaii DOH web sites. She also stated that these recommendations and reports are constantly changing so if interested, individuals should review the most current information online.

[CDC Recommendations and Guidelines for Vaccine Storage and Handling Resources and Vaccine Storage and Handling Toolkit](#)

[State of Hawaii COVID-19 Vaccination Plan Executive Summary \(10/16/2020\)](#)

[CDC COVID-19 Vaccination Playbook Supplement #1 \(11/25/2020\)](#)

The Chair asked if there was any questions or discussion by the Board members.

There was none.

The Chair asked if there was anyone attending who wishes to address the Board/testify on this agenda item.

Staff reported that no one raised their hand.

Correspondence

[Governor's Emergency Proclamations Relating to HRS 329](#)

The Chair stated that as you may recall, we received a request at the last Board meeting from Telijah Patterson who wanted to bring awareness to Hawaii pharmacists of Governor Ige's emergency proclamation(s) that authorizes out-of-state physicians to both treat and prescribe controlled substances to patients in Hawaii and that she has been denied her prescription because pharmacies in Hawaii are not aware of the Governor's emergency proclamation.

Unfortunately, this was not a specific agenda item and would be beneficial for the pharmacy community, so this item was placed on the agenda for today's meeting.

So, as a friendly reminder, the Governor's 17th emergency proclamation includes "waivers" to HRS Chapter 329, the Uniform Controlled Substances Act that includes the following:

Sections 329-32(a), 329-33(a), 329-38.2, HRS, uniform controlled substances act, and related administrative rules, to the extent necessary to allow out-of-state physicians and nurses to dispense (including prescribing and administering) controlled substances without having to register in Hawai'i, as contemplated in the United States Drug Enforcement Administration's (DEA) COVID-19 Policy Concerning Separate Registration Across State Lines dated March 25, 2020. Such physicians or nurses must maintain active registration in at least one state and be authorized under that state's law to dispense controlled substances. Such doctors or nurses must also otherwise comply with state laws, including those related to controlled substances.

Section 329-32(e), HRS, registration requirements, and related administrative rules, for the limited purpose of allowing the offsite dispensing of necessary take-home doses of medication for medication assisted treatment by an opioid treatment program (OTP) authorized under Section 329-40, HRS, without obtaining a separate state registration, as contemplated in the DEA's COVID-19 policy concerning DEA narcotic treatment programs dated April 7, 2020.

Section 329-38(a)(1)(C), HRS, prescriptions, and related administrative rules, only to the extent necessary to allow a facsimile, photograph, or scan of a written prescription to be delivered to the dispensing pharmacist within 15 days of an emergency oral prescription, as contemplated in the DEA's COVID-19 guidance concerning the issuance of oral schedule II prescriptions dated March 27, 2020.

Section 329-38(d), HRS, prescriptions, for the limited purpose and to the extent necessary to allow prescribing practitioners to authorize subsequent prescriptions for opioids and benzodiazepines through telephone consultation without an in-person consultation every 90 days. Such practitioners must otherwise comply with all other requirements of Section 329-38(d).

Section 329-40 (b)(7), HRS, methadone treatment program, and related administrative rules, for the limited purpose of permitting the issuance of up to 28 doses of methadone to qualified patients in an opioid treatment program in accordance with the United States Substance Abuse and Mental Health Services Administration's Opioid Treatment Program Guidance, updated on March 19, 2020.

Section 329-41(a)(8), HRS, prohibited acts B penalties, for the sole and limited purpose of enabling authorized physicians practicing telehealth as provided in section 453-1.3, HRS, to issue prescriptions for controlled substances. Such physicians must otherwise comply with all other requirements of Chapter 329, HRS.

Section 329-101(b), HRS, reporting of dispensation of controlled substances; electronic prescription accountability system; requirements; penalty, to the extent necessary to enable the Department of Public Safety to issue State controlled substance registrations prior to an applicant's registration with the electronic prescription accountability system.

These waivers will continue through February 14, 2021, unless terminated or superseded by a separate proclamation, whichever shall occur first and any questions regarding HRS Chapter 329, including these waivers should be directed to the Department of Public Safety, Narcotics Enforcement Division.

The Chair asked if there was anyone attending who wishes to address the Board/testify on this agenda item.

Staff reported that Mr. Hartsock raised his hand.

The Chair allowed Mr. Hartsock to address the Board.

Mr. Hartsock stated that pre-COVID, state law provides that an out of state controlled substance prescription, issued by an out of state prescriber, is not valid in Hawaii. The suspension of the laws previously noted by the Chair in the Governor's proclamation due to COVID-19, including but not limited to filling an out of state controlled substances prescription that is issued by an out of state prescriber permit pharmacists/pharmacies, if certain conditions are met, to then potentially, a pharmacist in Hawaii may consider filling that prescription.

And although the emergency exemptions might allow a Hawaii pharmacist to consider filling an out of state controlled substances prescription, I am unaware of any mandate that a pharmacist must fill a controlled substances prescription. As we have spoken substantially about in the past, a pharmacist has a corresponding responsibility under the Hawaii Uniform Controlled Substances Act when considering to fill a controlled substance prescription. Under the principle of corresponding responsibility, a pharmacist must use their independent professional judgement in filling a controlled substance prescription. Consequently, there are a multitude of things that a pharmacist must consider when using their independent judgment to fill a prescription. They include, but are not limited to: the law, company policies, ability or inability to contact the prescriber, understanding of the emergency proclamations and any exemptions, and the pharmacist's own personal comfort level with filling out of state controlled substances prescriptions that are issued by out of state prescribers. All of these things enter into a Hawaii pharmacist's decision making when filling a controlled substance prescription, including those issued by out of state prescribers.

Staff reported that Lauren Paul is raising her hand.

The Chair allowed Ms. Paul to address the Board.

Ms. Paul introduced herself as with CVS Health and asked if there was a difference between an out-of-state vs. an in-state prescription?

The DAG informed Ms. Paul to consult with her legal counsel.

The EO added that again, if anyone had any questions about the suspension of sections in HRS Chapter 329, to contact the NED.

Staff reported that Ms. Yajima raised her hand, however, we were unable to establish audio with Ms. Yajima and she eventually withdrew her request to address the Board.

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

Staff reported that no one raised their hand.

The Chair announced that the next agenda item under correspondence is in regard to HRS 457J Midwives.

HRS 457J, Midwives and Authorization to Prescribe and Administer Certain Legend Drugs.

The Chair stated that this is to bring to your attention, if you are not aware that HRS 457J now requires a license for midwives practicing in this State. Licensed midwives may purchase and administer non-controlled legend drugs and devices that are used in pregnancy, birth, postpartum care, newborn care, or resuscitation, and that are deemed integral to providing care to the public including legend drugs limited for:

- (1) Neonatal use to prophylactic ophthalmic medications, vitamin K, epinephrine for neonatal resuscitation per neonatal resuscitation guidelines, and oxygen; and
- (2) Maternal use to antibiotics for Group B Streptococcal antibiotic prophylaxis per guidelines adopted by the Centers for Disease Control and Prevention, postpartum antihemorrhagics, Rho(D) immune globulin, epinephrine for anaphylactic reaction to an administered medication, intravenous fluids, amino amide local anesthetic, and oxygen.

And legend devices limited to devices for:

- (1) Injection of medications;
- (2) The administration of intravenous fluids;
- (3) Adult and infant resuscitation;
- (4) Rupturing amniotic membranes;
- (5) Repairing vaginal tears; and
- (6) Postpartum hemorrhage.

HRS 457J also states that "A pharmacist who dispenses drugs and devices to a midwife as authorized by this section and in conformity with chapter 461 is not liable for any adverse reactions caused by the midwife's administration of legend drugs and devices."

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.

The Chair asked if there was any discussion by the Board.

There was no further discussion on this agenda item.

The Chair announced that the next agenda item the Board will be moving into executive session to discuss applications and then she will recess the meeting to discuss adjudicatory matters and that the next Board meeting will be held virtually on February 18, 2021.

The Chair asked if there was anyone attending wishing to address the Board or testify on the application.

Staff reported that no one raised their hand.

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

Executive Session:

At 9:54 a.m., upon a motion by Ms. Keefe, seconded by Ms. Tokumaru, 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 9:58 a.m., upon a motion by Ms. Keefe, seconded by Ms. Cross, it was voted on and unanimously carried to move out of executive session.

Applications:

Ratification Lists

The Chair moved to approve the ratification list(s) and asked for a second. Ms. Keefe seconded and it was voted on and unanimously carried to approve the ratification list(s).

Applications

Miscellaneous Permit

Ms. Keefe noted that based on the testimony at the December meeting that the applicant's attorney stated that there is a new compliance officer and that they are aware of filing any reports of disciplinary action pursuant to HRS 461 and 436B, including timely reporting in 30 days, she moved to approve the request for reconsideration and approve the application. It was seconded by Ms. Cross. It was voted on and unanimously carried to approve the reconsideration request and the application for the following miscellaneous permit application:

Drug Depot, LLC dba APS Pharmacy

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 10:03 a.m., the Chair called for a recess of the meeting to discuss and deliberate on the following adjudicatory matters.

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

In the Matter of the Miscellaneous Permit of **Direct Success, Inc., dba Direct Success Pharmacy Dept.; PHA 2020-180-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1";

In the Matter of the Miscellaneous Permit of **Florida Discount Drugs, Inc., dba Taylors Pharmacy; PHA 2020-81-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1" and "2";

In the Matter of the Miscellaneous Permit of **USRC Pharmacy, LLC; PHA 2020-148-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"; Declaration of a Representative of USRC Pharmacy LLC;

In the Matter of the Miscellaneous Permit of **Wellness Pharmacy, Inc., dba Wellness Health and Pharmaceuticals; PHA 2020-105-L**; Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order;

In the Matter of the Miscellaneous Permit of **Appling Enterprises LLC, dba Denton Prescription Shop; PHA 2019-142-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order;

In the Matter of the Miscellaneous Permit of **Diabetes Management & Supplies; PHA 2020-147-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"; Declaration of a Representative of Diabetes Management & Supplies;

In the Matter of the Miscellaneous Permit of **Manifest Pharmacy LLC; PHA 2020-161-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order

In the Matter of the Miscellaneous Permit of **Millers of Wyckoff Inc.; PHA 2020-74-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order

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 10:11 a.m.

Next Meeting: The Chair announced that the next meeting is as follows and asked if the members are able to attend. Everyone said they will be able to attend the following meeting:

February 18, 2021
9:00 a.m.
Virtual

Adjournment: There being no further business to discuss, the Chair adjourned the meeting at 10:12 a.m.

Taken by:

/s/ Lee Ann Teshima
Lee Ann Teshima
Executive Officer

Minutes approved as is.

Minutes approved with changes; see minutes of _____