

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

MINUTES

Date: June 15, 2023

Time: 9:00 a.m.

Place: Queen Liliuokalani Conference Room
HRH King Kalakaua Building
335 Merchant Street, 1st Floor
Honolulu, Hawaii 96813

Members Present: Alanna Isobe, Chairperson (“Chair Isobe”)
Catalina Cross, Public Member
Brandon Rabang, Public Member
Sheri Tokumaru, Pharmacist

Members Excused: Patrick Adams, Vice Chairperson
Mark Brown, Pharmacist
Kent Kikuchi, Pharmacist

Staff Present: James Skizewski, Executive Officer (“EO Skizewski”)
Shari Wong, Deputy Attorney General (“DAG Wong”)
Leanne Abe, Secretary
Mia Hoang, Tech Support Staff
Johnny Li, Tech Support Staff

Guest(s): Verina Guriguis
Chelsea – Lanai Community Health Center
Cindy Figuerres - Lanai Community Health Center
Annie Macapagal
Kellie Noguchi
Jared Medeiros - Lanai Community Health Center
Joseph Ahenkorah (PTCB)
Erik Abe
Cory Lehano
Jahmeelah
Ashlen Kinilau
Michael Nunez
Kailey H
Kyoung Heon Kim
Michelle Violi

Guest(s): continued Michael Burke - Department of Health
Dan Truong
Aaron Fredricks
Ben Blanchard
Bryan Jones
aelaydo
Tiffany Yajima
Sharla Glass
Gail Elliott
Jessica Adams
Joseph Joyce
Grace Sesi

Call to Order: Chair Isobe took a roll call of the Board members. After taking roll, quorum was not established, and the meeting was called to order at 9:06 a.m.

Chair's Report: **Announcements**

Chair Isobe noted she attended the National Association of Boards of Pharmacies ("NABP") annual meeting in Nashville, Tennessee on May 10 -12, 2023.

Approval of the Minutes of March 30, 2023, Meeting

Chair Isobe deferred the approval of the open session and the executive session minutes of the March 30, 2023 meeting due to lack of quorum.

Executive Officer's Report: **Public Readiness and Emergency Preparedness Act (PREP Act) Expiration and Update**

EO Skizewski reported that there was an 11th amendment to the Public Readiness and Emergency Preparedness ("PREP") Act, which extends the act through 2024. He noted that the public health emergency ended on May 11, 2023. He highlighted the key changes from the 11th amendment as follows:

- Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests;
- Extending coverage through December 2024 for federal agreements (includes all activities related to the provision of COVID-19 countermeasures); and
- Ending of coverage for certain activities. Once products are no longer distributed under a United States Government ("USG") agreement, PREP Act coverage will no longer extend to the following activities:

- COVID-19 vaccinations by nontraditional providers, recently retired providers, or students;
- COVID-19 vaccinations across state lines by licensed providers, pharmacists, and pharmacy interns; and
- Ending of coverage for routine childhood vaccinations: once there is no emergency in effect, the PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

EO Skizewski noted key features that will not change in the 11th amendment as follows:

- No impact on USG distributed COVID-19 countermeasures;
- No impact on COVID-19 vaccines, treatments, and tests currently distributed by the USG;
- No change to coverage for certain prescribing and dispensing of COVID-19 oral antivirals; and
- No change to the Test to Treat program.

2023 Legislative Session

- 1) S.B. 60, Relating to Health
EO Skizewski noted this bill was deferred.
- 2) S.B. 165 and H.B. 1221, Relating to Pharmacists
EO Skizewski noted both bills were deferred.
- 3) H.B. 218, Relating to Prescription Drugs
EO Skizewski noted this bill is before the Governor for signature. EO Skizewski added that if signed into law he will set up an informational briefing so the Board can be made aware of what technology and software is available related to placing QR codes on prescription labels for those who have difficulty reading prescription labels.
- 4) S.B. 602, CLA-Waived test.
EO Skizewski noted this bill is before the Governor. Amendments include a requirement that the pharmacist will report the results of the test to patient's medical home, which is the minor patient's pediatrician, or the adult patients primary care provider. There was also an amendment which requires the pharmacists to follow all applicable state laws related to test reporting.
- 5) S.B. 693, Requesting the Office of the Auditor

EO Skizewski noted that this bill was amended into a request to the Auditor's Office to study the social and fiscal impacts of mandating reimbursement for pharmacist services.

6) S.B. 473, Provides an exemption

EO Skizewski noted that this bill is before the Governor for signing. EO Skizewski noted he will provide an update to the Board if the bill is signed into law.

Hawaii Pharmacists Association

No updates.

Board Business:

Permitted Interaction Group (PIG) related to Pharmacy Technicians

EO Skizewski stated that they are working towards a proposal for the potential impacts of such regulation. The last meeting was held on May 18, 2023, and the group will likely meet a couple more times to finalize a proposal to present to the Board at a regular meeting for final approval.

Permitted Interaction Group (PIG) related to Pharmacy Miscellaneous Permits

EO Skizewski stated that this PIG is finalizing a proposal. They last met on May 18, 2023, and will likely meet a couple more times before they present to the Board at a regular meeting for final approval.

Lanai Community Health Center Pilot Project Update

Erik Abe and Jared Medeiros were promoted to panelist.

EO Skizewski noted that the Board provided an extension to the Lanai Community Health Center ("LCHC") related to their tele pharmacy pilot project in June of 2022. LCHC has submitted their findings report to the Board highlighting data gathered over the first year of the project.

Eric Abe, Public Affairs and Policy Director, Hawaii Primary Care Association (HPCA), noted that HPCA stands in strong support of the Lanai Community Health Center tele pharmacy pilot project and urged the Board to consider continuing the project.

Jarod Medeiros, Associate Medical Director here at LCHC noted that they approached the Board back in 2021 with the goal of helping our patients on Lanai

through telemedicine. LCHC has utilized telemedicine since 2014 to provide various services to patients that are not readily available on Lanai. It took about a year for LCHC to work with pharmacy benefit managers (“PBM”) to get approved. The first prescription was dispensed in June 2022. Corey Lehano a pharmacist at Mauiola Pharmacy, has been integral in helping LCHC implement the project and provide medication verifications along with the pharmacists at the Mauiola location on Maui. A total of 5838 prescriptions have been dispensed in the first year which averages 486 prescriptions per month. LCHC services over 75 percent of the island of Lanai as it applies to medical, dental, behavior health, and optometry. LCHC delivers prescriptions to those without transportation as well as provide transportation to patients to come to the health center for appointments. Tele pharmacy has helped increase access to medication and increase medical compliance. The 340B program has also benefited patients as it relates to cost saving. LCHC has complied with all regulations related to the security and storage of controlled substances. Since June 2022, only a small number of controlled substances have been dispensed. LCHC utilizes two (2) verification times with Cory Lehano and Mauiola Pharmacy. A pharmacist will utilize tele-verification through working with LCHC pharmacy technicians. Patients have enjoyed pharmacy care being provided in the same place that they receive their other medical services. Cory Lehano and Mauiola staff has been readily available to bridge the patient relationship gap through being available via tele-conference with patients to answer any questions regarding medications. Medeiros concluded that this model could benefit other rural areas that have limited access to medical care.

Chair Isobe asked and Medeiros responded that LCHC came to the Board in 2021 for approval to expand the pilot project to include controlled substances. Once approved by the Board, LCHC worked with regulators to obtain controlled substance dispensing authority.

Erik Abe noted that the Federally Qualified Health Center (“FQHC”) model of care discourages controlled substance. LCHC dealing with controlled substances in relation to this pilot project were highlighted in the report as extremely low. LCHC stressed that they would continue to follow the FQHC model of practice and only use or prescribe controlled substances when it was necessary. Abe used cough medicine as an example. Abe concluded that they do not anticipate a large influx in controlled substance prescriptions.

EO Skizewski asked if LCHC is requesting an extension of the pilot project.

Abe responded that LCHC is before the Board to discuss how the Board would like to proceed. Abe added that LCHC has shown that this concept can work and has gathered objective data that would allow the Board to make a decision regarding the viability of tele pharmacy. LCHC is willing to continue the project and to gather

additional information. HPCA is committed to supporting LCHC in this project and its benefits for the people of Lanai.

Chair Isobe noted that the intent of the pilot project is to work toward legislation that will initiate permanent change through the legislative process. Chair Isobe added she did not believe controlled substances were initially permitted in the pilot project.

Erik Abe noted that the pilot project was amended in 2022 to allow controlled substances. LCHC was having issues obtaining a PBM which led to a delay in the pilot project start. LCHC worked with the Drug Enforcement Agency (“DEA”) to address issues related to the security and storage of controlled substances. Once the controlled substance approval was obtained, LCHC was able to acquire a PBM and begin the implementation of the pilot project.

Catalina Cross asked and Chair Isobe responded that this is the first update from LCHC since the extension provided in June 2022.

Chair Isobe requested additional information on the controlled substance approval issued by the DEA.

Erik Abe noted that in regard to public policy, if the Board acknowledges the merit of the concept, LCHC and HPCA could work with the Board to draft legislation.

Chair Isobe stated that a pilot project’s intent is to demonstrate a change that could be made permanent through the legislative process.

Chair Isobe asked Medeiros for information on the DEA approvals and information on their tele pharmacy services.

Medeiros noted that medical verifications are arranged with offsite pharmacists. Refill and acute medications are being provided. LCHC functions as a normal pharmacy with chronic medication being refilled and urgent medication being provided if needed.

Cory Lehano was promoted to panelist.

Cory Lehano, of Mauiola Pharmacy, noted that has had lengthy conversations with the DEA, Honolulu Office, and worked closely with the State of Hawaii, Department of Public Safety, Narcotics Enforcement Divisions (“NED”). PBMs were not willing to contract with them until a DEA number and a Hawaii controlled substance permit was obtained. The process to obtain those items took seven (7) months. Once issued, they were able to bill PBMs for services. Cory Lehano

added that this project is extremely beneficial and serves as an example for the rest of the state on how to provide quality care to underserved areas.

Chair Isobe noted the next step would be to draft legislation.

EO Skizewski highlighted that the pilot project extension was provided to June 2023.

Chair Isobe noted that draft legislation needs to be drafted if this project is working to make the project permanent. Chair Isobe asked that LCHC draft legislation. Chair Isobe added that she would like to see that tele pharmacy be limited to rural areas and not serve as a loophole for all pharmacies to eliminate on site pharmacists.

Erik Abe requested that the Board consider granting LCHC the ability to continue the pilot project for a period or at least through the 2024 legislative session. HPCA and LCHC will work with the Board to draft legislation.

Chair Isobe asked HPCA and LCHC to take the lead on drafting the proposal for Board review.

Erik Abe asked about the timeline related to the legislation being included in the 2024 administration package.

EO Skizewski noted he would look into the timeline but added most proposed initiatives are currently going through the review process.

Erik Abe asked the Board to show their willingness to support the initiative through a motion of support for the concept of tele pharmacy.

EO Skizewski noted his concern over the appropriateness of such an action as the Board listed this agenda item as only an update on the pilot project and not possible Board action on the concept of tele pharmacy as a whole.

Chair Isobe thanked HPCA and LCHC for attending and for the information provided.

Erik Abe, Jared Medeiros, and Cory Lehano were returned to attendee.

At 9:53 a.m., upon a motion by Ms. Cross, seconded by Ms. Tokumaru, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-4 and 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 10:28 a.m., upon a motion by Ms. Tokumaru, seconded by Mr. Rabang, it was voted on and unanimously carried to move out of executive session.

It was moved by Chair Isobe, seconded by Ms. Tokumaru, and unanimously carried to extend the Lanai Community Health Center Pilot Project to the Board's meeting date of October 19, 2023, at which the proposed draft legislation must be submitted for Board review; if no proposed legislation is presented, the Lanai Community Health Center Pilot Project will end on October 19, 2023.

Pharmacy Tech Resolution

EO Skizewski noted that prior to any regulation of a vocational area there is usually a study required on the potential impacts of such regulation. EO Skizewski noted that the Board has a draft before them today to request the State of Hawaii Auditor's Office evaluate the potential impact of regulating pharmacy technicians. EO Skizewski concluded that if adopted by the Board the resolution could be included for consideration in the upcoming legislative session.

Chair Isobe presented the resolution draft to the Board, which stated:

Draft of Resolution for Pharmacy Technicians

REQUESTING THE AUDITOR TO CONDUCT A SUNRISE ANALYSIS ON LICENSING AND/OR CERTIFICATION/REGISTRATION OF PHARMACY TECHNICIANS.

WHEREAS, during the coronavirus disease 2020 pandemic, many rural areas in the State were disconnected and unable to received adequate health care services; and

WHEREAS, pharmacists are well positioned to increase access to vaccinations, particularly in certain areas or for certain populations that have too few healthcare providers, or that are otherwise medically underserved. As of 2018, nearly 90 percent of Americans lived within five miles of a community pharmacy. Pharmacies often offer extended hours and added convenience.

WHEREAS, pharmacists are trusted healthcare professionals with established relationships with their patients. Pharmacists also have strong relationships with local medical providers and hospitals to refer patients as appropriate.

WHEREAS, the Public Readiness and Emergency Preparedness Act (PREP Act) authorized the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

WHEREAS, October 20, 2020, the HHS issued a "Guidance" for PREP Act Coverage to allow for "Qualified" Pharmacy Technicians and State-Authorized Pharmacy Interns to administer childhood and COVID-19 vaccines in order to increase access to vaccinations.

WHEREAS, the HHS recognized Pharmacy Technicians to administer childhood and the COVID-19 vaccines and recognizing that states vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. For purposes of this guidance, to be a "qualified pharmacy technician," pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or National Healthcareer Association.

WHEREAS, the pharmacy technician's scope of practice is determined in HAR Chapter 95.

WHEREAS, according to the Pharmacy Technician Certification Board (PCTB), Hawaii is one of two states that have no requirements for pharmacy technicians. The other state is Delaware.

WHEREAS, in 2014, the Board of Pharmacy conducted a survey. 250+ surveys were sent to in-state pharmacies. 81 retail and 15 institution/other setting pharmacies responded. The survey revealed that there were at least 423 pharmacy technicians working in the 96 pharmacies that responded.

WHEREAS, Hawaii has one nationally accredited pharmacy program, the Daniel K. Inouye, College of Pharmacy, University of Hawaii at Hilo.

WHEREAS, pharmacy technicians have access to the pharmacy area, including controlled substances and diversion is an occurrence with little to no consequences except to terminate the individual from employment.

BE IT RESOLVED by the Senate of the Thirty-second Legislature of the State of Hawaii, Regular Session of 2024, the House of Representatives concurring, that the Auditor is requested to conduct a sunrise analysis of the licensing of and/or certification/registration of pharmacy technicians; and

BE IT FURTHER RESOLVED that the Auditor's analysis is requested to include a recommended for license requirement to include both pharmacy technicians who are nationally certified and pharmacy technicians who are not nationally certified but have received on-the-job training and have years of experience as a pharmacy technician.

BE IT FURTHER RESOLVED that the Auditor is requested to submit findings of the program analysis to the Legislature no later than twenty days prior to the convening of the Regular Session of 2025; and

BE IT FURTHER RESOLVED that certified copies of this Concurrent Resolution be transmitted to the Governor, Auditor, and Director of Commerce and Consumer Affairs.

It was moved by Ms. Tokumaru, seconded by Ms. Cross, and unanimously carried to approve the language for the Pharmacy Tech Resolution.

Executive Session:

At 10:41 a.m., upon a motion by Mr. Rabang, seconded by Ms. Tokumaru, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-4 and 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 11:05 a.m., upon a motion by Ms. Tokumaru, seconded by Ms. Cross, it was voted on and unanimously carried to move out of executive session.

Applications:

Ratification List

Upon a motion by Ms. Tokumaru, seconded by Ms. Cross, it was voted on and unanimously carried to approve the ratification list(s) for pharmacists, pharmacies, miscellaneous permits, wholesale prescription drug distributors, and

pharmacy/miscellaneous permits closures/cancellation, change of PIC, relocations, and name change.

Pharmacist

- i. **Kim, Kyoung Heon**
Upon a motion by Ms. Cross, seconded by Mr. Rabang, it was voted on and unanimously carried to approve the application of Kyoung Heon Kim.
- ii. **Kinilau, Ashlen – Exam Extension**
Upon a motion by Mr. Rabang, seconded by Ms. Cross, it was voted on and unanimously carried to approve the one (1) year NABP exam extension for Ashlen Kinilau.
- iii. **Joyce, Joseph – Exam Extension**
Upon a motion by Mr. Rabang, seconded by Ms. Cross, it was voted on and unanimously carried to approve the one (1) year NABP exam extension for Joseph Joyce.
- iv. **Saad, Batoul**
The application was deferred to the next meeting.
- v. **Schultz, Steven**
Upon a motion by Ms. Cross, seconded by Mr. Rabang, it was voted on and unanimously carried to approve the application of Steven Schultz.
- vi. **Truong, Dan – Request for Reconsideration**
Upon a motion by Ms. Tokumaru, seconded by Mr. Rabang, it was voted on and unanimously carried to approve the request for reconsideration of the application of Dan Truong.

Upon a motion by the Chair, seconded by Mr. Rabang, it was noted on and unanimously carried to approve the application of Dan Truong subject to the following conditions:

- (1) Mr. Truong is required to notify all future employers in Hawaii of the 2015 disciplinary action taken by the Nebraska Department of Health and Human Services on his pharmacy intern license, and
- (2) Mr. Truong's employer must provide a signed acknowledgement of your disclosure to the Board.

Miscellaneous Permit

Upon a motion by Mr. Rabang, seconded by Ms. Tokumaru, it was voted on and unanimously carried to approve the following miscellaneous permit applications:

- i. Brava CA LLC
- ii. Diabetes Supply Center of the Midlands, LLC

- iii. Lehigh Pharmacy and Supplies Inc., dba Cerebral RX
- iv. MedQuest Pharmacy, Inc.
- v. Symphony Clinic, LLC (Arizona Location)
- vi. Symphony Clinic, LLC (Florida Location)
- vii. TrustedMedRx, LLC
- viii. Wickliffe LLC, dba Wickliffe Veterinary Pharmacy

Chapter 91, HRS
Adjudicatory Matters:

Chair Isobe called for a motion in regard to the following adjudicatory matters:

Upon a motion by Ms. Cross, seconded by Ms. Tokumaru, it was voted on and unanimously carried to approve the following adjudicatory matters:

- a. In the Matter of the Miscellaneous Permit of **Marley Drug, Inc.; PHA 2022-38-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1",
- b. In the Matter of the Miscellaneous Permit of **Praxis Specialty Pharmacy, LLC; PHA 2022-85-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1"- "2",
- c. In the Matter of the Miscellaneous Permit of **Pharmamedrx, LLC dba Mint Pharmacy & Skin Clinic; PHA 2023-7-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order,
- d. In the Matter of the Miscellaneous Permit of **Pillpack LLC dba Amazon Pharmacy; PHA 2022-57-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order,
- e. In the Matter of the Miscellaneous Permit of **A E Pharmacy, LLC dba Amazon Pharmacy #001; PHA 2022-59-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order,
- f. In the Matter of the Miscellaneous Permit of **AZ Pharmacy, LLC dba Amazon Pharmacy #002; PHA 2022-60-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order,
- g. In the Matter of the Miscellaneous Permit of **M.N. Pharmacy, LLC dba Amazon Pharmacy #003; PHA 2022-58-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order,
- h. In the Matter of the Miscellaneous Permit of **Pillpack LLC dba Amazon Pharmacy #005; PHA 2022-61-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order,
- i. In the Matter of the Miscellaneous Permit of **Pillpack LLC dba Amazon Pharmacy #006; PHA 2022-62-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order, and
- j. In the Matter of the Miscellaneous Permit of **Pillpack LLC dba Amazon Pharmacy #007; PHA 2022-63-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order.

Next Meeting: There being no further agenda items, Chair Isobe announced the next scheduled meeting.

August 17, 2023
9:00 a.m.

In-Person: Queen Liliuokalani Conference Room
HRH King Kalakaua Building
335 Merchant Street, First Floor
Honolulu, Hawaii 96813

Virtual Participation: Virtual Videoconference Meeting
Zoom Webinar

Adjournment: There being no further business to discuss, Chair Isobe adjourned the meeting at 11:10a.m.

Taken by:

/s/ Lorna Eugenio
Lorna Eugenio
Secretary

Reviewed by:

/s/ James Skizewski
James Skizewski
Executive Officer

LE:js

06/31/23

- [] Minutes approved as is.
[] Minutes approved with changes. See minutes of _____.