

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

MINUTES OF MEETING

Date: Thursday, January 20, 2022

Time: 9:00 a.m.

Place: Virtual Videoconference Meeting – Zoom Webinar

Members Present: Alanna Isobe, Chairperson
Patrick Adams, Pharmacist
Sheri Tokumaru, Pharmacist
Kent Kikuchi, Pharmacist
Mark Brown, Pharmacist
Catalina Cross, Public Member

Staff Present: James Skizewski, Executive Officer (“EO Skizewski”)
Shari Wong, Deputy Attorney General (“DAG”)
Kellie Teraoka, Secretary
Wilma Balon, Secretary
Christopher Fernandez, Tech Support Staff

Excused: Julie Takishima-Lacasa, PhD, Public Member, Vice-Chairperson

Guests: Brian Petrone
Cherylynn Cheng
Corrie Sanders – Hawaii Pharmacists Association
Deeb Eid
Gail Elliott-guest
Kellie Noguchi
Lorri Walmsley – Walgreens
Maimuna Bruce Uzzell
Stacy Pi
Tiffany Yajima – Walgreens

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 and called the meeting to order at 9:11 a.m. All Board members were in attendance, with the exception of the Vice-Chair who was excused from the meeting.

Chair's Report: **Announcements**

The Chair reported she had no announcements.

Approval of Minutes of the December 16, 2021 Meeting

The Chair asked if there were any corrections or discussion of the December 16, 2021 meeting minutes.

There being no corrections/amendments, upon a motion by Mr. Adams, seconded by the Ms. Tokumaru, it was voted on and carried by the majority, with the exception of Mr. Brown who abstained, to approve the minutes as circulated.

The Chair asked if anyone attending wanted to address the Board on this agenda item.

Staff reported that no one raised their hand.

Executive Officer's Report:

2022 Legislative Session

EO Skizewski reported that the Pharmacists' renewal period ended and is now in the audit phase with more information forthcoming. He also announced that the opening day for the 2022 Legislative session was on January 19, 2022.

The Chair asked if anyone attending wanted to address the Board on this agenda item.

Staff reported that no one raised their hand.

Draft of Bill – CLIA Waived Tests:

Tiffany Yajima and Lorri Walmsley were promoted to panelists.

Ms. Yajima thanked the Board for the opportunity to discuss their draft bill, Relating to Routine Patient Assessment Tests. The bill addresses the Clinical Laboratory Improvement Amendment ("CLIA") waiver requirement which requires pharmacies to collaborate with the clinical lab director to sign off on applications to perform CLIA waived tests in pharmacies. The bill will remove this requirement and instead will allow the pharmacist-in-charge ("PIC") to serve as the clinical lab director to sign off on applications for CLIA waived testing. She further stated that the draft bill is going to the Legislature and has not been assigned a bill number yet. This would amend HRS chapter 461 and chapter 321.

The Chair reviewed amendments to HRS chapter 321 which state:

- (2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:
 - (A) A duly licensed clinical laboratory scientist; or
 - (B) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs tests waived pursuant to the federal

Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a), as authorized by HRS 461 or that performs the collection of a specimen that is processed by a clinical laboratory.”

Another amendment they are proposing to change in (2)(B) is, “pharmacist in charge” to “pharmacist,” in lieu of the clinical lab director.

The Chair also reviewed the amendments to HRS chapter 461, which state:

- (B) Ordering drug therapy and diagnostic related laboratory and CLIA waived tests, including:
 - (i) Performing any FDA-approved or FDA-authorized test that is classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) 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, and any regulations adopted thereunder by the federal Health Care Financing Administration, provided that:
 - (1) The test does not require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid.
 - (2) The test is used to detect or screen for any of the following illnesses, conditions, or diseases:
 - (i) SARS-CoV-2 or other respiratory illness, condition or disease;
 - (ii) Mononucleosis;
 - (iii) Sexually transmitted infection;
 - (iv) Strep throat;
 - (v) Anemia;
 - (vi) Cardiovascular health;
 - (vii) Conjunctivitis;
 - (viii) Urinary tract infection;
 - (ix) Liver and kidney function or infection;
 - (x) Thyroid function;
 - (xi) Substance use disorder;
 - (xii) Diabetes; or
 - (xiii) Other tests classified as waived under the federal Clinical Laboratory Improvement Amendment of 1988 (42 U.S.C. Sec. 263a) and any corresponding regulations.

Ms. Yajima stated that it was important to list all the types of tests that could be performed rather than generalizing as, “CLIA waived tests.”

The Chair acknowledged that she understood the rationale for listing examples of CLIA waived tests so that everyone can clearly understand what is included.

Mr. Kikuchi opined that it would be better to generalize the list to avoid revising the statute if there are any revisions or additions in the future.

Ms. Yajima responded that they are open to amendments.

Mr. Adams shared that in his past experience with the legislature, simple is better. Because this language is within the scope of practice, it is better to leave it general as it could change in the future.

The Chair added that the CLIA waived tests are generally self-diagnosing tests, which do not require interpretation of the results.

Ms. Yajima confirmed that pharmacists are currently performing these tests in pharmacies under the Public Readiness and Emergency Preparedness ("PREP") Act. This amendment would remove the administrative requirement for the clinical labs director to sign-off on the form. She added that Hawaii and a few other states who still have this requirement are in the minority, and this amendment would put us in line with the rest of the nation.

Mr. Adams asked if have they've reached out for support from any of the other stakeholders.

Ms. Yajima responded that they did some research and outreach, however since they started the process in December 2021, they have not heard back from the other stakeholders. She added that the draft bill currently states that the PIC would be serving as the clinical lab director, however it might be better to be amended to "pharmacist", as some pharmacies have someone in the back of the house or in an administrative role who could sign-off, not necessarily the PIC.

Mr. Adams agreed with the amendment, as it may be a bit ambiguous for the scope of practice for a PIC.

Ms. Walmsley and Ms. Yajima thanked the Board for their time and stated that they are available for questions or suggestions.

The Board's consensus was to support the proposed bill, Relating to Routine Patient Assessment Tests.

The Chair asked if anyone attending wanted to address the Board on this agenda item.

Staff reported that no one raised their hand.

Ms. Yajima and Ms. Walmsley returned back to attendees.

EO Skizewski pointed out an error on the meeting agenda.

- a. 2021 Legislation Session should be changed to, "2022"
2. Creation of a 2021 Legislative Committee should be changed to, "2022"

The Board's consensus was to approve the amendment to the agenda.

Creation of a 2022
Legislative Committee:

EO Skizewski proposed that the Board create a 2022 Legislative Committee for the upcoming session, which would assist with addressing emergency issues that came up between Board meetings without needing to convene the entire Board.

Upon a motion by Mr. Brown, seconded by the Mr. Kikuchi, it was voted on and unanimously carried to appoint Chair, Mr. Adams, and Mr. Brown to the Legislative Committee.

The Chair asked if anyone attending wanted to address the Board on this agenda item.

Staff reported that no one raised their hand.

Hawaii Pharmacists
Association:

Corrie Sanders was promoted to a panelist.

Ms. Sanders, from Hawaii Pharmacists Association ("HPA"), shared that the annual meeting will be held on April 23, 2022, at the Oahu Country Club, and will include networking sessions with live speakers.

She also provided a 2022 legislative update that, due to the upcoming turnover in elected officials, they have opted to transition their legislative initiative to one large pharmacy related package in the 2023 session. HPA has strong working groups in place for provider status however, they are seeking input from community pharmacies and pharmacists for legislation centered around the PREP act. They are also seeking input on the technician certification requirements, as Hawaii is one of the few states that currently does not have technician certification requirements. HPA will prioritize legislation as one of their main initiatives moving forward.

Ms. Sanders provided the following updates:

- The ipledgeprogram.com website was recently updated to include a troubleshooting link to assist pharmacists who were experiencing long wait times.
- The covidtest.gov website was launched to provide 4 free tests per household.
- The FDA's Emergency Use Authorization ("EUA") omitted pharmacists from the list of providers to prescribe the EUA antiviral medications. HPA is working with stakeholders to amend the guidance to allow pharmacists the leverage to prescribe the oral antiviral medication for patients who are COVID-19 positive.

The Chair asked if anyone attending wanted to address the Board on this agenda item.

Staff reported that no one raised their hand.

Ms. Sanders returned back to an attendee.

Applications:

Executive Session:

At 9:38 a.m., upon a motion by Ms. Cross, seconded by Mr. Brown, 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 10:18 a.m., upon a motion by Mr. Brown, seconded by Ms. Tokumaru, it was voted on and unanimously carried to move out of executive session.

Mr. Adams experienced technical difficulties and left the meeting at 10:18 a.m.

Ratification Lists

Upon a motion by the Mr. Kikuchi, seconded by Mr. Brown, it was voted on and carried by the majority, with the exception of Mr. Adams who was absent, to approve the ratification list(s) for pharmacists, pharmacies, miscellaneous permits and pharmacy/miscellaneous closures, change of PIC and relocations.

Applications

Pharmacist

The Chair asked for a motion regarding the following pharmacist application:

i. Francine Amoa

Ms. Tokumaru stated that she knows the applicant but can consider and vote objectively on the application.

Upon a motion by Mr. Brown, seconded by Mr. Kikuchi, it was voted on and carried by the majority, with the exception of Mr. Adams who was absent, to approve the application pending contingent on passing the NAPLEX.

Miscellaneous Permit

The Chair asked for a motion regarding the following miscellaneous permit applications:

i. PathWrite, Inc. dba Paragon Infusion Services

ii. **Brooksville Pharmaceuticals Inc.**

iii. **Avita Drugs, LLC dba Avita Pharmacy 1040**

Upon a motion by Ms. Cross, seconded by Ms. Tokumaru, it was voted on and carried by the majority, with the exception of Mr. Adams who was absent, to approve the aforementioned miscellaneous permit applications.

Wholesale Prescription Drug Distributor

i. **Medline Technologies, L.P.**

Upon a motion by Mr. Brown, seconded by Mr. Kikuchi, it was voted on and carried by the majority, with the exception of Mr. Adams who was absent, to defer the application.

Chapter 91, HRS
Adjudicatory Matters:

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

Upon a motion by Mr. Tokumaru, seconded by the Ms. Cross, it was voted on and carried by the majority, with the exception of Mr. Adams who was absent, to approve the following adjudicatory matter:

- a. In the Matter of the Miscellaneous Permit of **Pacifico National, dba Amesx Pharmacy; PHA 2020-187-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order

Next Meeting:

There being no further agenda items, the Chair announced the next meeting. All members stated that they are available, except Ms. Cross who was tentative.

February 10, 2022
9:00 a.m.
Virtual

Adjournment:

There being no further business to discuss, the Chair adjourned the meeting at 10:24 a.m.

Taken by:

/s/ Kellie Teraoka
Kellie Teraoka, Secretary

Reviewed and Approved by:

/s/ James Skizewski
James Skizewski, Executive Officer

JS:kt
2/7/22

[X] Minutes approved as is.
[] Minutes approved with changes; see minutes of _____