

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

MINUTES OF MEETING

Date: Thursday, June 17, 2021

Time: 9:00 a.m.

Place: Virtual Videoconference Meeting – Zoom Webinar

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

Staff Present: James Skizewski, Executive Officer ("EO Skizewski")
Lee Ann Teshima, Executive Officer ("EO Teshima")
Rochelle Araki, Executive Officer
Shari Wong, Deputy Attorney General ("DAG")
Kellie Teraoka, Secretary
Stephanie Karger, Tech Support Staff
Denise Saffery, Secretary (Training)
Marc Yoshimura, Secretary (Training)

Guests: Ademola Are
Allen Bagalso
Brenda Fletcher
CarrieBaker
Cheryl Williams
Cherylynn Cheng
Corrie Sanders
EJSmith
Elizabeth Vuong
Emily Haugh
Gail Elloitt-guest
Jennifer Ontai
Jessica Adams
Jessica.zuniga
Lauren Paul
Marcella C
Stacy Pi
Tiffany Yajima

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 9:04 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 May 20, 2021 Meeting

The Chair asked if there were any corrections or discussion of the May 20, 2021 meeting minutes.

There being no corrections/amendments, upon a motion by Ms. Tokumaru, seconded by Mr. Adams, it was voted on and unanimously carried 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:

2021 Renewals

EO Skizewski reported that other professions renewing now are encountering some glitches in the system and that hopefully these issues will be addressed before the upcoming pharmacy renewals.

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

Staff reported that no one raised their hand.

Correspondence:

Adding Vitamins to IVs for Hydration

The Chair stated that the Board received the following 2 emails:

Tam Tran

I have a medical practice and was thinking about adding vitamin infusion therapy to my practice. I was wondering what the rules and regulations were surrounding this. Does this require a license? Can I mix vitamins in a bag in my office? Do I need a hood? Any information would be greatly appreciated.

Melissa Robinson

I am in the process of opening a Mobile IV hydration business and had a few questions in regards to regulations. First, does the board of pharmacy have any regulatory authority over this type of business? If so, how would I go about obtaining the necessary licensing? Next, are there any rules/laws regarding the necessary use for a hood when compounding/mixing vitamins in IV fluid in the state of Hawaii? Next, does the board of pharmacy have any rules regarding who can compound/mix said vitamins (ie. RNs, Physicians, etc) in the state of Hawaii?

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

Mr. Adams stated that the FDA regulations on sterile compounding, USP 797 guidelines, should be followed and if a pharmacy is compounding, then the Board would have jurisdiction over the matter and pursuant to the USP 797 guidelines, that would require a hood, use-by-date and address bulk/commercial products.

Ms. Keefe stated that it would be essential to refer to the FDA USP 797 guidelines as Mr. Adams referred to as sterile compounding is a patient safety issue.

The Chair stated the Board will refer the inquirers to the FDA USP 797 guidelines on sterile compounding.

Mr. Adams stated that he would recommend that the Board address the inquiries specifically as well as refer to the FDA USP 797 guidelines.

EO Teshima stated that for the inquiry from "Tam", in the first sentence, it states, "I have a medical practice..." and therefore she assumed that a physician was inquiring and that based on the FDA, pharmacists and physicians can compound.

Mr. Adams stated that the inquiries are asking the Board for information and that the Board should provide information including compliance with USP 797.

The Vice Chair agreed with Mr. Adams and admitted that as a public member, she is not familiar with the practice, however, her role as the public member is to ensure that patient safety and the protection of the public is considered.

Ms. Cross agreed with the Vice Chair, as a public member herself, and with Mr. Adams that safety is a key and compliance with federal regulations should be addressed. She also stated that for a pharmacist to compound a product, a patient specific prescription order is required.

Ms. Tokumaru stated that she also agrees with Mr. Adams that compounding a product should be in compliance with FDA USP 797.

Mr. VandenBussche questioned whether the Board is the appropriate authority to require a hood or other compliance issues for non-pharmacist compounding and suggested

referring all inquiries to the FDA.

After further discussion, upon a motion by Mr. Adams, seconded by Mr. VandenBussche, it was voted on and unanimously carried to respond to the inquiries as follows:

Pharmacists and physicians are allowed to compound pursuant to the federal Food, Drug and Cosmetic Act. An IV is considered a “sterile” drug product and therefore adding vitamins to the IV appears to be considered sterile compounding addressed in USP 797.

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

Staff reported that Corrie Sanders raised her hand.

Ms. Sanders was elevated to panelist and thanked the Board for the discussion and wanted to offer comments that USP 797 may refer to state regulations and may not address the reporting of adverse events or recalls as referred to in USP 800.

EO Teshima asked if Mr. Adams wanted to amend his motion.

Mr. Adams stated that USP 800 is not addressed in the pharmacy practice act and does not believe his motion needs to be amended.

The Chair asked the Board members if there was any further discussion related to Melissa Robinson’s inquiry.

The Chair noted and Ms. Cross agreed that it was unclear as to what the inquirer’s profession was.

Hearing no objections, the Chair noted that the response to Tam’s inquiry can be used to address the inquiry from Melissa Robinson.

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

There being no further discussion on this matter, the Chair announced the next agenda item and asked if anyone attending wanted to address the Board.

Staff reported that no one raised their hand.

Executive Session:

At 9:40 a.m., upon a motion by Ms. Cross, seconded by Mr. Adams, 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 9:45 a.m., the Board moved out of executive session.

Applications:

Ratification Lists

The Chair asked for a motion to approve the ratification list(s) for pharmacists, pharmacies, miscellaneous permits and pharmacy/miscellaneous closures, change of PIC and relocations.

Upon a motion by Mr. VandenBussche, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the ratification lists.

Applications

Miscellaneous Permit

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

PillPack, LLC, dba Amazon Pharmacy #006

Upon a motion by Mr. VandenBussche, seconded by Mr. Adams, it was voted on and unanimously carried to approve the application.

The Chair announced the next agenda item 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:

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

In the Matter of the Miscellaneous Permit of **KEBD Enterprises, LLC, dba Belmar Pharmacy, PHA 2020-110-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 **UBC Pharmacy, LLC, PHA 2020-121-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; and

In the Matter of the Miscellaneous Permit of **Drug Depot, INC, dba APS Pharmacy, PHA 2020-115-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order.

Next Meeting:

The Chair announced that the next meeting is as follows and asked if the members are able to attend.

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

The Vice Chair and Mr. Adams stated that they would not be able to attend.

EO Teshima reported that this was Ms. Keefe and Mr. VandenBussche last meeting and thanked them for their invaluable contribution to the Board in the last 4 and 8 years.

Adjournment: There being no further business to discuss, the Chair adjourned the meeting at 9:55 a.m.

Taken by:

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

Reviewed and Approved by:

/s/ James Skizewski
James Skizewski, Executive Officer

LAT:js

[X] Minutes approved as is.

[] Minutes approved with changes; see minutes of _____