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

MINUTES OF MEETING

Date:	Thursday, April 15, 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 Mary Jo Keefe, RPh, Pharmacist Sheri Tokumaru, Pharmacist
Members Excused:	Patrick Adams, Pharmacist Catalina Cross, Public Member Kenneth VandenBussche, RPh, BCACP, Pharmacist
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:	Aaron Lopez Corie Hawks Greg Edwards Amy Este Brenda Fletcher Cherylynn Cheng Corrie Sanders Kellie Noguchi JR Smith Keawe Hurst Allen Bagalso Pua Akana Kellie Noguchi Nicole JRSmith Stacy Pi Susan Tevnan Tiffany Yajima AM

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 Mr. Adams, Ms. Cross and Mr. VandenBussche from today's meeting and called the meeting to order at 9:05.

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 March 18, 2021 Meeting

The Chair asked if there were any corrections or discussion of the March 18, 2021 meeting minutes.

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

Executive Officer's Report:

2021 Legislative Session

The EO reported that it appears that both SB 1191 and SB 1192 are not moving forward. These are 2 admin bills under the Narcotics Enforcement Division.

She stated that since she was tracking most of the pharmacy related bills, for more information on the status of any legislative bills, she referred to the legislative web page at capitol.hawaii.gov/.

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 she understands that pharmacies are receiving the COVID vaccine and to administer to eligible patients but also understand that those pharmacies who received the Johnson & Johnson vaccine may run into an issue with the COVID vaccine but that will hopefully not impact the pharmacy's ability to vaccinate if they are able to receive another COVID vaccine.

2021 Renewals

The EO reminded the members and attendees that all pharmacy related licenses/permits will expire on December 31, 2021 and that only ACPE approved CE courses are acceptable and must be completed before the pharmacist renews his/her license. After the renewal period, those selected for the random audit will receive a letter but a list of those selected will also be posted on the Board's web page as a reference.

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.

Correspondence: **Creating Greater Access for Outsourcing Facilities**

The Chair read excerpts of a letter regarding the Inclusion of Federally Regulated Outsourcing Facilities for Compounded Veterinary Medication from Mr. Lopez, Political Capital, LLC:

We encourage the greater integration of State Licensed, Federally Regulated Outsourcing Facilities in veterinary medicine and encourage the Board to review its policies to ensure that products from Outsourcing Facilities are available to veterinarians and their patients to have on hand when needed. Outsourcing facilities were created by congress for the express purpose of providing sterile and non-sterile office-stock products while maintaining FDA regulations for safety and current Good Manufacturing Practice (cGMP) standards. Although outsourcing facilities were created to address human health, FDA allows outsourcing facilities to manufacture products for animal health.

When Congress saw a need for more regulatory control within the compounding industry, the solution came in the form of 503B outsourcing facilities. While traditional compounding pharmacies are best suited to create medications quickly, meeting state issued USP standards for individual patients and prescriptions, outsourcing facilities are FDA registered and inspected to better regulate the ingredients, conditions, and manufacturing processes of these more widely distributed medications for office use. 503B Outsourcing Facilities are mandated by congress to produce medications at a

cGMP level, adhering to stability testing for accurate expiration dates, and finished product testing to ensure quality control. They must also maintain a higher level of documentation to enable traceability and tracking of all medications by batch. As compounded medications are essential to patient and veterinary care in the United States, outsourcing facilities offer a safe, highly controlled process of manufacturing these medications, like traditional pharmaceutical companies.

The FDA published a compounding progress report in January 2017 stating, "*FDA encourages health care facilities that purchase compounded drugs to obtain them from outsourcing facilities because they are subject to increased quality standards and federal oversight."* Similarly, in June 2019, the Office of Inspector General published a report stating, "*OIG recommends that FDA further communicate with hospitals about the importance of obtaining their non-patient-specific compounding drugs from outsourcing facilities.*" These reports clearly describe the FDA-encouraged use of outsourcing facilities for office use medications where an FDA product is unavailable and further promote the utilization of these federally regulated manufacturers. These statements make clear that outsourcing facility products are the preferred, safer, higher quality choice for office-use medications. Veterinarians should be encouraged to administer and dispense these products from their office when an FDA approved product is unavailable or not suitable.

Although FDA guidance advises that if the **only** activity conducted at a facility is the compounding of animal drugs it should not register as an outsourcing facility, FDA highlights the word only in the guidance. This highlighting clearly establishes that compounding drugs for animal health is allowed if it is not the only activity conducted and the facility meets the other requirements that are listed. In addition, given the limited number of FDA approved products available for veterinary office-use, outsourcing facilities may be in a better position to assist animal-health practitioners than those treating human patients.

In June 2018 the Connecticut Department of Consumer Protection issued guidance regarding compounded pharmaceuticals for veterinary office use and mandated that compounded medications for animals must be obtained from a properly licensed outsourcing facility. Michigan's veterinary medical association also requires all compounded office-stock medication to be purchased from an outsourcing facility, and other states are seeing the benefits of requiring hospitals and veterinarian clinics to first seek to obtain compounded medications from an outsourcing facility. While a requirement that all compounded veterinary office-stock be ordered from an outsourcing facility protects companion animals to the greatest extent, regulatory steps in this direction, such as allowing all cGMP products to be dispensed for the same period of time or allowing 503B products to be dispensed for a longer period of time than USP compounded product, would significantly help to protect (State)'s companion animals. Requiring veterinarians to obtain an office-use product from an outsourcing facility first, prior to obtaining the medication from a traditional compounding pharmacy, serves to encourage veterinarians to order cGMP quality products and thereby increases patient safety.

Whether created by a traditional compounding pharmacy for a specific patient or pet or manufactured by an outsourcing facility for office-stock, these non-commercially available medications play a vital role in modern medicine. We ask you to keep these therapeutic options available to the veterinarians in your state and follow the FDA's example in utilizing federally registered, state licensed outsourcing facilities for office-stock. When medical professionals have access to these options, they can ensure the best possible outcomes for the patients and companion animals they serve.

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

Mr. Lopez and Ms. Hawks raised their hand.

Mr. Lopez stated that they are working on a national campaign on compounded drugs availability for practitioners, i.e. veterinarians and wrote to the Board as they did not see anything specific prohibiting or allowing compounding for office use.

Ms. Keefe asked if he was aware of any 503B outsourcing facilities in Hawaii.

Mr. Lopez said no, it is hard to research as to where these registered outsourcing facilities are located.

Ms., Keefe asked if he was aware of any State requirements for 503B facilities.

Mr. Lopez said no, the FDA has very strict requirements.

The EO asked about the cost of registering with the FDA as a outsourcing facility.

Mr. Lopez stated that it can cost $15,000 annually and that cost includes inspections and other requirements under the FDA. He also stated that some states may have additional registration fees/costs for their own inspections.

Ms. Keefe asked if he was aware of any cost to the state in regard to signing the FDA compounding MOU.

Mr. Lopez stated that the MOU applies to 503A, compounding pharmacies, not outsourcing facilities.

Ms. Keefe asked about the beyond use date (BUD) for 503A and 503B facilities.

Mr. Lopez stated that for 503A, the BUD is 45 days and may not be extended as opposed to products compounded by 503B facilities where there is testing to ensure the efficacy and sterility of the compounded products.

The EO wanted to clarify that a 503A is a pharmacy that does sterile and non-sterile compounding pursuant to a patient specific order/prescription and that a 503B is not

necessarily a "pharmacy" but that the compounding for office use product must include a pharmacist and/or have pharmacist oversight.

Mr. Lopez said that is correct, the 503B outsourcing facility must have a pharmacist.

The EO asked Mr. Edwards if he had anything to add to the discussion and was promoted to a panelist.

Mr. Edwards introduced himself as the supervisor for the Department of Health, Food and Drug Branch and that he had 3 points he wanted to address:

1. That the prescription wholesale distribution license applies to entities who wholesale "human" drugs specifically and not animal drugs;
2. That he agree with Mr. Lopez that a 503B outsourcing facility may be considered a manufacturer and subject to requirements under the FDA; and
3. 503A pharmacies may compound products pursuant to a patient specific prescription.

The Chair stated that she would like to hear from others who may be impacted should the Board move forward to amend their laws and rules to allow for compounding for office use, because she has cause for concerned that based on her experience on the Board, she has seen applicants who allegedly compound for veterinarians, applying for a Hawaii miscellaneous permit as an out of state pharmacy who had prior disciplinary action taken against them in other states for compounding issues and she would not want to see any outsourcing facility distributing unsafe products endangering human or any animal.

The EO stated that she would also recommend that the Board reach out to the Hawaii Medical Board as besides the veterinary community, the Board has received inquiries from ophthalmologists as well.

Ms. Keefe asked if she could get Mr. Lopez' email/contact information as she had additional questions.

The DAG advised Ms. Keefe and the members that any additional questions should be forwarded to the EO since this is a Board agenda matter and the information may have to be shared with the rest of the Board members during an open meeting.

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

Seeing none, the Chair announced the next agenda item is HHS' Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency – Guidance for Industry, June 2020 and asked if there is anyone attending wishing to address the Board on this agenda item please raise your hand now.

Staff reported that no one raised their hand.

Prescription Drug Sample Distribution During COVID-19

The Chair stated that the PDMA requires in part that licensed practitioners who request drug samples do so in writing and mandates storage, handling, and recordkeeping requirements for drug samples. During the COVID-19 PHE, manufacturers that use drug samples as part of their marketing programs have been relying more on mail and common carriers, rather than sales representatives, to deliver drug samples. In this guidance, HHS is addressing their current policy regarding drug sample requirements in PDMA and part 203 related to the collection of physical signatures upon delivery of drug samples and the ability of licensed healthcare providers to request that drug samples be delivered to various locations during the COVID-19 PHE.

This guidance document addresses the:

- **Physical Collection of Signatures upon Receipt of Drug Samples;**
- **Place of Delivery of Prescription Drug Samples;**
- **Delivery to Patient's Home;**
- **Delivery to Licensed Practitioner's Home; and**
- **Delivery to Pharmacies**

She stated that in addition, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

She asked if there was any discussion by the members.

Seeing none, she asked if there was anyone attending wishing to address the Board on this matter.

Mr. Edwards was promoted to panelist.

He stated that although distribution of drug samples do not require a PWD license in this State, there are concerns as to who is actually ordering the drug samples since these "guidances" appear to be relaxing some of the requirements.

The Chair asked if there was any further discussion.

Seeing none, she announced that the next agenda the Board will be reviewing applications and asked if there anyone attending wishing to address the Board on any application to please raise your hand.

Seeing none, the Chair asked for a motion to move into executive session to consider and evaluate personal information relating to individuals applying for licensure;" and "To consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities.

Executive Session: At 9:52 a.m., upon a motion by Ms. Keefe, seconded by the Vice Chair, it was voted on and unanimously carried to move into executive session to "consider and evaluate personal information relating to individuals applying for 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 9:59 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 Ms. Keefe, voted on and unanimously carried to approve the ratification list(s).

Applications

Miscellaneous Permit

The Chair asked for a motion in regard to the applications for miscellaneous permit.

Upon a motion by the Vice Chair, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the following applications for miscellaneous permits and pharmacists for the miscellaneous permits:

Express RX, LLC, dba Carepharm Pharmacy
Caremark North Carolina Specialty Pharmacy, LLC, dba CVS/Specialty
(PMP1772) – Pharmacists Teresa Jones and Genny Brewer
Caremark Massachusetts Specialty Pharmacy, LLC, dba CVS/Specialty

The Chair announced that the Board will now recess pursuant to Chapter 91, HRS to discuss adjudicatory matters and asked the members to please turn off your video and mute yourself in ZOOM and go back to the Teams meeting.

Chapter 91, HRS Adjudicatory Matters: At 10:04 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 Pharmacist License of **Melissa Ann Fossum, PHA 2021-2-L,** Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1" – "2";

In the Matter of the Miscellaneous Permit of **McGruff Compounding Pharmacy Services, Inc., PHA 2020-70-L,** Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

The Board deferred the following adjudicatory matter due to lack of quorum to vote on the matter as the Chair recused herself:

In the Matter of the Miscellaneous Permit of **Safeway Inc., PHA 2020-22-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 10:08 a.m.

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

May 20, 2021
9:00 a.m.
Virtual

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

Taken by:

__/s/ Lee Ann Teshima___
Lee Ann Teshima
Executive Officer

[X] Minutes approved as is.

[ ] Minutes approved with changes; see minutes of _____