

## BOARD OF PHARMACY

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

### MINUTES OF MEETING

Date: July 14, 2022

Time: 9:00 a.m.

In-Person Meeting Location: Queen Liliuokalani Conference Room  
King Kalakaua Building  
335 Merchant Street, 1<sup>st</sup> Floor  
Honolulu, Hawaii 96813

Virtual: Virtual Videoconference Meeting – Zoom Webinar (use link below)  
Participation: <https://dcca-hawaii-gov.zoom.us/j/91551211842>

Members Present: Alanna Isobe, Chair  
Patrick Adams, Vice Chair  
Kent Kikuchi, Pharmacist  
Sheri Tokumaru, Pharmacist  
Catalina Cross, Public Member

Excused: Mark Brown, Pharmacist

Staff Present: James Skizewski, Executive Officer (“EO Skizewski”)  
Lee Ann Teshima, Executive Officer (“EO Teshima”)  
Candace Ito, Acting Supervising Executive Officer (“SEO Ito”)  
Shari Wong, Deputy Attorney General (“DAG”)  
Jaymie Nakama, Secretary  
Mia Dao Linh Trung Hoang, Tech Support Staff  
Sandra Matsushima, Executive Officer, Tech Support Staff

Guests: In-person:  
Stacy Pi, Kaiser

Virtual:  
Alyson Soranaka  
BFletcher  
Cherylynn Cheng  
Chris Rochon, Pillpack  
Corrie Sanders, HPA  
Emily Haugh  
Gavin Sanjume  
Grace Sesi  
Kellie Noguchi

Lisa Dimick  
Rafael Del Castillo  
Tiffany Yajima

Call to Order:

The agenda for this meeting was posted on the State electronic calendar as required by Hawaii Revised Statutes (“HRS”) section 92-7(b).

A short video was played to explain the meeting procedures and how members of the public could participate in the virtual meeting.

Chair Isobe welcomed participants and proceeded with a roll call of Board members. All Board members confirmed that they were present and alone, with the exception of Mr. Adams who had a household member present at his nonpublic location. Mr. Brown was excused from the meeting. Quorum was established and the meeting was called to order at 9:12 a.m.

Chair’s Report:

**Announcements**

Chair Isobe reported that an application listed under miscellaneous permits, HDK Enterprises, LLC dba Southside Infusion was withdrawn and the adjudicatory matter for Archway Apothecary LLC; PHA 2022-13-L, was already approved at the Board’s June 16, 2022, meeting.

**Approval of Minutes of the June 16, 2022, Meeting**

Chair Isobe asked if there were any corrections or discussion of the June 16, 2022, meeting minutes.

There being no corrections/amendments to the minutes, upon a motion by Mr. Adams, seconded by Ms. Tokumaru, it was unanimously carried to approve the open session minutes of the June 16, 2022, meeting, as circulated.

Chair Isobe asked if members of the public would like to provide testimony on this agenda item.

Staff reported that no one raised their hand.

Election of Vice  
Chairperson:

Chair Isobe announced the next agenda item was the election of Vice Chairperson.

Chair Isobe opened the floor for volunteers for the position of Board Vice Chairperson. Mr. Adams volunteered for the position, it was voted on and was unanimously carried to elect Mr. Adams as the Board’s Vice Chairperson.

Executive Officer  
Report:

**Correspondence**

FDA Compounding Guidelines

EO Skizewski reported that the Board’s office received the following email from Vice

Chair Adams:

I have a question about Compounding medications and Miscellaneous Permits. I have supplied guidelines in 2 attached documents as well as an FDA question and answer on compounds in a previous email. The documents discuss the regulation of compounded medications.

The guidelines state that the State Boards regulate compounded meds, and the FDA's role is secondarily responsible. I have concerns about the Hawaii's miscellaneous permit process and the lack of information on these meds.

I believe the miscellaneous works very well for purposes of FDA approved medications. These would be any medication that has gone through the new drug application process and have been approved after FDA scrutiny. Since compounded medication have not gone through this process the FDA has deferred to state boards pharmacy to help regulate these medications. In Hawaii the Miscellaneous Permit process may not give a description of what a compounding pharmacy is making and where it is going. This may represent a safety concern for the citizens of Hawaii. There is a need to have compounded medications sent into the state and the state's residents need many of the compounds being sent to Hawaii. Presently this practice is controlled loosely with Miscellaneous Permits. This type of permit gives any Miscellaneous pharmacy the right to send medications to the state even if they have not been approved by the FDA. This would include TPN and sterile IV meds that may involve considerable risk. Often these meds have a short beyond use date so expiration could happen during transit.

I would like to discuss whether the board thinks that compounded medications should have a different permit or should be a subset of the Miscellaneous permit that requires a greater degree of discovery so the board can see what unapproved FDA meds are coming into the state. Questions might include what is being sent in, where it is going and what quantities. It may be that the board is comfortable with the Miscellaneous Permit process, but I think the discuss considering the attached documents would be prudent.

EO Skizewski asked the members if there was any discussion and requested Vice Chair Adams to elaborate on his email.

Vice Chair Adams mentioned that the riskiest medications that are being sent into the State are compounds, which includes sterile compounds. His main concern is if people are doing sterile compounding and sending them into the State, the Board should be aware of what is being brought as it poses the biggest risk. Vice Chair Adams noted the need for the Board to look harder at a compounding company's applications as it may provide compounds not approved by the FDA.

Ms. Cross noted her desire for more discussion to learn about this situation.

Ms. Tokumaru stated her willingness to discuss more ideas for the Board to realistically

improve this process to ensure the safety of the consuming public.

Mr. Kikuchi would like further discussion either in a sub-committee as it is complex and a big task to evaluate this process.

Chair Isobe noted her agreement with the previous comments and feels that the Board will need to collect additional information. Chair Isobe asked the Board members if they would be interested in forming a working group.

Vice Chair Adams noted his interest in forming a working group.

Chair Isobe asked if anyone in the audience wanted to address the Board on this agenda item.

Staff reported that no one raised their hand.

Chair Isobe advised that the working group would need a maximum of three (3) Board members and interested candidates to join. If you are interested, please email the Board of Pharmacy at: [pharmacy@dcca.hawaii.gov](mailto:pharmacy@dcca.hawaii.gov).

Based on the Board's comments, EO Teshima asked the Board if they would be interested in forming a working group.

Mr. Kikuchi acknowledged that it is important to gather more information and believes if all the Board members join the working group but would cause conflicts with the terms of the approving process. Mr. Kikuchi noted that there are people in the public who are interested, and they should be a part of the working group.

EO Teshima stated that the maximum number of members to serve on the working group is three (3) because it is less than quorum for the Board.

Vice Chair Adams explained that the working group would bring its research and recommendations to the Board to consider.

SEO Ito noted that the Board would be creating a permitted interaction group ("PIG") and the Board would clearly need to outline the purpose of the group.

Chair Isobe noted this will be placed on next month's agenda and that if members of the public would like to participate to email [pharmacy@dcca.hawaii.gov](mailto:pharmacy@dcca.hawaii.gov).

Chair Isobe asked if anyone in the audience wanted to testify on this agenda item.

Staff reported that there was no one present who wished to provide testimony.

#### FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations

EO Skizewski reported that the Board's office received the following email from the U.S. Food and Drug Administration ("FDA") on the authorization for pharmacists to prescribe

Paxlovid with certain limitations for patients with high risk for severe COVID:

The U.S. Food and Drug Administration's (FDA or Agency) Intergovernmental Affairs (IGA) team would like to share an important update with you. Today, FDA revised the Emergency Use Authorization (EUA) for Paxlovid (nirmatrelvir and ritonavir), to authorize state-licensed pharmacists to prescribe Paxlovid to eligible patients, with certain limitations to ensure appropriate patient assessment and prescribing of Paxlovid.

EO Skizewski noted that, included in the ninth amendment of the Public Readiness and Emergency Preparedness ("PREP") Act, was an expansion of authority to pharmacists to prescribe, dispense, and administer COVID therapeutics as long certain criteria is met.

Ms. Cross asked if any licensed pharmacists are allowed to evaluate and dispense medications for patients. She assumed that pharmacists could order, write a prescription, and dispense Paxlovid to patients.

EO Skizewski responded that criteria must be met outlined in the 9<sup>th</sup> amendment of the PREP Act for pharmacists to meet the requirements that permit the expansion of authority to prescribe, dispense, and administer COVID therapeutics. EO Skizewski noted that the related notices will be posted under announcements of the Board of Pharmacy website.

Ms. Tokumaru had no comment on this agenda item.

Vice Chair Adams indicated that he would like more information about the dispensing procedures of Paxlovid.

Lastly, Mr. Kikuchi noted that Paxlovid is prescribed based on allocation, and not easily accessible as there is a limited supply Statewide. Mr. Kikuchi added that it is critical for a pharmacist who undertakes the responsibility to dispense Paxlovid follow the guidelines.

Chair Isobe asked if there was anyone attending who wished to address the Board or testify on this agenda item.

Ms. Corrie Sanders was promoted to address the Board.

Ms. Sanders noted her concern about the American Medical Association ("AMA") statement regarding pharmacists not being able to prescribe Paxlovid as it violates the medical practice act. She asked if the Hawaii Medical Board is aware of the statement.

Ms. Sanders informed the Board that the Hawaii Pharmacist Association ("HPA") is receiving many questions related to sufficient provider relationship and sufficient consultation.

About informing the Hawaii Medical Board about AMA's statement, EO Teshima clarified that the Hawaii Medical Board does not regulate or oversee the pharmacist scope of practice.

Ms. Sanders stated that the AMA released such a strong statement against pharmacists dispensing Paxlovid. Many physicians were questioning the overall implications of this. She wanted to know if Hawaii Medical Board and the Board were aware of the statement.

EO Teshima asked if HPA came up with another statement.

Ms. Sanders answered no and stated that the AMA statement is a legal interpretation and HPA was waiting for the Board's meeting before releasing information on HPA's website.

Chair Isobe stated that the FDA's article is a permissive authority related to Amendment 9 of the PREP Act. Pharmacists' can prescribe Paxlovid and expand access to this medication.

EO Teshima reassured Ms. Sanders that the Hawaii Medical Board is aware of allowing pharmacists to prescribe Paxlovid.

Chair Isobe asked the audience if anyone would like to testify on this agenda item.

Staff reported that there was none.

### **Hawaii Pharmacists Associations**

Ms. Sanders shared that the HPA has completed their draft for a bill to address Medicaid payment for pharmacists who provide cognitive services. She stated that the bill does not expand the pharmacist's scope of practice, but is seeking reimbursement for services already being provided. It will increase access to care and the bill will give the pharmacist the payment that they need to continue to provide care to the community and increase public health.

Ms. Sanders noted that related to the September 30th general meeting, they have chosen Michael Murphy from the American Pharmacist Association, advisor for state government affairs, will speak about the public health initiative and other national initiatives that Hawaii can be a part of.

Regarding the overturn of Roe vs Wade, Ms. Sanders asked the Board if there will be any guidance or documentation purposes on abortion related bills in Hawaii.

EO Teshima stated that the Supreme Court's decision to overturn Roe vs. Wade did not affect our State law, but removes the constitutional protection. The State of Hawaii remains status quo unless the Legislature amends the statutes. The Hawaii Revised Statutes that refer to abortion is the Hawaii Medical Board's Chapter 453 and the Board of Nursing's Chapter 457. EO Teshima noted she is not aware of any legislation to be introduced in 2023 by organizations or by the Medical or Nursing Boards to change the situation.

Ms. Sanders referred to the previously discussed working group, and asked if there

would be an interest in a pharmacist working group being created that would address and discuss national initiatives when they arise before the monthly Board meetings.

Chair Isobe asked the Board if they had further questions.

Vice Chair Adams asked if there are any other initiatives HPA is evaluating participating in.

Ms. Sanders noted that HPA must consider how they utilize their manpower which causes issues taking on many initiatives. Ms. Sanders added that HPA is willing to provide input and support other initiatives.

Chair Isobe announced the next agenda item and asked if anyone attending wished to address the Board.

There being no further discussion, Chair Isobe asked for a motion to move into executive session.

Executive Session:

At 9:47 a.m., upon a motion by Vice Chair Adams, seconded by Ms. Cross, 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 professional or vocational licenses cited in section 26-9 or both, and, to consult with the board's attorney on questions and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities.

At 11:19 a.m., upon a motion by Vice Chair Adams, seconded by Mr. Kikuchi, it was voted on and unanimously carried to move out of executive session.

Applications:

**Ratification Lists**

Upon a motion by the Chair Isobe, seconded by Vice Chair Adams, it was unanimously carried to approve the ratification lists.

**Applications**

Miscellaneous Permit

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

I. UpScript Pharmacy LLC

Upon a motion by Ms. Tokumaru, seconded by Mr. Kikuchi, it was voted on and unanimously carried to grant the request for reconsideration related to the denial of UpScript Pharmacy LLC application.

Upon a motion by Chair Isobe, seconded by Mr. Kikuchi, it was voted on and carried by majority with all in favor except for Vice Chair Adams

who voted in opposition, a conditional approval of UpScript Pharmacy LLC's application that includes an exclusion of pharmacist Robert Lammle. Mr. Lammle will not be able to dispense or handle Hawaii resident prescriptions under the license issue to UpScript Pharmacy LLC.

Chair Isobe announced the next agenda item and asked if there was anyone attending who wishes to address the Board.

Rafael Del Castillo raised their hand.

EO Skizewski explained to Mr. Del Castillo that if he would like to speak on this settlement agreement, the Board would have to defer this item until a Regulated Industries Complaints Office ("RICO") attorney is present.

Mr. Del Castillo advised the Board that he and his client are available to answer questions that the Board might have. Mr. Del Castillo noted they are not offering testimony and would prefer the Board to go forward by considering the adjudicatory matter.

Chair Isobe asked the Board if they have any further questions.

There were none.

Chapter 91, HRS  
Adjudicatory  
Matters:

Chair Isobe called for a motion regarding the following adjudicatory matter.

Upon a motion by Vice Chair Adams, seconded by Ms. Cross, it was voted on and unanimously carried to approve the following adjudicatory matter:

In the Matter of the Miscellaneous Permit of **Pillpack LLC; PHA 2022-17-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 meeting.

Date: Thursday, August 18, 2022  
Time: 9:00 a.m.  
In-Person: Queen Liliuokalani Conference Room  
King Kalakaua Building, 1st Floor  
335 Merchant Street  
Honolulu, Hawaii 96813  
Virtual: Zoom Webinar

Adjournment:

There being no further business to discuss, the Chair adjourned the meeting at 11:26 a.m.



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Taken by:

/s/ Jaymie Nakama  
Jaymie Nakama, Secretary

Reviewed and Approved by:

/s/ James Skizewski  
James Skizewski, Executive Officer

JS: jn  
8/3/22

Minutes approved as is.

Minutes approved with changes; see minutes of \_\_\_\_\_