BOARD OF PHARMACY

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

MINUTES

<u>Date</u>: August 24, 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")

Catalina Cross, Public Member Kent Kikuchi. Pharmacist

Brandon Rabang, Public Member Sheri Tokumaru, Pharmacist

Members Present

Virtual:

Patrick Adams, Vice Chair Mark Brown, Pharmacist

Staff Present: Lee Ann Teshima, Executive Officer ("EO Teshima")

Shari Wong, Deputy Attorney General ("DAG")

Lorna Eugenio, Secretary Mia Hoang, Tech Support Staff Johnny Li, Tech Support Staff

<u>Guest(s)</u>: Cherylynn Cheng – Walgreens

Virtual Guests: Annie Macapagal

Chelsea – Lanai Community Health Center Cindy Figuerres - Lanai Community Health Center Corrie Sanders – Hawaii Pharmacists Association

Cory Lehano

Erik Abe – HPCA (Hawaii Primary Care Association

Grace Sesi James S

Jared Medeiros - Lanai Community Health Center

Jessica Adams

<u>Call to Order:</u> The agenda for this meeting was posted on the State electronic calendar as required by

section 92-7(b), Hawaii Revised Statutes ("HRS").

The Chair took a roll call of the Board members. After taking roll, quorum was

established, and the meeting was called to order at 9:07 a.m.

Chair's Report: Announcements

No announcements were provided.

Approval of the Minutes of March 30, 2023, Meeting

The Chair asked for a motion in regard to the minutes of the March 30, 2023 meeting.

Upon a motion by Mr. Kikuchi, seconded by Mr. Rabang, it was voted on and unanimously carried to approve the minutes of the March 30, 2023 meeting.

Approval of the Minutes of June 15, 2023 Meeting

The chair asked for a motion in regard to the minutes of the June 15, 2023 meeting.

Upon a motion by Mr. Rabang, seconded by Ms. Cross; it was voted on with the Chair, Mr. Rabang, Mr. Kikuchi, Ms. Tokumaru voting yes and Mr. Brown and the Vice Chair abstaining, to approve the minutes of June 15, 2023 meeting.

The Chair announced the next agenda item as the Executive Officer's report.

Executive Officer's Report:

Public Readiness and Emergency Preparedness Act (PREP Act) Expiration and Update

EO Teshima stated that due the wildfires on Maui, Governor Green has issued an Emergency Proclamation, which includes pharmacists and pharmacies on page 12. This section of the proclamation suspense certain pharmacy laws to allow residents on Maui access to their prescription medications. The wildfires have caused many logistical issues related to providing prescribed medications to patients who have lost their residences and whose pharmacy was destroyed in the wildfires.

Hawaii Pharmacist Association (HPhA)

Corrie Sanders of HPhA was promoted to panelist.

Ms. Sanders stated that HPhA will hold their general meeting on October 13, 2023. Speakers will discuss upcoming potential legislation, including, medical abortions for Pharmacists. HPhA will be sending out information regarding some of the ways pharmacists can help related to the Maui fires. Currently HPhA is directing people to the DOH (Department of Health) website for medical volunteer opportunities. HPhA has members willing to volunteer and help coordinate volunteer response when the time comes.

Ms. Sanders asked if the Board has any information related to emergency response as it applies to the Maui Wildfire.

EO Teshima referred Ms. Sanders to the emergency proclamation and that the Board does not have recommendations at this time.

Mr. Brown suggested the NDMS (National Disaster Medical System) which has disaster teams that include health care professionals who can assist. There are also State health

agencies with health care professionals that respond when a disaster occurs. Mr. Brown urged pharmacists willing to volunteer to coordinate with those entities. NDMS is under United States Department of Health and Human Services.

The Chair announced the next agenda item as further discussion regarding Lanai Community Health Center's Pilot Project.

Board Business

Lanai Community Health Center ("LCHC") Pilot Project Draft Legislation.

Mr. Abe of Hawaii Primary Care Association ("HPCA") was promoted to panelist.

Mr. Abe testified in support of the extension of the pilot project and requested the Board support the concept of telepharmacy as demonstrated in the project and to extend the authority for the project to operate until June 30, 2024.

Mr. Abe noted that as directed by the Board at the June 15, 2023, meeting, HPCA worked with LCHC to draft proposed legislation that would provide the statutory authority to continue its telepharmacy operations. As a demonstration pilot project, the Board, and the Department of Public Safety's, Narcotics Enforcement Division (NED), required LCHC to obtain a pharmacy license for the purpose of operating the telepharmacy project. This necessitated a comprehensive review of the policies and procedures to be used. Inspection of the site where the medications will be stored, secured, and dispensed and the technology that will be used in supervision of staff activities by the licensed pharmacist on another island. The proposed bill as currently drafted, ensures that the same standard be applied.

Mr. Abe added that because of concerns that the proposed legislation would make telepharmacy available to areas other than geographically isolated ones, the bill would only be applied to federally qualified health centers (FQHC) situated within the State of Hawaii. There are currently only 14 in the state, seven on Oahu, two on the Big Island, two on Maui, and one each on Lanai, Molokai, and Kauai. Based on discussions with our member FQHCs, other than LCHC, only two, one on the Big Island, the other on Maui are looking into the feasibility of doing something similar to the LCHC project. However, both have indicated reluctance because of the regulatory complexity involved and the difficulties experienced in working with pharmacy benefit managers. It should be noted that unlike pharmacies in the private sectors, FQHCs are required by Federal law to utilize any savings or profits gained specifically for the direct benefit of the current or proposed patient population. This would be in the form of reductions in any co-payments or the provision of additional health care services to patients. This project solely benefits the patients of LCHC. The HPCA has already had discussions with lawmakers who have indicated their willingness to introduce legislation and shepherd it through the process. While the rule of thumb is that any new bill takes between two or three sessions to be enacted, it is our hope that this bill can be approved during the 2024 Hawaii State Legislature. As such, we ask that the project be continued to June 30, 2024. Which would occur after bill signing deadline and following the 45 days the Governor would have to lead to any measure that was approved.

The Chair asked if there were any questions from the Board for Mr. Abe.

Mr. Kikuchi asked if he knew the reason Rainbow Pharmacy does not participate in the 340B program.

Mr. Abe responded that it is his understanding that they do not want to participate in the 340B program for administrative burdens that the program involves. The program did engage Rainbow Pharmacy to see whether they would be willing to participate as a 340B participant. They declined at that time. Back then very little pharmaceuticals were being prescribed by LCHC. LCHC made up of 20% of the patient based on the island. However, after they declined, LCHC began figuring out the logistics involved with putting together telepharmacy. When COVID hit, patients on Lanai began to flock LCHC. Today, approximately 75 to 80% of the patients on the island go to LCHC. With the success of the tele pharmacy program, more of the market share shifted away from Rainbow Pharmacy over to the federally qualified health center. That resulted in a lot of concerns and a lot of angry phone calls being made by Rainbow Pharmacy to LCHC. As mentioned in the testimony, federally qualified health centers are restricted on the use of any profits. By Federal law, any sort of profits must be embedded back into the benefits for the patients. LCHC's main concern is trying to improve the benefits and the health care outcomes of the patient.

Mr. Kikuchi asked if with the new volume and the new numbers, has anyone approached Rainbow Pharmacy and try to include their support of Lanai Community Health Center.

Mr. Abe stated, that because of the prior leadership at LCHC, there was some bad blood that had come about from the initial discussions. Since there has been a change in leadership at LCHC, whether current management at the center would be willing to engage them remains to be seen. Mr. Abe added that he thinks that a possibility might be there but because LCHC has put in so much time, effort, and resources into this existing program, it's their position that they want to continue to make it work.

Mr. Brown asked if LCHC, ever fill scripts that are not included in the 340B program.

Mr. Abe responded it's almost solely 340B. Mr. Abe couldn't confirm or deny whether there are other prescriptions but, most of the patient based at a federally qualified health center, are going to be Medicaid patients. It is primarily as a Medicaid provider that they would be involved 340B.

Mr. Adams noted that as volume has increased and even though the funds are redistributed, there is a profit on 340B prescriptions that pays for labor. As volume goes up, there is the ability to pay an in-house pharmacist. Mr. Adams noted his concern that Lanai has a pharmacy on island who may vacate based off another business because it will go out of business. We'll lose out on that island pharmacy and not only will the island lose the pharmacist to prescriptions, patients will lose all the consultation that that pharmacist does over the counter for free. It sounds like the business is moving over from Rainbow to the 340B without a pharmacist. Mr. Adams concluded that he thought it is a positive thing having a pharmacist on the island.

Mr. Abe responded that it is already occurring. Ultimately, if 80% of the population base is shifting over to the federally qualified health center. It shoes that the federally qualified health center is able to provide needed medications at a cheaper cost and quicker turnaround time. The reason why LCHC choose to pursue a telepharmacy program, was because there was no pharmacy on the island that would participate in the 340B program. They must contract a pharmacist on Maui to get that same savings over to those patients, and because of that, they would have to wait a day or two before their medications could be received because they would have utilize the mail. Ultimately, it's a bad situation because of the geography. Business decisions will not always be in the interest of patients. But as a federally qualified health center, our focus is to try to improve the health care outcomes of patients. These patients are a part of a vulnerable population, underprivilege in most cases, and they're also geographically isolated. While it is unfortunate that there may be market impacts on this to commercial entities, Mr. Abe explained if it is truly the role of the Board to be looking after the health and welfare of patient's consideration of continuing the project must be made.

Mr. Adams reiterated that we want to improve the healthcare of the patients and by removing a pharmacist you would not be doing that. Mr. Adams noted Mr. Abe's response related more to a financial outcome instead of a health care outcome. Mr. Adam's added that it's important that we look at what happens to the people of Lanai when they lose their pharmacist. We have these remote places all over the country. For example, we don't have a 340B in Waikoloa. Waikoloa residents must drive 40 miles. If it was Washington State, and they don't have a 340B on some of those islands in Washington State. The remote nature of these areas is a problem, but we've don't put ourselves in a situation where we make healthcare more dangerous and not as fluid for the patient.

The Chair asked if a patient at LCHC is going to be able to fill a prescription faster than Rainbow Pharmacy and is it more expensive for the patient to go to the Rainbow Pharmacy versus LCHC.

Mr. Abe responded in the affirmative. There's nothing to prevent a patient from having their prescription filled at Rainbow Pharmacy. The only issue is Rainbow Pharmacy is not a 340B participant, it will not be able to pass along any of the savings from that program to the patient. So, yes, for ease, if they wanted to go and pay double for their prescriptions, they could. These patients can't afford it, we're trying to figure out ways to get essential medications to the patients. Which is why the federally qualified health center is a participant in the 340B program. This is the reason why the 340B program was established, which is to provide essential medical services and products to patients who cannot afford it.

The Chair asked if the Medicaid copay is zero.

Mr. Abe responded that it would depend. The 340B program works with drug manufacturers who can sell the medications at a reduced cost to certain participating providers. Those savings are passed along to the providers with the understanding that that savings would go back for the benefit of the patients. That's why this program has

been so effective in providing additional medical services and products to patients who are underserved.

The Chair asked if they approached the other FQHCs.

Mr. Abe responded that they are looking into it. Hamakua Community Health Center on the Big Island and the other one is Hana Health are interested. Hana Health has looked at this concept for many years. They currently have worked out an agreement with pharmacists in Hana and they do not believe that a telepharmacy project would enhance their current operations. While they're looking at it, they're not inclined to pursue this. Hamakua Kohala are looking at it a little more in depth but also trying to establish a program with the pharmacy program on that island.

EO Teshima asked about the number of 340B pharmacies in Hawaii.

Mr. Abe replied that he doesn't have a number, but can get that information. Not all the federally qualified health centers participate. All of the hospitals throughout the State are eligible to participate but it's unclear as to whether they participate.

EO Teshima noted that we don't license pharmacies by type. We wouldn't know how many of the pharmacies that are currently permitted in the state are 340B participants. EO Teshima asked, prior to the pilot program, how are patients on Lanai getting their drugs?

Mr. Abe responded that they would get them from Rainbow Pharmacy.

EO Teshima asked if the consumer is a Medicaid patient who wouldn't be able to get their drugs cheaper, they must go to another pharmacy that is a nonparticipating 340B pharmacy and pay more?

Mr. Abe responded in the affirmative. Mr. Abe added that they wouldn't be able to get the 340B discount because the pharmacy would need to be participating in the program.

EO Teshima asked, if there was no 340B pharmacy available on Lanai before the pilot project, how are the patients getting their drugs if they're a Medicaid patient?

Mr. Kikuchi noted that Medicaid patients would be able to get it from Rainbow Pharmacy and have a zero copay. The only difference is that the savings is passed along to the entity. Either the contracted pharmacy along with the health care center, or in this case, the pharmacy would get that business plus the LCHC center gets that discount. Then in return, they put the savings back into their services. So, it's not like a patient sees a cheaper product, they're already paying zero. It goes back into the community center.

Mr. Adams noted his concern with if and how the savings go back into the community. The community also suffers form not having a pharmacist. This issue is not about whether the people pay more.

Mr. Adams explained that in the past the 340B program started to change their rules on

who was able to go to a FQHC and receive 340B benefits. If a patient went to one of the centers, and even though you didn't qualify particularly for that service, you could still be included. It was a slight change in the rules for patients. There was a question about whether all the people that were able, were getting prescriptions in a 340B, were qualified. Mr. Adams noted his experience looking into all the rules and regulations on participating in the 340B program. Mr. Adams concluded that he doesn't see the savings going to the patients, and only sees the loss of a pharmacist.

EO Teshima asked if not all patients on Lanai are Medicaid patients.

Mr. Abe responded in the affirmative.

EO Teshima noted if there was no pharmacy on Lanai when the pilot project was first introduced to the Board and asked if the pharmacy opened later?

Mr. Abe noted that LCHC had a dispensary prior to the establishment of this program. The dispensary gave medication samples. In the process of doing this they received the proper licensure to operate as a pharmacy.

EO Teshima asked while LCHC was only a dispensary, if a non-Medicaid Lanai resident can still go to the facility and get prescriptions filled or did LCHC only service Medicaid patients?

Mr. Abe responded that federally qualified health centers accept any patient, regardless of their ability to pay. Medicaid covers all Medicaid patients. If they're unable to pay but they are not Medicaid eligible then the federal law requires that they be charged on a sliding fee scale based on their ability to pay. That's what LCHC has done all these years.

Mr. Abe noted that one of the things that needs to be stressed ultimately is that the project has one year of experience. LCHC has improved the healthcare outcomes of patients. Patients have been able to get their medications quicker than if they just gotten it through the mail. LCHC is still looking to see whether this is sustainable. LCHC has committed to making this work because patients like the program. They like getting their medications and healthcare at a one place. However, without the Board's support for this program, it's not going to work. We are trying to work with the Board to try to continue this program that has demonstrated it improves the health care outcomes of these patients. Mr. Abe asked for the support of this Board for at least the concept of this project. If the Board cannot support it, we understand, but it's going to have direct impacts on this very small island.

Mr. Adams noted that 340B discounted drugs can go only to 340B eligible patients. Those drugs are not owned by the pharmacy. They're owned by the federal government. The only thing the pharmacy gets is the dispensing fee and administration fee. Anybody else that comes to the pharmacy, there must be another set of inventory. A pharmacy cannot pour out of the same bottle. This is one of the reasons why pharmacists are apprehensive to get involved because of the record keeping inventory between two different inventories in the pharmacy. If caught dispensing those drugs, that you don't own, then obviously you're in serious federal trouble. People that come to the pharmacy that do not qualify for

340B are getting medications from a wholesale location that the pharmacy has bought. There's not supposed to be comingling of medications between non-340B and 340B patients.

EO Teshima asked if between June 2022 and April 2023, LCHC billed five thousand, eight hundred, thirty-eight prescriptions.

Mr. Abe answered in the affirmative.

EO Teshima stated out of those five thousand, eight hundred, thirty-eight, there were a couple of dispensing errors that occurred.

Mr. Abe confirmed the statement.

EO Teshima asked if the number of dispensing errors was two or forty? The report states that errors which were made during process but were caught at verification was thirty-six, and the total number of medication dispensing errors was four.

Mr. Abe noted he will reach out to the pharmacist to confirm the reported numbers and get more information.

EO Teshima asked what has the pharmacy done to correct these procedures to prevent this from happening in the future?

Mr. Abe noted that the discrepancy was the result of some miscommunications regarding controlled substances. The pharmacy benefit manager had required LCHC to obtain a DEA number to provide controlled substances. There were instances where controlled substances were prescribed. However, before they were dispensed, discrepancies occurred. Mr. Abe noted that he will get more information from the pharmacist.

Mr. Adams asked if Rainbow Pharmacy was not there, would you be able to dispense controlled drugs to the population of Lanai?

Mr. Abe responded LCHC would be allowed to dispense controls. LCHC has a DEA number which was an expansion allowed by the Board.

Ms. Figuerres was promoted to panelist.

Ms. Figuerres, interim Director of LCHC, noted their intention is not to have the pharmacist leave. In the beginning, we did reach out to Rainbow Pharmacy who was not interested in participating in the 340B program. This project allowed for the health center to serve as the sole place patients can come to get all their healthcare needs. Any profits gained through the 340B program is put back into the community through social programs. Sliding scale fees are provided to patients related to all provided health care services. The tele-pharmacy project has helped reduce the number of errors to a less than one percent error rate.

Mr. Medeiros Associate Medical Director of LCHC was promoted to panelist.

Mr. Medeiros stated LCHC initially contracted Molokai Drugs to provide 340B prescriptions to patients via mail. Following Molokai Drugs, LCHC did approach Rainbow Pharmacy who declined which resulted in LCHC working with Mauliola Pharmacy. Some patients utilize Humana which is a mail order pharmacy as well as other patients who utilize Veterans Affairs (VA) pharmacies who also mail prescriptions. Some patients are denied by other pharmacies which results in LCHC utilizing 340B program providers to provide services. LCHC can aide patients using 340B participating pharmacies. LCHC has no issues sending prescriptions to Rainbow Pharmacy for those patients who request that service. The more options available to patients is a benefit for the patients. As Lanai is majority privately owned, it is essential LCHC can work independently.

EO Teshima asked if Mr. Medeiros is a medical doctor and if he works out of LCHC.

Mr. Medeiros noted he is a nurse practitioner and works at LCHC full-time. Prior to the project, he would dispense medications directly to patients as needed but adding the telepharmacy project has expanded benefits available to patients.

Executive Session:

The Chair asked if there were any further questions from the Board. Seeing none, at 10:01 a.m., the Chair motion to move into d 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 11:10 a.m., upon a motion by Mr. Brown, seconded by Ms. Cross, it was voted on and unanimously carried to move out of executive session.

Mr. Adams departed the meeting.

Chair Isobe reported that while in executive session, the Board discussed the testimony of Lanai Community Health Center's Cindy Figuerres, Erik Abe, and Nurse Practitioner Jared Medeiros. The Board requests a signed statement regarding specific details about the near misses, actual errors, and the corrective measures taken as detailed by the pharmacist. In Erik Abe's testimony he referred to improved outcomes. The Board requests information from their interim Director or the Lanai Comprehensive Health Care Facility regarding the improved outcomes. The Board requests the list of drugs proposed to be dispensed when pilot project began and what currently is being dispensed. The proposed language is in the drafted bill missed compounding. The Board would like information regarding current compounding and any plans to compound prescriptions. The Board also requests information on how they process the prescriptions that are adjudicated by the Maui pharmacy and dispensed by the clinic on Lanai. The Board deferred any extension request to the October 2023 regular meeting.

EO Teshima clarified that the extension request is deferred until the October meeting. The Board wants more information and want if from the pharmacist, Mr. Medeiros and the

interim Director. The tele pharmacy language for the proposed legislation was deferred as well. The Board has directed EO Tashima to do additional research and consider your pharmacist's testimony at their October 2023 meeting.

Mr. Abe was promoted to panelist.

Mr. Abe noted that they will be present on October 19, 2023, and be prepared to answer all the provided questions.

EO Tashima noted that she will send an email to Mr. Abe outlining the Board's request.

Mr. Abe concluded that they appreciate the opportunity to work with the Board and greatly appreciated all of the support from Ms. Teshima in trying to work this out. As mentioned, for this to work, we must get the support of the Board.. Whatever we can do to resolve any concerns that the Board may have concerning this project, we want to work with you.

Ms. Cross motioned, seconded by Mr. Kikuchi, for the EO to contact the Narcotics Enforcement Division (NED) to get feedback on the pilot project. The motion was approved by unanimous consent.

Mr. Brown asked how the recent fire in Lahaina has affected Lanai.

Jared Medeiros and Cory Lehano were promoted to panelist.

Mr. Medeiros noted that as far as for Lanai, it has hindered getting off the island. Expeditions lost their office and most of their staff members have lost their homes. They quickly geared up into action and started to provide what they could at Maalaea Harbor. Starting next week, they are going to start to resume trips which will allow for same day travel to Maui and back. The fire has hindered some patients getting to medical appointments. It's caused a lot more of strain on Mokulele airline as well, which is already an issue for those trying to get off the island. We already have limited flights and now everyone has shifted to having to get flights. It has impacted us being able to leave island.

Mr. Lehano noted that there will be a very large microscope placed on pharmacy services for the island of Maui. We've been in a lot of the Department of Health and State briefings. There's going be a strong focus on pharmacy because of the dynamics and what's been affected. Both large retail stores have been incapacitated and we are doing our best to serve the needs of the patients in Lahaina. There's no stability and there's no consistency as to current services.

Mr. Lehano added that regarding the project, LCHC pharmacy operates independently. Previously, his 340B contract pharmacy was facilitating prescriptions. LCHC pharmacy runs independent of any pharmacy now. There are no shipments of medications or any ferrying of medications that need to be done. Everything is a completed, processed, and signed out in Lanai. Mr. Lehano will work with the team to make sure that everything is answered accordingly. Mr. Lehano concluded that he is very grateful for the work on this project. LCHC is doing a great service to the island.

Approval of Applications:

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

pharmacies, miscellaneous permits, wholesale prescription drug distributors and pharmacy/miscellaneous permits closures/cancellation, change of PIC, relocations, and name changes.

name chan

Applications:

Pharmacist

DULIN, Matthew

Upon motion by Mr. Brown, seconded Mr. Rabang, it was voted on and unanimously carried to deny the application of Matthew Dulin pursuant to Hawaii Revised Statutes (HRS) section 461-21(a)(5), and Hawaii Administrative Rules (HAR) section 16-95-110(a)(3).

Miscellaneous Permit

Polaris Specialty Pharmacy, LLC

Upon motion by Mr. Kikuchi, seconded by Mr. Rabang, it was voted and unanimously carried to defer this application. The Board requests a summary of all listed disciplinary action of each pharmacist, an active list of pharmacists that is currently employed, clarification on the statement to the Board written by CEO David Rambro.

Best Pet Rx, LLC

Upon motion by Ms. Tokumaru, seconded by Mr. Brown, it was voted and unanimously carried to approve the application of Best Pet Rx, LLC

Election of Chair and Vice Chair – HRS §436B-6.

Upon consensus, it was agreed for motioned to keep Chair Alana Isobe as Chair.

Chair Isobe deferred the election of Vice Chair to the next meeting on October 19, 2023.

Next Meeting:

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

Date: October 19, 2023

Time: 9:00 a.m.

In-Person: King Kalakaua 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 11:34 a.m.		
Reviewed by: /s/ Lorna Eugenio			Taken by: /s/ James Skizewski	
Lorna E Secreta	•		James Skizewski Executive Officer	
LE:js				
10/09/2	023			
[X] []		approved as is. approved with changes.	See minutes of	