

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

MINUTES OF MEETING

Date: Thursday, August 19, 2021

Time: 9:00 a.m.

Place: Virtual Videoconference Meeting – Zoom Webinar

Members Present: Alanna Isobe, Chairperson
Julie Takishima-Lacasa, PhD, Public Member, Vice-Chairperson
Catalina Cross, Public Member
Sheri Tokumaru, Pharmacist
Patrick Adams, Pharmacist
Mark Brown, Pharmacist

Staff Present: James Skizewski, Executive Officer ("EO Skizewski")
Lee Ann Teshima, Executive Officer ("EO Teshima")
Shari Wong, Deputy Attorney General ("DAG")
Kellie Teraoka, Secretary
Phyllis O'Donoghue, Secretary (training)
Erin Emerson, Tech Support Staff
Chelsea Fukunaga, Tech Support Staff

Excused: Kent Kikuchi, Pharmacist

Guests: Allen Bagalso
Berni Middendorf
Brenda Fletcher
Cherylynn Cheng
Cindy Figuerres
Corrie Sanders, Hawaii Pharmacists Association
Diana Shaw, Lanai Community Health Center
E115822
Erik Abe, Hawaii Primary Care Association
Gail Elliott, Guest
Greg Edwards, Hawaii Department of Health
Jared Crumly
Jennifer Ontai
Jenny C.
JGH
Kellie Noguchi
Laura Anderson
Lou Bishop

Maimana Bruce Uzzell
Marcella C
Phone Caller ID
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 9:05 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 July 15, 2021 Meeting

The Chair asked if there were any corrections or discussion of the July 15, 2021 meeting minutes.

There being no corrections/amendments, upon a motion by Ms. Cross, seconded by the Vice-Chair, 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 the pharmacist renewal website will go live on November 8, 2021 and the reminder postcards will be mailed out on November 5, 2021. Due to PVL transitioning to a new system, there have been issues with past renewals for other Board areas, however, we are learning from those experiences and EO Skizewski hopes that the pharmacist renewals will go smoothly.

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 from the Hawaii Pharmacists Association (“HPA”) was in attendance and was promoted to a panelist. She shared that the HPA is working on legislation and wants to keep the Board in the loop. The HPA has two major legislative initiatives that they plan on submitting this legislative session. First, is the permanent expansion of the pharmacist’s scope of practice as authorized by the Public Readiness and Emergency Preparedness (“PREP”) Act. She hopes to keep the permanent rights for anything that has been expanded to the pharmacist’s scope of practice, such as vaccination related rights, after the PREP Act is no longer in place. Second, is the pharmacist’s provider status. Ms. Sanders shared that she spoke with different states to see how they have initiated this. They are not looking to expand the pharmacist’s scope of practice, but to be reimbursed from an insurance provider for things they are already doing in everyday practice.

Ms. Sanders added she attended a recent meeting with the Department of Health (“DOH”) and noted that a few different independent pharmacies and smaller chains are waiting for input from the Board before starting to schedule the third dose of the U.S. Food and Drug Administration (“FDA”) approved COVID-19 vaccine (“vaccine”) for immunocompromised or higher risk patients. Ms. Sanders was under the impression that since it’s under federal guidance, it is okay to proceed. However, some chains are still waiting on guidance from the Board.

The Chair explained the Board previously agreed that the PREP Act preempts any state or local legal requirement which effectively prohibits ordering or administering the vaccine. She added that there currently isn’t anything in the State’s laws or rules that would prevent administering the third dose of the vaccine, if that is what the FDA is recommending.

Ms. Sanders clarified that the point of confusion amongst pharmacists was that other states, specifically with technician immunizations, have stricter rules than what has been put in place on the national level, and is requiring additional training and requirements.

The Chair asked if she is referring to technicians or pharmacists, to which Ms. Sanders replied, “pharmacists”. Ms. Sanders explained that she referenced the technicians because she was trying to figure out where the point of confusion might have been.

EO Teshima stated that they need to refer to PREP Act guidance document on the Board’s website. The guidance document does not specifically refer to the first, second, or third vaccination dose, but it refers them back to the PREP Act. EO Teshima stated that she will review the additional documentation submitted by HPA regarding the Advisory Committee on Immunization Practices (“ACIP”) vaccine recommendations for the influenza vaccine to see if the PREP Act guidance document needs updating. EO Teshima explained that the guidance document on Board’s website refers to ACIP recommendations and guidelines which includes the COVID-19 updates. If they are recommending a third dose, then it does include that under the PREP Act.

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

Staff reported that no one raised their hand.

EO Skizewski announced that the Lanai Community Health Center ("LCHC") was in attendance to request an extension on their pilot project, which was approved earlier this year.

The Chair announced that the Board will address agenda item 3.d. out of order.

Pilot Projects:

Erik Abe, Public Affairs and Policy Director for the Hawaii Primary Care Association ("HPCA"), was promoted to a panelist. He stated that he is in attendance to support LCHC's request to extend their telepharmacy pilot demonstration project. Over the past 6 months, LCHC has done all they could to make the project work. They established protocols and procedures, purchased equipment and trained staff, and despite this they ran into problems with the pharmaceutical distributors and insurers in allowing them to participate. As such, they are unable to provide medications to patients and fulfill prescriptions by telepharmacy. The HPCA strongly supports this concept and believes this could serve as a model not only isolated communities in Hawaii but throughout the nation. The HPCA is closely monitoring this project and will continue to provide support to LCHC and their efforts. The HPCA agrees that more time is needed to see if this concept works and believes an extension is needed to give LCHC the best opportunity to succeed and to compile data to see if the patient outcomes improved over time.

The Chair noted that the Board typically allows a 6-month approval and then will reevaluate and extend accordingly at the end of the period.

Diana Shaw, Executive Director for LCHC, was promoted to a panelist. Ms. Shaw reemphasize how difficult it has been to establish their telepharmacy pilot project and that they have encountered many roadblocks along the way. One issue is that in order to get the Pharmacy Benefit Managers ("PBMs") involved, one is requiring LCHC to be in business for 6-months. Another issue is that when LCHC did their initial pilot study, they agreed to not dispense controlled substances through telepharmacy so they did not require a United States Drug Enforcement Administration ("DEA") registration. However, PBMs are now requiring that they obtain a DEA. LCHC approached the State to obtain a DEA, however they were denied since they are not dispensing controlled substances. LCHC wants to move forward and be able to serve patients, thus requesting for a full year extension because it will allow them time to focus on the project and obtain the proper required permits.

Ms. Cross empathized with the logistical issues that are delaying the process and understands the logistical set up that needs to take place before testing the model to see how effective it is. She agrees that the 1-year extension is reasonable.

The Chair asked for confirmation that LCHC will not be dispensing controlled substances.

Ms. Shaw replied they do not provide controlled substances as it is out of their philosophy. However, due to the PBMs requirement, they are asking for the Board's assistance with working with the State to obtain their DEA. Earlier this week, LCHC's pharmacist and medical manager had an interview with a State representative who refused to move forward since they will not be dispensing and distributing controlled substances.

EO Skizewski asked if the DEA is required for billing purposes?

Ms. Shaw explained that the DEA is required by CVS and Health Mart to become part of the PBM. As they are trying to move forward with enrollment in each one of these programs to be affiliated with the PBM, the DEA permit is required.

The Vice-Chair expressed her support of LCHC's pilot project. She had the opportunity to serve at LCHC and knows first-hand how great the need is and how difficult it can be in neighbor island community with limited resources. The Vice-Chair had a question regarding the pilot study side and if there is an Institutional Review Board ("IRB") or comparable review and oversight that approved this pilot study to begin with?

Ms. Shaw replied that they did not seek IRB's approval because she did not think that they would publish anything. However, since that might change, she will look into it. She thanked the Vice-Chair for raising that concern.

Mr. Adams asked if they have a pharmacist involved in the project? He stated that he has personal experience with this and understands how difficult the process is.

Ms. Shaw explained that LCHC has had an in-house dispensing program, under the guidance of Dr. Cory Lahano, pharmacist of Mauiola Pharmacy on Maui, a 340B contracted pharmacy. Dr. Lahano has always been interested in telepharmacy so LCHC contracted with him to be their telepharmacist. Dr. Lahano set up his own pharmacy and has been functioning under rules and regulations under his authority.

The Chair asked Ms. Shaw if she foresees this project taking more than 6-months.

Ms. Shaw replied that they've had to communicate all of their doing to the National Council for Prescription Drug Programs ("NCPDP"), who is drastically behind. Ms. Shaw anticipates that it will take 2-months before they obtain their DEA, assuming that they can overcome that hurdle. They are actively testing protocols and policies behind the scenes and will not be able to obtain the 6-month data collection needed if the extension is not approved by the Board.

Ms. Shaw added that currently the few controlled substances they have (sinus and cough medication) are locked up in a cabinet. All other prescriptions are sent to the contracted pharmacy, who dispenses it. No controlled substances would come through LCHC however, they are unsure how to prove to the State that they are abiding by that.

The Chair stated that she is aware of other consultant pharmacies that do not dispense controlled substances and believes those entities are participating with CVS. These entities do not dispense a single drug, do not have DEA numbers, and are able to bill for services.

Ms. Shaw added that she has reached out numerous times to McKesson, since they are responsible for Health Mart, and asked them for assistance with Humana and CVS. McKesson stated that they are unable to assist until LCHC gets their DEA.

Mr. Adams suggested that they could tell Narcotics Enforcement Division ("NED") that they plan to dispense controlled substances in order to obtain their DEA but have a locked cabinet with nothing in it. LCHC could use the DEA at a later time if they plan to dispense controlled substances in the future.

The Chair clarified that the Board approved this pilot project with the understanding that LCHC would not dispense controlled substances. The terms are stated in the approval letter and she does not want to put the NED into a position to make exceptions.

EO Teshima wanted to clarify that the Board is NOT making any recommendations on how to "circumvent" any laws, including obtaining a registration with the NED in order to obtain a DEA registration to satisfy the PBM's requirement for reimbursement.

Mr. Adams clarified that he meant to suggest obtaining a full license, not to circumvent any laws.

EO Teshima explained that it is her understanding that there are other options besides a DEA registration such as obtaining a National Provider Identifier ("NPI") number.

Ms. Shaw confirmed that they already have an NPI number and the distributors will not accept that.

EO Teshima asked Ms. Shaw to provide the contact information of those she has been communicating with so that the Board can reach out.

EO Teshima was told that an NPI number can be used in lieu of a DEA so she is a little concerned why they are unable to get what they need with an NPI number.

Ms. Shaw thanked EO Teshima for the suggestion and will try to list the NPI number into the document to see if it will be accepted.

Mr. Brown asked if they are having issues with the PBM side or wholesaler side?

Ms. Shaw responded that she is having issues with both. Their wholesaler account is set up and they are going through the wholesaler's organization which connects to the various PBMs. However, Health Mart, which is the wholesaler group that connects to the PMBs isn't connected to Humana Pharmacy, so they have to do that one separately. CVS Caremark also has a separate pre-application. There are 3 entities that will not proceed without the DEA.

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

Staff reported that no one raised their hand.

Upon a motion by Ms. Cross, seconded by the Vice-Chair, it was voted on and approved by a majority, with the exception of Mr. Adam who voted, "no", to approve the 1-year extension of LCHC's pilot project.

The Chair requested a 6-month update to be provided to the Board in February 2022.

The Chair resumed the agenda in order.

RICO Proposed
Pharmacy Advisory
Committee Members:

EO Skizewski explained that a list of proposed advisory committee members was provided to the Board from the Regulated Industries Complaints Office ("RICO"). RICO uses these members to advise on cases they are investigating regarding pharmacies or pharmacists.

Mr. Adams stated that he would like a Board member to serve on the advisory committee to provide updates to the Board.

EO Teshima explained that advisory committee members do not assist RICO with all pharmacy cases, only when something is very specific to the pharmacy practice and they need an expert opinion. If a Board member served on the advisory committee at the same time, when reviewing a pending open investigation case, the Board member would not be able to vote on that matter. Board members are normally appointed to the advisory committee after their term on the Board has ended.

DAG Wong clarified that this is not a committee that meets collectively as a group, these are individual persons who may be asked by RICO to assist on an investigation. There is no report of their efforts, as the individuals would be independently solicited by RICO.

Mr. Adams confirmed that he misinterpreted the purpose of the advisory committee, and thought it was a committee group that met regularly to discuss RICO matters.

Upon a motion by the Chair, seconded by Mr. Adams, it was voted on and unanimously carried to approve the list of proposed advisory committee members.

Executive Session: At 9:49 a.m., upon a motion by Mr. Adams, seconded by Ms. Tokumaru, 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".

EO Teshima left the Teams meeting at 9:58 a.m.

Mr. Heatherington joined the Teams meeting at 10:04 a.m.

EO Teshima re-joined the Teams meeting at 10:13 a.m.

Mr. Heatherington left the Teams meeting at 10:15 a.m.

At 10:24 a.m., the Board moved out of executive session.

Applications:

Ratification Lists

Upon a motion by the Chair, seconded by Mr. Adams, it was voted on and unanimously carried to approve the ratification list(s) for pharmacists, pharmacies, miscellaneous permits and pharmacy/miscellaneous closures, change of PIC and relocations.

Applications

Miscellaneous Permit

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

i. Hy-Vee, Inc., dba Hy-Vee Mail Order

Upon a motion by Ms. Cross, seconded by Mr. Brown, it was voted on and unanimously carried to approve the application.

ii. United Apothecary, Inc., dba Riddle Drug

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

iii. Marley Drug, Inc. – Petition for Reconsideration

Upon a motion by the Mr. Adams, seconded by Mr. Brown, it was voted on and unanimously carried to approve the request for reconsideration.

Upon a motion by Ms. Cross, seconded by the Vice-Chair, it was voted on and unanimously carried to approve the application, with the exception of including Brent Clevenger.

Chapter 91, HRS
Adjudicatory Matters:

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

Upon a motion by Mr. Brown, seconded by the Vice-Chair, it was voted on and unanimously carried to approve the following adjudicatory matters:

- a. In the Matter of the Miscellaneous Permit of **BET Pharm, LLC, PHA 2020-151-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1" – "2";
- b. In the Matter of the Miscellaneous Permit of **Tailor Made Compounding, LLC, PHA 2018-6-L**, Settlement Agreement After of Filing of Petition for Disciplinary Action and Board's Final Order and copy of Petition for Disciplinary Action Against Pharmacy Miscellaneous Permit; Demand for Disclosure;

Next Meeting:

There being no further agenda items, the Chair announced the next meeting. All members stated that they are available, except for the Vice-Chair.

September 16, 2021
9:00 a.m.
Virtual

Adjournment:

There being no further business to discuss, the Chair adjourned the meeting at 10:30 a.m.

Taken by:

/s/ Kellie Teraoka
Kellie Teraoka, Secretary

Reviewed and Approved by:

/s/ James Skizewski
James Skizewski, Executive Officer

JS:kt
9/3/21

[X] Minutes approved as is.

[] Minutes approved with changes; see minutes of _____