

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

MINUTES OF MEETING

Date: Thursday, September 17, 2020

Time: 9:00 a.m.

Place: Virtual Videoconference Meeting – Zoom Webinar

Members Present: Alanna Isobe, Chair
Patrick Adams, Pharmacist
Catalina Cross, Public Member
Mary Jo Keefe, RPh, Pharmacist
Sheri Tokumaru, Pharmacist

Members Excused: Julie Takishima-Lacasa, PhD, Public Member – Vice Chair
Kenneth VandenBussche, RPh, BCACP, Pharmacist

Staff Present: Lee Ann Teshima, Executive Officer ("EO")
Shari Wong, Deputy Attorney General ("DAG")
Rochelle Araki, Secretary
Ahlani Quiogue, Supervising Executive Officer
Daniel Jimenez, Executive Officer
Karyn Takahashi, Staff
Terry Akasaka-Toyama, Staff
Kelly Wei, Staff

Guests: Carolyn Ma, Dean Daniel K. Inouye College of Pharmacy
Galen Chock, M.D.
Ashok Kota, Foodland
Marcella Chock, Hawaii Pharmacists Association
Mike Ching, M.D., President, HAAP
Lorri Walmsley, Walgreens
Corrie Sanders, President, Hawaii Pharmacists Association
Alec Daily
Wendy Iwasaki
Ronald Balajadia, Department of Health
Ryan Shiroma
Scott Collins
Tiffany Yajima, SanHi Government Strategies
Marcus Oi
Gavin Sanjume
F. Butler
Albert Denis

Mattison Mason
Cherylynn Cheng
Tim Frost
Keri Oyadomari
Miki Morita
Alyssa
Emily
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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 attendees.

The Chair provided information on internet and phone access for today's virtual meeting.

The Chair took roll call to establish quorum. The Vice Chair and Mr. VandenBussche was excused, all other members being present, quorum was established and the Chair called the meeting to order at 9:04 a.m.

All Board motions requiring a vote were conducted by roll call.

The EO introduced Board staff present.

Approval of Minutes:

Minutes of the February 13, 2020 Meeting

The Chair asked for a motion in regard to the minutes of the February 13, 2020 meeting.

Upon a motion by Ms. Keefe, seconded by Ms. Cross, it was voted on and unanimously carried to approve the minutes as circulated.

Minutes of the August 20, 2020 Meeting

The Chair asked for a motion in regard to the minutes of the August 20, 2020 meeting.

Upon a motion by Ms. Keefe, seconded by Mr. Adams, it was voted on and unanimously carried to approve the minutes as circulated.

New Business:

Pharmacists Administering Immunizations to Minors (3 years old and up) - HHS Amendment to PREP Act

The Chair stated that on August 19, 2020, the Health and Human Services (HHS) issued a third amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.

According to HHS' press release, this action means easier access to lifesaving vaccines for our children, as we seek to ensure immunization rates remain high during the COVID-19 pandemic. The amendment authorizes State-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her State board of pharmacy) to order and administer vaccines to individuals ages three through eighteen years, subject to several requirements:

- The vaccine must be approved or licensed by the Food and Drug Administration (FDA);
- The vaccination must be ordered and administered according to the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedules;
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation;
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

HHS is expanding access to childhood vaccines to avoid preventable diseases in children, additional strains on the healthcare system, and any further increase in avoidable adverse health consequences—particularly if such complications coincide with an additional resurgence of COVID-19.

The EO stated that there are several individuals who informed her that they would be present and would like to provide testimony on this matter and advised everyone that each testifier will have 5 minutes, depending on the number of individuals wishing to testify on this agenda item. She asked that each testifier be concise so that everyone may have an opportunity to speak.

The Chair asked if Dr. Mike Ching was attending to please raise his hand.

Dr. Ching raised his hand.

Dr. Ching, President of HAAP referred to his written submission and expressed concerns regarding the PREP Act to allow pharmacists to immunize minors, stating there could be unforeseen circumstances that may affect the minor's comprehensive health care, including no functioning immunization registry, well care visits that include nutrition and health care, and parents/guardian questions on contraindications.

He also recommended that pharmacists review the vaccine history of the minor, consider contraindications, comply with DOH immunization registry requirements, and report to the minor's medical home.

Ms. Keefe asked if well care visits only include vaccines.

Dr. Ching stated that vaccines were only one part, but that it also includes blood pressure, growth monitoring, etc.

Ms. Keefe stated that a friend went to a Pediatrician, but the Pediatrician did not have the vaccine.

Dr. Ching stated he could not comment as he was not aware of Pediatricians not having access to vaccines.

Mr. Adams asked how many minors don't have access to a Pediatrician.

Dr. Ching stated he did not know.

The Chair stated that with the upcoming flu season, pharmacies can administer flu shots and if the Pediatrician did not order vaccines, including school vaccines that are required to attend school, then this would make it more accessible.

Dr. Ching responded that the medical home is the appropriate place for minors to get the best medical care and that the flu shot is different from a vaccine, but he also encouraged the collaboration between pharmacists and the medical home.

The EO asked if there is a list of Pediatricians that parents/guardians can refer to if they do not have a Pediatrician?

Dr. Ching stated there was none at this time, but that would be something to look into.

Mr. Adams stated that a prescription is required for flu vaccines and that the Board should consider removing the prescription requirement.

Ms. Cross stated that as a public member of the Board, she is concerned with access to care and how can minors not covered under Quest still get vaccinated.

Dr. Ching stated that there is a vaccines for children program.

There being no further discussion or questions for Dr. Ching, the Chair called on Dr. Galen Chock and asked if Dr. Chock was attending to please raise his hand.

Dr. Chock referred to his written submission and added that a Pediatrician that does not have vaccines may refer patient to the pharmacy or medical clinic and that a list of Pediatricians may be problematic as it will also depend on the health plan.

Dr. Chock also added that this was not an “access” issue and that flu shots is a separate issue.

There being no further discussion or questions for Dr. Chock, the Chair asked if there was anyone representing the Department of Health to please raise his/her hand.

Mr. Ronald Balajadia raised his hand.

Mr. Balajadia stated he wanted to report on the status of the State Immunization Registry. He stated that the registry has been down for approximately 2 years but that they are testing a new program to go live in the next few weeks.

The EO asked if DOH was receiving immunization data from pharmacists administering to 11 – 17 and 14 – 17 years old as the law requires pharmacists to report to the DOH immunization registry as well as to the medical home.

Mr. Balajadia stated they have received information by fax or email.

There being no further discussion or questions for Mr. Balajadia, the Chair asked if anyone representing the Hawaii Pharmacists Association to please raise his/her hand.

Ms. Marcella Chock and Ms. Corrie Sanders raised their hands.

Ms. Chock stated that the Hawaii Pharmacists Association offers ACPE approved immunization training that meets the HHS standards/requirements that consist of twenty (20) hours of which 8 hours are in person.

Ms. Keefe asked if the 20 hours include administration to babies?

Ms. Chock said no.

Mr. Adams stated that as a APhA trainer, there is not a lot of hands-on training, especially for 3 year olds and although a pharmacist may have gone through the training, some pharmacists may lack the confidence to administer to minors.

Ms. Chock responded that they don't train by injecting oranges and are aware of this issue and provide as much training to ensure that the pharmacists is confident to perform this activity.

Ms. Sanders stated that not every pharmacist may wish to administer vaccines to minors and that there are good resources for online and in-person training.

There being no further discussion or questions for Ms. Chock or Ms. Sanders, the Chair asked if there was anyone from the Daniel K. Inouye, College of Pharmacy to please raise his/her hand.

Dean Carolyn Ma raised her hand.

Dean Ma referred to her written submission.

Ms. Keefe asked if there was a distinction between administering vaccines and the flu vaccination?

Dean Ma stated no.

The EO stated that the PREP Act requires a completion certificate of the immunization training and if the DKICOP would be able to issue documentation for the pharmacy interns in compliance with the PREP Act.

Dean Ma stated yes, the college will be able to issue a completion certificate and stated that the college will also be able to administer vaccines to minors vs. a pharmacy.

There being no further discussion or questions for Dean Ma, the Chair asked if anyone else attending would like to provide testimony on this agenda item.

Ms. Walmsley from Walgreens raised her hand.

Ms. Walmsley stated that they support the HHS guidance to allow pharmacists to administer vaccines to minors and will work collaboratively with the medical home or the current person of record for which they have a collaborative practice agreement.

Mr. Kota from Foodland raised his hand.

Mr. Kota asked for guidance from the Board for pharmacists to administer vaccines to minors pursuant to the PREP Act, including but not limited to if a prescription is required, training requirements and reporting requirements.

The Chair stated that the HHS' guidance provides immunity to a pharmacist who administers vaccines to minors pursuant to certain requirements and that state law cannot prohibit pharmacists from doing so.

Mr. Adams agrees and acknowledges the concerns raised by the Pediatricians that there are safety and access issues, but that there are also barriers to access for this service.

Ms. Cross stated that this guidance provides for more access for minors to receive immunizations and that pharmacists should work collaboratively with the patient's medical home or ensure a primary care provider through a collaborative practice agreement if the patient does not have a medical home.

Ms. Tokumaru agrees that this guidance increases access to health care, whether it be the flu or other vaccination and that it is important for pharmacists to have access to the DOH immunization registry and check with the patient's medical home to check the immunization history of a patient.

Ms. Keefe agreed that this guidance would provide more access to care and that it is essential for pharmacists to work collaboratively with the patient's medical home and other health care professionals.

The Chair stated that this guidance requires pharmacist to report to the medical home, and allows a pharmacist to prescribe and administer a vaccine but also encourages pharmacists to work collaboratively with the patient's medical home and check the vaccine history of a patient before administering the vaccine.

The EO added that this guidance also allows a pharmacy intern to administer a vaccine to a minor under the supervision of a pharmacist.

Mr. Adams asked if completion of the continuing education/training is required before a pharmacist administers the vaccine to a minor.

The Chair said yes.

Mr. Adams clarified that the training course has to be completed within the 2 years of the current biennium.

Ms. Sanders stated that the training requirement appears to be aligned with the state's renewal cycle.

Ms. Yajima asked if a pharmacist can administer the vaccine to a minor if the pharmacist has a collaborative practice agreement.

The Chair stated that if the collaborative practice agreement was specific to administering vaccines to minors and that the pharmacist should still be reporting to the patient's medical home.

The DAG clarified that the PREP Act guidance is not amending the HRS definition of "Practice of pharmacy" in Chapter 461 and that the HHS' PREP Act overlays on top of the pharmacy practice and that a collaborative practice agreement although not necessary to administer to minors, is preferable and that this guidance does NOT amend HRS Chapter 461.

There being no further discussion, the Chair moved on to the next agenda item.

Anonymous Complaint on Pharmacist's Workload

The Chair summarized a letter from a "Concerned Pharmacist" regarding the working conditions he is forced to endure that can result in misfills and an unhealthy working environment for pharmacist and pharmacy technicians due to the demand placed on them by CVS.

The Chair stated that this has been an issue raised and that the Board should revisit this matter.

There being no further discussion, the Chair moved to the next agenda item and asked if Mr. Wheatland was in attendance to please raise his hand.

Staff stated that no one raised their hand.

Does a Pharmacist Have the Legal Authority to Require a Prescription for an OTC Product – Additional Question from Mr. Rand Wheatland

The Chair stated that Mr. Wheatland had additional questions and comments and requests the Board response to his email below:

“My question was not whether a prescription is required for an OTC product. It was whether a pharmacist has the legal authority to require a prescription for an OTC product.

Is the board's official response yes or no?

If the board's official response is yes, a pharmacist can require a prescription for an OTC product, in the interest of safety, as authorized by state legislation, "Practice of pharmacy," what due process protections are provided to the person that is being deprived of the medication? As you should be aware, the 5th Amendment to the United States Constitution and Point 4 of the Hawaii Constitution Preamble require that "No person shall be deprived of life, liberty or property without due process of law." If no due process is provided to contest the pharmacist's deprivation decision, then the pharmacist's actions are unconstitutional and illegal. Furthermore, the Board of Pharmacy is violating people's constitutional rights by allowing it.

Is the Board authorizing that pharmacists have unappealable authority?"

Mr. Adams stated that this is not addressed in the pharmacy practice act as the practice of pharmacy pertains to drugs that require a prescription.

Ms. Cross agreed.

Ms. Keefe stated that in response to Mr. Wheatland's question if a pharmacist has the legal authority to require a prescription for an OTC product, then the answer is no.

Ms. Tokumaru said she had no additional comments as the Board already responded to Mr. Wheatland but added that in response to his specific question, the answer is that it is not addressed in the pharmacy practice act, however a pharmacist can use his/her professional judgement considering the safety of the patient.

The Chair agreed that a prescription is not required for an OTC and that prescriptions for an OTC is not addressed in the pharmacy practice act. The pharmacy cannot require a prescription, but they do not have to sell it and the Board cannot mandate it. The FDA

has guidance on this drug but if the pharmacist has concerns then they do not have to sell it and the Board cannot make them sell it.

The DAG recommended that if Mr. Wheatland has any further questions, that in order for the Board to respond, he will be asked to appear.

The Board took a vote regarding the DAG's recommendation with the Chair, Mr. Adams, Ms. Cross and Ms. Tokumaru voting yes and Ms. Keefe voting no. The motion carried.

It was the consensus of the Board that in response to Mr. Wheatland's specific question, a prescription is NOT required for an OTC product.

There being no further discussion, the Chair announced that the Board will be reviewing applications and asked for a motion to move into executive session.

Executive Session:

At 11:02 a.m., upon a motion by Ms. Keefe, seconded by Ms. Tokumaru, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 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 11:22 a.m., upon a motion by Ms. Cross, seconded by Ms. Keefe, it was voted on and unanimously carried to move 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 lists.

Applications

Miscellaneous Permit

Upon a motion by Mr. Adams, seconded by Ms. Keefe, it was voted on and unanimously carried to deny the following application for Miscellaneous Permit pursuant HRS §§461-21(a)(1) and 436B-19(13) as the Board had concerns with the applicant's "no" response to question #3 on the application that conflicted with the information provided:

Drug Depot, LLC, dba APS Pharmacy

Pharmacist

Upon a motion by Mr. Adams, seconded by Ms. Cross, it was voted on with the Chair, Mr. Adams, Ms. Cross, and Ms. Tokumaru voting yes and Ms. Keefe voting no to defer making a decision on the following application until more information, as requested, is received:

Andrew J. Scott

The motion carried.

Chapter 91, HRS
Adjudicatory Matters:

At 11:32 a.m., the Chair called for a recess of the meeting to discuss and deliberate on adjudicatory matters.

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

In the Matter of the Miscellaneous Permit of **American Specialty Pharmacy Inc., dba ASP Cares; PHA 2019-81-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 **Wells Pharmacy Network LLC; PHA 2020-29-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1" – "2"; Declaration of a Representative of Wells Pharmacy Network LLC

In the Matter of the Miscellaneous Permit of **Coram Alternate Site Services Inc., dba Coram CVS/Specialty Infusion; PHA 2020-113-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 **Diabetic Care Rx, LLC; PHA 2017-63-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1" – "10"

In the Matter of the Miscellaneous Permit of **Healthcare Specialty Transaction Services, LLC; PHA 2019-57-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1" – "4"

In the Matter of the Miscellaneous Permit of **LLC Patient Services Inc.; PHA 2020-150-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 **Inverness Apothecary Trinity, LLC, dba Inverness Apothecary Trinity; PHA 2020-67-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

Next Meeting:

Thursday, October 15, 2020
9:00 a.m.
Virtual

The Chair asked if everyone would be able to attend. All members said yes.

Adjournment:

There being no further business to discuss, the Chair adjourned the meeting at 11:40 a.m.

Taken by:

/s/ Lee Ann Teshima
Lee Ann Teshima
Executive Officer

Minutes approved as is.

Minutes approved with changes; see minutes of _____