

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

MINUTES OF MEETING

Date: Thursday, February 14, 2019

Time: 9:00 a.m.

Place: **Daniel K. Inouye College of Pharmacy – New Location**
722 South A’ohoku Place
Joseph M. Long Pavilion #1 (LPLH1)
Hilo, Hawaii 96720

AND

Daniel K. Inouye College of Pharmacy – New Location
677 Ala Moana Blvd., Suite 1025
Honolulu, Hawaii 96813

Members Present: Kerri Okamura, RPh, Chair, Pharmacist
Mary Jo Keefe, RPh, Pharmacist
Alanna Isobe, Pharmacist
Carolyn Ma, Pharmacist
Ronald Weinberg, Public Member

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

Staff Present: Lee Ann Teshima, Executive Officer ("EO")
Shari Wong, Deputy Attorney General ("DAG")
Nohelani Jackson, Secretary

Guests: Corey Fujii, ESI Accredito
Wes Sumida, DKICP
Veronica Morales, DKIP
Kellie Noguchi, Kaiser Permanente
Catalina Cross, Times Pharmacy
Ashok Kota, Foodland
Tiffany Yajima, SanHi/Walgreens
Gurinder Kaur, DKICP
Chris Kamei, CVS Caremark
Justin Machia
Dennis Macaster, Express Scripts
Stacy Pi, Kaiser Permanente
Rene Chavez, DKIP

Carla Felix, DKICP
Patrick Uyemoto, Times
Reece Uyen, Pharmacare Hawaii

Guest from the Daniel See attached list.
K. Inouye UH Hilo
College of Pharmacy
("DKICP") via webcast:

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").

There being a quorum, the Chair called the meeting to order at 9:01 a.m.

Chair's Report **Announcements and Introductions**

The Chair asked the audience to introduce themselves.

Approval of the Previous Minutes –January 17, 2019 Meeting

The Chair called for a motion for the minutes of the January 17, 2019 meeting.

There being no substantive amendments, upon a motion by Mr. Weinberg, seconded by Dr. Ma, it was voted on and unanimously carried to approve the minutes for the January 17, 2019 meeting as circulated.

Executive Officer's **Conferences/Seminars/Meetings**
Report:

NABP Annual Meeting, May 16-18, 2019, Minneapolis, Minnesota
Ms. Keefe to attend.

MPJE Item Review

The Board will not be sending any representatives but will try to do it remotely.

2019 Legislation

The EO provided information on the following bills:

Opioid Antagonist

SB 535 Relating to Pharmacists Prescribing and Dispensing of Opioid Antagonist - This bill clarifies the scope of practice of pharmacists to authorize pharmacists to prescribe and dispense an opioid antagonist to individuals at risk for an opioid overdose or the family members and caregivers of individuals at risk for an opioid overdose or individuals requesting the opioid antagonist – This bill is scheduled to be heard by the Senate CPH tomorrow.

HB 700 Relating to Pharmacists Prescribing and Dispensing of Opioid Antagonist – The companion to SB 535, this bill authorizes pharmacists to prescribe and dispense an opioid antagonist to patients, and family members and caregivers of opioid patients – This bill was heard by the House HLT and IAC, both passed out with a defective date of 7/1/2050.

Vaccinations

SB 203 Relating to Vaccinations – This bill clarifies that pharmacists may perform certain vaccinations or immunizations and are required to maintain immunization records – This bill is scheduled to be heard by the Senate CPH tomorrow.

HB 686 Relating to Vaccinations – The companion to SB 203 – This bill has not yet been referred to any committee.

SB 304 Relating to Vaccinations – This bill authorizes pharmacists to administer vaccines to persons between eleven and seventeen years pursuant to a valid prescription. Specifies requirements pharmacists must meet prior to administering any vaccine to a person between eleven and seventeen years – HMS deferred this bill on 2/4/2019.

HB 900 Relating to Vaccinations – The companion to SB 304 – This bill was heard by the House HLT, IAC and CPC and referred to FIN.

Return for Disposal

SB 808 Relating to Prescription Drugs – This bill authorizes pharmacies to accept the return of any prescription drug for disposal via collection receptacles or mail-back programs; prohibits pharmacies from redispensing returned prescription drugs or from accepting returned prescription drugs in exchange for cash or credit; requires the pharmacist-in-charge to ensure that only authorized reverse distributors acquire prescription drugs collected via collection receptacles or mail-back programs – This bill is scheduled to be heard by CPH tomorrow.

HB 1272 Relating to Prescription Drugs – The companion to SB 808, House HLT passed out with defective date of 7/1/2050.

HB 1443 Relating to Drug Disposal – This bill permits hospitals and clinics with on-site pharmacies, retail pharmacies, and law enforcement agencies to install and maintain take-back collection receptacles for controlled substances – This bill was referred to HLT and CPC.

HB 667 Relating to Health – This bill was originally intended to prohibit pharmacists from accepting prescription drugs for return or exchange once the drug has been dispensed or sold by prescription unless the pharmacist is an authorized collector for the disposal of controlled substances or the prescription drug is recalled – This bill was gutted and amended by HLT to allow for the use of either words or figures to indicate quantity in prescriptions where electronic prescriptions are permitted.

Our Care, Our Choice Act

SB 542 Relating to Health – This bill requires reimbursement for prescriptions issued pursuant to the our care, our choice act, regardless of the prescription drug coverage provisions of the patient's health insurance. Establishes penalties for pharmacies and pharmacists, or their agents, that refuse to honor prescriptions issued under the our care, our choice act – This bill was referred to CPH and JDC.

Pilot Projects

SB 540 Relating to the Board of Pharmacy - This bill allows the Board of Pharmacy to approve pilot and demonstration research projects for innovative applications in the practice of pharmacy under certain conditions – This bill is scheduled to be heard by CPH tomorrow.

HB 75 Relating to the Board of Pharmacy – The companion to SB 540, this bill was heard by HLT and amended to remove the provision that would allow the Board to approve a project that implements a drug take-back program and including a defective date of 7/1/2050. This bill was also heard by CPC, who passed it out unamended and referred to FIN.

Formulary Advisory Committee

HB 153 Relating to the Practice of Pharmacy – This bill establishes the public health and pharmacy formulary advisory committee to advise the Board of Pharmacy in developing a formulary of drugs and devices that a pharmacist may prescribe and dispense. Authorizes the Board of Pharmacy to allow pharmacists to prescribe vaccines as well as drugs and devices from the formulary developed with the assistance of the advisory committee – This bill was referred to HLT, CPC and FIN.

Reimbursement (Insurance)

SB 1210 Relating to Insurance – This bill would, among other things, reimburse pharmacists for practicing within their scope – This bill was heard by CPH and passed with substantive amendments but still includes the reimbursement for “health care provider”.

HB 984 Relating to Insurance – The companion to SB 1210, was amended by CPC that included the removal of the reimbursement and other “nonaccreditation” sections so that this bill now only addresses sections to ensure the State meets NAIC accreditation standards.

Other Board/Pharmacy/Pharmacist Related Bills

SB 548 Relating to Health – This bill authorizes a pharmacy to provide a customized patient medication package to any patient of an institutional facility or any member of the general public, subject to certain conditions – This bill was referred to CPH.

HB 220 Relating to Health – The companion to SB 548, this bill is scheduled for hearing tomorrow.

HB 902 Relating to Loan Repayment for Health Care Professionals – This bill appropriates funds to the DOH for the health care provider loan repayment program administered through the John A. Burns School of Medicine of the University of Hawaii at Manoa; provided that the funds are matched on a dollar-for-dollar basis by a private or another public source – This bill was passed with amendments by HLT and LHE that included changing the appropriation amount, adding RNs and including a defective date of 7/1/2050.

SB 1404 Relating to Relating to Loan Repayment for Health Care Professionals -The companion bill to SB 902 – This bill was amended by CPE and HRE to expand eligible health care professionals under the health care provider loan repayment program administered through the John A. Burns school of medicine to include licensed social

workers, advanced practice registered nurses, and registered nurses. Appropriates funds for the Hawaii rural health care provider loan repayment program administered through the John A. Burns School of Medicine of the University of Hawaii at Manoa; provided that the funds are matched on a dollar-for-dollar basis by a private or another public source and a defective date of 7/1/2050.

SB 507 Relating to PBMs – This bill requires pharmacy benefit managers to notify contracting pharmacies of changes to maximum allowable costs for any drug, identified by its National Drug Code, fifteen days prior to the change. Requires pharmacy benefit managers to disclose where an equivalent drug can be obtained at or below the maximum allowable cost, when a maximum allowable cost appeal is upheld on appeal. Requires pharmacy benefit managers to: allow contracting pharmacies to reverse and rebill claims if the pharmacy benefit manager establishes a maximum allowable cost that is denied on appeal; and pay the difference to the contracting pharmacies. Permits contracting pharmacies to decline to dispense a drug if the reimbursement is less than the acquisition cost. Permits the insurance commissioner to revoke a pharmacy benefit manager's registration if the manager does not comply with state law. Requires the Department of Health to annually report to the legislature and any other state agency on appeals and disposition – This bill was referred to CPH and WAM.

SB 1401 Relating to PBMs – This bill provides that a pharmacy benefit manager may not prohibit the sharing of an insured individual's cost share for a prescription drug and clinical efficacy of a more affordable alternative drug and prevents penalization of a pharmacy or pharmacist for sharing such information – This bill was amended by CPH to clarify the information provided under the transparency report to the Insurance Commissioner and identifiable to a PBM, is not disclosable as a public record, but permitting the Commissioner to report nonidentifiable aggregated information of multiple PBMs, increased the PBM application, renewal and penalty fees from \$140 to \$500 and including a defective date of 7/1/2050.

HB 1361 Relating to PBMs – The companion to SB 1401 – This bill was referred to HLT, CPC/JUD and FIN.

HB 1442 Relating to PBMs – This bill transfers regulatory jurisdiction for pharmacy benefit managers from the Department of Health to Department of Commerce and Consumer Affairs, including provisions for reimbursement amounts, disclosure of information, complaints process, and enforcement – This bill was passed with amendments by HLT. This bill was also heard jointly by CPC/JUD and passed out unamended and referred to FIN.

SB 1521 Relating to PBMs – The companion to HB 1442, this bill establishes contract, cost disclosure, reimbursement, appeals, and information protection requirements for pharmacy benefit managers that contract with small, independent, and isolated pharmacies. Establishes enforcement jurisdiction in the Department of Commerce and Consumer Affairs – This bill was passed with amendments by CPH and referred to JDC.

SB 202 Relating to Professional and Vocational Regulatory Programs – This bill establishes repeal dates for all professional and vocational regulatory programs under the professional and vocational licensing division of the department of commerce and consumer affairs. Requires the auditor to perform an evaluation of each program prior to repeal – This bill was referred to CPH and WAM.

HB 112 Relating to Taxation – This bill requires a tax clearance before a professional or vocational license may be issued or renewed. Applies to taxable years after 12/31/2020 – This bill was deferred by CPC.

SB 1114 Relating to Taxation – This bill requires a tax clearance before renewal or issuance of a professional or vocational license – This bill was deferred by CPH.

HB 1528 Relating to Commerce and Consumer Affairs – This bill repeals the existing statutory requirement that \$2,000,000 of certain taxes collected on bank and financial corporations be deposited to the compliance resolution fund. Requires adjustments to fees and assessments collected by the Division of Financial Institutions based on the amount of moneys credited to the division in the compliance resolution fund. Establishes criteria to determine the amounts to be assessed for fees and expenses regulated under title 25, HRS. Provides for the reduction or cessation of fees or interest paid into the mortgage loan recovery fund, contractors recovery fund, contractors education fund, real estate recovery fund, real estate education fund, and condominium education fund if the balance in the funds attain a certain dollar amount. Sets the annual fee assessed on cable operators at 4.5% of the income received from subscribers for cable services rendered during the preceding calendar year. Authorizes the Director of the Department of Commerce and Consumer Affairs to reduce the fee if the amount exceeds the amount necessary to administer chapter 440G, HRS – This bill was amended by IAC and referred to FIN.

SB 774 Relating to Professional and Vocational Licensing – This bill prohibits a licensing authority from using rules to supersede requirements set forth in licensing laws and adopting rules that authorize an unlicensed individual to perform duties, activities, or functions that, if performed by another professional, would require licensure of that professional – This bill is scheduled for hearing tomorrow with CPH.

HB 73 Relating to Professional and Vocational Licensing – The companion to SB 774, this bill was referred to IAC, CPC and JUD.

SB 439 Relating to Licensed Professionals – This bill requires the department of commerce and consumer affairs to post the business address and business phone number of each licensed professional on its public website – This bill was referred to CPH.

Amendments to Title 16, Chapter 95

Return for Disposal, HAR §16-95-87

The EO stated that this is on hold until the “fate” of SB 540 or HB 75 Relating to the Board of Pharmacy is known.

Revisions to Pharmacist’s Corresponding Responsibility Guidance Statement - Draft

The EO reported that she is still working on the final draft.

Working Conditions Survey

No change to the last status report.

State Board of Pharmacy ACPE CPE Activity

Ms. Isobe reported that the cost of developing a course for ACPE approval was more than what was indicated and she is still working with ACPE to follow-up on their previous notice to the Board.

Correspondence:

NABP – State News Roundup

- 1/24/19

The Chair asked if there were any questions or items the members wanted to discuss. There were none.

Out-of-State Pharmacy Conducting Wholesale Distribution

The Chair asked Ms. Keefe to lead the discussion on the following email inquiry:

"Mandell's Clinical Pharmacy is a specialty pharmacy in NJ that has a misc permit to conduct business in HI. We have a physician's office who has asked to purchase a supply of fertility drugs to keep in their office for emergency situations with their patients. I have checked online to verify the regs with regards to direct physician sales and I would like some clarification.

The reg below states that unless you obtain a license, wholesaling is unlawful. §461-8.6 Wholesale prescription drug distributor license. It shall be unlawful for any person to operate, maintain, open, change location, or establish any wholesale prescription drug distribution business within the State without first having obtained a license from the board.

Then the description of wholesale distribution states:

"Wholesale distribution" means the transfer of prescription drugs to persons other than a consumer or patient, but does not include: (1) Intracompany sales, defined as any transaction or transfer between an entity and any division, subsidiary, parent, or affiliated or related company under common ownership and control; (2) The purchase or other acquisition, by an institutional facility that is a member of a group purchasing organization, of a drug for use by the entity's patient, from the group purchasing organization or from other institutional facilities that are members of the group purchasing organization; §16-95-2 95-7 (3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law; (4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among institutional facilities that are under common control. For purposes of this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, working rights by contract, or otherwise; (5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this paragraph, "emergency medical reasons" includes but is not limited to transfers of prescription drugs by a pharmacy to

another pharmacy to alleviate a temporary shortage, except that the gross dollar value of the transfers shall not exceed five per cent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any period of twelve consecutive months; (6) The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription; (7) The distribution of drug samples by manufacturers' representatives or distributors' representatives. For purposes of this paragraph, "drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug; or (8) The sale, purchase, or trade of blood and blood components intended for transfusion. For purposes of this paragraph, "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing; and "blood component" means that part of blood separated by physical or mechanical means.

It seems from the description of #5 that direct physician sales would be ok as long as they are less than 5% of the total drug sales of the pharmacy? IF this is ok, is the 5% total sales of the pharmacy in 12 months or 5% of the total sales in HI only. After speaking with a representative from the BOP office, I am including addition information regarding my question below.

We have been aware that other fertility pharmacies in other states have been providing physicians in Hawaii with medications via direct physician sales. It is our practice to verify that we are not in violation of any regulations so we are verifying the question at hand.

NJ state law allows its pharmacies to distribute commercially available medications to physicians for emergency purposes as long as they do not exceed 5% of the total sales during the calendar year.

The physician may not have access to the medications via a wholesale distributor because the medications in question are specialty, injectable medications for the treatment of fertility. Many wholesalers do not carry these medications and often times these wholesalers will only open accounts that are promising high purchase volume. A physician who is looking to store medications for emergency situations is not going to be able to provide said volume.

Fertility patients administration and dosing is based on bloodwork and ultrasound results and often times must be taken during a small window in order to obtain the desired results. For all of these reasons, many reproductive endocrinologists across the US keep a small supply of these medications in their office to administer to patients in emergent situations."

Ms. Keefe stated that:

- A 503A pharmacy requires a patient specific prescription to dispense a prescription drug whereas a 503B pharmacy does not;
- That pursuant to Hawaii's pharmacy practice act, a Hawaii miscellaneous permit is required in order for an out-of-state pharmacy to dispense a prescription drug pursuant to a patient specific prescription;

- That the prescription wholesale distributor's license only applies to in-state wholesale distributors; and
- That under the definition of "Wholesale distribution" it allows for the sale, purchase or trade of a drug for emergency medical reasons, but between pharmacies, not pharmacies and physician offices.

It was the consensus of the Board that in order for a pharmacy to distribute compounded drugs to a physician to be administered/dispensed to the physician's patients would require a wholesale distribution license in the domicile state.

FDA – New Efforts to Support Development of OTC Naloxone

The Chair asked Ms. Keefe to lead the discussion on this agenda item.

Ms. Keefe summarized a statement from the FDA on their efforts to support development of an OTC naloxone to help reduce the opioid overdose deaths. To encourage drug companies to enter the OTC market and increase access to naloxone, the FDA took steps to develop a model drug facts label (DFL) with easy-to-understand pictograms on how to use the drug and also conducted label comprehension testing to ensure the instructions were simple to follow.

U.S.P. 800 Handling Hazardous Drugs

The Chair asked Ms. Keefe to lead the discussion on the email inquiry:

"My name is Amy Cole and I support the Regulatory Services Team at a Government Affairs firm called Stateside. I'm wondering how the Board of Pharmacy intends to handle the U.S. Pharmacopeial Convention's new standard for handling hazardous drugs (HDs) in health care settings (the USP 800). Does the Board of Pharmacy intend to incorporate the standard into rules?"

Ms. Keefe referred to HRS §461-21 that states:

§461-21 Disciplinary action. (a) In addition to any other actions authorized by law, the board may deny, revoke, or suspend any license or permit applied for or issued by the board, in accordance with this chapter, and fine or otherwise discipline a licensee or permit holder for any cause authorized by law, including but not limited to the following:

- (5) Violation of any state or federal drug, controlled substance, or poison law;

She stated that since USP 800 was a federal regulation that it may fall under this section that requires pharmacies to comply with federal drug laws.

The Board concurred with Ms. Keefe's conclusion and determined that specifically requiring compliance with USP 800 was not necessary at this time.

Non-Dispensing Pharmacies

The Chair lead the discussion on the following email inquiry:

"I have a question around licensing a new/potential business venture and want to ensure that the company moves forward correctly and compliantly. The business is considered "non-resident."

I am working with a company launching an FDA approved medication which requires a Rx. The actual prescription is for an "activation code" that will be dispensed (given via text message or email) to patients by network pharmacy. The "activation code", which requires the facility have no onsite physical inventory, will be valid for 35 days which constitutes a normal course of treatment for a single patient. Refills will similarly dispensed by a pharmacy in the form of "activation codes" and valid for an additional 35 days.

Questions we currently have for this type of business venture include:

1. Do you have specific non-dispensing rules for pharmacies that are performing data input, insurance adjudication, benefit investigation similar to HUBs, that carry no inventory?
2. What type of license would this pharmacy need in your state?
3. If regular dispensing pharmacy license required, do the same requirements apply?
4. Are there any other special scenarios/factors we should consider while pursuing this type of permit (i.e. presentation to the board, PIC with state license)?"

After some discussion, it was the consensus of the Board to respond to the questions as follows:

1. Do you have specific non-dispensing rules for pharmacies that are performing data input, insurance adjudication, benefit investigation similar to HUBs, that carry no inventory?

The pharmacy laws and rules do not have language pertaining to "non-dispensing" pharmacies and that since the activities specified in the email fall within the definition of "Practice of pharmacy" a pharmacy license would be required or miscellaneous permit for an out-of-state pharmacy.

2. What type of license would this pharmacy need in your state?

A pharmacy license would be required or miscellaneous permit for an out-of-state pharmacy.

3. If regular dispensing pharmacy license required, do the same requirements apply?

Yes.

4. Are there any other special scenarios/factors we should consider while pursuing this type of permit (i.e. presentation to the board, PIC with state license)?

Not at this time.

OTC Drugs – License Requirements

The Chair led the discussion on the following email inquiry:

"I have a client who is wondering if they need license to hold or sell OTC/nonprescription medications in the state of Hawaii. Thanks for any direction you can provide."

The Chair referred to the definition of "Pharmacy" in HRS chapter 461 that states:

"Pharmacy" means every store, shop, or place:

- (1) Where prescription drugs are dispensed or sold at retail, or displayed for sale at retail;
- (2) Where practitioners' prescriptions or drug preparations are compounded;
- (3) That has upon it, displayed within it, or affixed to or used in connection with it, a sign bearing the words "pharmacist", "pharmacy", "apothecary", "drug store", "druggist", "drugs", "medicines", "medicine store", "drug sundries", "remedies", or any words of similar or like import; or
- (4) Where any of the above words or combination of words are used in any advertisement.

Consequently, it was the consensus of the Board that no pharmacy license was required to sell OTC drugs.

eFaxing Prescriptions/eRx

The Chair led the discussion on the following email inquiry:

"We would like to get some information on eFaxing prescriptions. We have been told by a pharmacy in town that we should no longer be eFaxing prescriptions and should only eRx them. Is this a change in prescribing and sending medications?"

The Chair stated that she was not aware of any changes and also stated that no prescription for C II drugs can be faxed.

It was the consensus of the Board to respond to refer the inquirer to NED.

Conventional Manufacturer License Requirements/Outsourcing Facility Registration

The Chair asked Dr. Ma to lead the discussion on the following email inquiry:

"I am helping a New Jersey based client streamline licensing requirements, and it is not immediately clear what application a dual-registered CONVENTIONAL prescription manufacturer and non-resident 503B/Outsourcing Facility needs. Their primary business activity will be as a conventional manufacturer, but they will have a 503B business unit as well.

They will only be shipping non-patient specific doses to hospitals, they will not be dispensing pursuant to a prescription.

What applications should they fill out to ensure they are compliant?"

Dr. Ma stated that it would appear that since this entity is not a pharmacy but acting as a manufacturer/distributor, then the Hawaii pharmacy laws and rules do not have a specific permit for this activity. However, although Hawaii does not have a license/permit for an outsourcing facility, the out-of-state entity should be licensed/permitted in their domicile state and with the FDA to perform such activity.

The Board agreed.

In accordance with HAR §16-201-90, the above interpretation is for informational and explanatory purposes only and based solely on the information provided. It is not an official opinion or decision and therefore not binding upon the Board.

Remote Data Entry by Pharmacy Technicians

The Chair asked Dr. Ma to lead the discussion on the following email inquiry:

Original email:

"My name is Susan with Empower Pharmacy and I have a pharmacy licensing question. We are currently registered as a non-resident pharmacy with your state. We want to add additional customer service roles to our current location, but are limited on space. We plan to lease office space at a separate address nearby to house our additional customer service and data entry staff. No drugs will be stored or dispensed at this additional location.

The Texas Board of Pharmacy requires that this additional location be registered as a Class G Pharmacy (Central Prescription Drug or Medication Order Processing). This Class G Pharmacy will only serve the patients from our main location. We will not perform any order processing for any other pharmacy. Given this scenario and the fact that our current location is already registered as a non-resident pharmacy, does your state require us to apply for an additional license? If so, what application must we fill out?"

Follow-up email:

“Data entry will be performed by technicians with some pharmacist supervising and taking consultation questions from the call center pharmacy technicians that will also be taking verbal requests for refills and new prescriptions.”

Dr. Ma stated that according to the original email inquiry, although no drugs will be stored or dispensed from that location, outside the premises of the permitted pharmacy, the activity being performed does fall within the definition of practice of pharmacy. However, she also stated that previously, the Board did require a pharmacist to hold a Hawaii pharmacist license in order to perform remote order entry and that if performing this activity within a pharmacy, that pharmacy must hold a Hawaii miscellaneous permit as an out-of-state pharmacy but also allowed for this activity to be performed outside of a licensed/permitted pharmacy.

Dr. Ma also noted that in the follow-up email, besides data entry, “technicians” will also be taking verbal requests for refills and new prescriptions. She stated that although pharmacy technicians may be able to perform these activities, they would be required to be immediately supervised by a registered pharmacist who is physically present in the area or location where a pharmacy technician is working.

After further discussion, it was the consensus of the Board that the activity does fall within the definition of pharmacy scope of practice and if performed by a pharmacy technician, the pharmacy technician shall be immediately supervised by a pharmacist who is physically present in the area or location where the pharmacy technician is working and the activity shall be conducted in a licensed/permitted pharmacy.

In accordance with HAR §16-201-90, the above interpretation is for informational and explanatory purposes only and based solely on the information provided. It is not an official opinion or decision and therefore not binding upon the Board.

License Requirements for Reverse Distributors

The Chair asked Dr. Ma to lead the discussion on the following email inquiry:

“I’m inquiring if we need to apply for a state license for Hawaii. We are a reverse distributor of expired medicines. We have Hawaii as not required to have a state license but I am double checking if we need one.”

Dr. Ma stated recommended referral to the Department of Public Safety, Narcotics Enforcement Division and the DEA.

Prescription Topical Products

The Chair asked Ms. Isobe to lead the discussion on the following email inquiry:

“I am researching applicable state requirements regarding a prescription topical drug product for aesthetic use. I have a few questions about Hawaii’s requirements that I am hoping you can help with:

- Who can purchase and prescribe prescription topical drug products for aesthetic use (e.g., physicians, dentists, nurses, estheticians)?
- Are there any specific requirements for manufacturers of such a drug product before sending the product to an account (e.g., confirmatory steps regarding licensure, record-keeping requirements)?
- Who at an account can sign for receipt of such a drug product (e.g., receptionists)?
- Who can administer such a drug product (e.g., physicians, dentists, nurses, estheticians)?”

Ms. Isobe responded to the questions as follows:

- Who can purchase and prescribe prescription topical drug products for aesthetic use (e.g., physicians, dentists, nurses, estheticians)?

Refer to the appropriate professional Board for prescriptive authority, dispensing/administering to patients.

- Are there any specific requirements for manufacturers of such a drug product before sending the product to an account (e.g., confirmatory steps regarding licensure, record-keeping requirements)?

If distributing prescription drugs, should be licensed as a wholesale distributor in their domicile state to perform such activity. If any controlled substances, need to contact the Hawaii Department of Public Safety, Narcotics Enforcement Division.

- Who at an account can sign for receipt of such a drug product (e.g., receptionists)?

Pharmacy laws/rules do not specifically address.

- Who can administer such a drug product (e.g., physicians, dentists, nurses, estheticians)?”

Again, refer to the appropriate professional Board for prescriptive authority, dispensing/administering to patients.

The Board concurred with Ms. Isobe’s responses.

Questions Regarding Immunization of Children

The Chair asked Ms. Isobe to lead the discussion on the following email inquiry:

“I have some questions regarding the list of approved Pharmacists immunizers for children ages 11-17 years old.

1. How does a pharmacists or their organization know once they have sent in all their information that they are able to immunize in this age group?

2. How often is this list updated on the website and does a pharmacist have to wait till the list is updated on line in order to immunize in this age group? Or is proof that the information was sent to the Board of Pharmacy sufficient (ie, email showing that information was sent)?
3. For organizations that have pharmacists that float to different stores, what would be the best way to list this on the pediatric immunizer website?
4. Can an organization list all pharmacists as possible immunizers without a specific store or location assignment? Many of our pharmacists float or rotate through different stores.
5. What legal ramifications would exist if a pharmacist who is a certified immunizer gives an immunization in this age group before the list is published on the web site?
6. Given that pharmacists can immunize and Hawaii law allows for pediatric immunization, would it be appropriate to not have the pediatric immunizer list published since it is a common practice?
7. Regarding the FAQ's on the CE requirement: The requirement states one hour of continuing education in the area of immunization every 3 years. Should the pharmacist send in the specific CE documentation to the BOP?
8. Is the every 3 year update from the original date of certification, or the last day of a CE? For instance, original certification is 2011 and a pharmacist would like to apply to be on the Approved list of Pharmacists to Immunize Children this year (2019), then is their next CE due by 2022 or immediately if they haven't completed an immunization specific CE within the past 3 years?

Side question, unrelated to immunizations:

Would it be possible to update HRS Statute 16-95-87 Return of Exchange of Drugs Prohibited to include processing returns (albeit not re-dispensing) of recalled medications? There has recently been multiple recalls from manufacturers for commonly dispensed medications (losartan and valsartan) where patients may have received medications from affected lot numbers. Are our pharmacies able to process the return so we can remove recalled medication from the patient and the pharmacy rebill the prescription under the appropriate replacement medication? The returned medications are then returned to the manufacturer for credit or destroyed, never re-dispensed."

After some discussion, the Board responded to the questions as follows:

1. How does a pharmacist or their organization know once they have sent in all their information that they are able to immunize in this age group?

Time permitting, the Board's office will amend the list that is posted on the Board's web site.

2. How often is this list updated on the website and does a pharmacist have to wait till the list is updated on line in order to immunize in this age group? Or is proof that the information was sent to the Board of Pharmacy sufficient (ie, email showing that information was sent)?

Because there is no requirement for the Board to post this list, as long as the pharmacist has completed the required training, they do not have to wait for the list to be updated.

3. For organizations that have pharmacists that float to different stores, what would be the best way to list this on the pediatric immunizer website?

When submitting the completion certificate, the pharmacist can provide the name, address, phone number and PHY number so that we can add them to the list.

4. Can an organization list all pharmacists as possible immunizers without a specific store or location assignment? Many of our pharmacists float or rotate through different stores.

No, the purpose of the list to inform the public where and who can administer these vaccinations.

5. What legal ramifications would exist if a pharmacist who is a certified immunizer gives an immunization in this age group before the list is published on the web site?

As stated earlier, because there is no requirement for the Board to post this list, as long as the pharmacist has completed the required training, they do not have to wait for the list to be updated.

6. Given that pharmacists can immunize and Hawaii law allows for pediatric immunization, would it be appropriate to not have the pediatric immunizer list published since it is a common practice?

Again, the list is not required...see response to question #4.

7. Regarding the FAQ's on the CE requirement: The requirement states one hour of continuing education in the area of immunization every 3 years. Should the pharmacist send in the specific CE documentation to the BOP?

Yes, pursuant to Hawaii Revised Statutes §461-8 Renewal of license; continuing education requirement.

- (e) A pharmacist who administers any vaccine to persons between the ages of fourteen and seventeen years or administers the human

papillomavirus, Tdap (tetanus, diphtheria, pertussis), meningococcal or influenza vaccine to persons between eleven and seventeen years of age pursuant to section 461-11.4 shall complete a training program approved by the board within every other biennial renewal period and submit proof of successful completion of the training program to the board; provided that the pharmacist shall meet these requirements prior to administering any vaccine to persons between the ages of fourteen and seventeen years or administering the human papillomavirus, Tdap (tetanus, diphtheria, pertussis), meningococcal, or influenza vaccine to persons between eleven and seventeen years of age.

8. Is the every 3 year update from the original date of certification, or the last day of a CE? For instance, original certification is 2011 and a pharmacist would like to apply to be on the Approved list of Pharmacists to Immunize Children this year (2019), then is their next CE due by 2022 or immediately if they haven't completed an immunization specific CE within the past 3 years?

See section cited above that the training shall be "completed" within every other biennial renewal period.

Side question, unrelated to immunizations:

Would it be possible to update HRS Statute 16-95-87 Return of Exchange of Drugs Prohibited to include processing returns (albeit not re-dispensing) of recalled medications? There has recently been multiple recalls from manufacturers for commonly dispensed medications (losartan and valsartan) where patients may have received medications from affected lot numbers. Are our pharmacies able to process the return so we can remove recalled medication from the patient and the pharmacy rebill the prescription under the appropriate replacement medication? The returned medications are then returned to the manufacturer for credit or destroyed, never re-dispensed."

There is a bill moving through the Legislative Session that would allow pharmacies to take back drugs for disposal purposes only.

Wholesaler Question

The Chair asked Ms. Isobe to lead the discussion on the following email inquiry:

"I work for a Florida company who will be buying medical oxygen from a Hawaii business and selling to another Florida company which will then sell the oxygen to a U.S. government agency located in Hawaii. Neither company has any physical presence in Hawaii and the Hawaii company which we buy from will distribute the product with its own trucks and employees.

My question is this:

Will my company be required to register for any type of license to distribute medical oxygen? If so, then will the company that I sell to be required to have a license also?"

Ms. Isobe stated that since neither company is located in this State and the pharmacy laws/rules do not require out-of-state wholesale distributors be licensed in this State, then no license/permit is required.

The Board concurred with Ms. Isobe's conclusion.

Central Pharmacy Filling

The Chair asked Ms. Isobe to lead the discussion on the following email inquiry:

"I'm trying to find some information on your laws for central pharmacy filling, but I don't see is in the law book. Would you be able to tell me where I can find that information? If it's not allowed would you be able to tell me why?"

Ms. Isobe stated that the pharmacy laws and rules do not address "central fill" but HRS Chapter 329, the Uniform Controlled Substances Act, defines Central fill pharmacy as, "a pharmacy located in the State that is registered pursuant to section 329-32 to prepare controlled substance orders for dispensing to the ultimate user pursuant to a valid prescription transmitted to it by a registered pharmacy."

It was the consensus of the Board to refer to HRS 329 for the definition of central fill pharmacies and the Department of Public Safety, Narcotics Enforcement Division.

Chapter 91, HRS Adjudicatory Matter(s):

At 10:48 a.m., the Chair called for a recess pursuant to Chapter 91, HRS to discuss and deliberate on the following adjudicatory matters:

In the Matter of the Miscellaneous Permit of **Rx Unlimited LLC; PHA 2017-60-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

Upon a motion by Ms. Keefe, seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the Board's Final Order.

In the Matter of the Pharmacy Permit of **COSTCO Wholesale Corporation, dba COSTCO Pharmacy #667, COSTCO Pharmacy #119, COSTCO Pharmacy #120, COSTCO Pharmacy #140, COSTCO Pharmacy #640, and COSTCO Pharmacy #1038; PHA 2018-35-L, PHA 2018-36-L, PHA 2018-37-L, PHA 2018-38-L, PHA 2018-39-L, PHA 2018-40-L, and PHA 2018-41-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"- "4"

Upon a motion by Ms. Keefe, seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the Board's Final Order.

In the Matter of the Pharmacy Permit of **COSTCO Wholesale Corporation, dba COSTCO Pharmacy #581, COSTCO Pharmacy #562, and COSTCO Pharmacy #570; PHA 201-43-L, PHA 2018-44-L, and PHA 2018-45-L**, Settlement Agreement Prior to

Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"- "4"

Upon a motion by Ms. Keefe, seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the Board's Final Order.

In the Matter of the Pharmacy Permit of **COSTCO Wholesale Corporation, dba COSTCO Pharmacy #583, PHA 2018-42-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

Upon a motion by Ms. Keefe, seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the Board's Final Order.

In the Matter of the Pharmacy Miscellaneous Permit of **Pharmaceutical Care Solutions, Inc, dba Pharmacy Solutions; PHA 2016-44-L**, Settlement Agreement After Filing of Petition for Disciplinary Action and Board's Final Order; Petition for Disciplinary Action Against Pharmacy Miscellaneous Permit; Demand for Disclosure

Upon a motion by Ms. Keefe, seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the Board's Final Order.

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 10:31 a.m.

Executive Session:

At 10:54 a.m., upon a motion by Mr. Weinberg, seconded by Ms. Keefe, it was voted on and unanimously carried to move into executive session pursuant to §92-4 and §92-5(a)(1) and (4), HRS, "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 11:14 a.m., upon a motion by Ms. Isobe, seconded by the Vice Chair, it was voted on and unanimously carried to move out of executive session.

Applications:

Ratification Lists

Upon a motion by Ms. Keefe seconded by Mr. Weinberg, it was voted on and unanimously carried to approve the attached ratification list(s).

Applications

Pharmacy Intern

Upon a motion by the Chair, seconded by Ms. Keefe, it was voted on and unanimously carried to approve the following application for a pharmacy intern permit:

Erica Feldhege

Pharmacist

It was the consensus of the Board to defer the following application for additional information:

Jarrett W. K. Chang

Miscellaneous Permit

Upon a motion by the Chair, seconded by Mr. Weinberg, it was voted on and unanimously carried approve the following application for a miscellaneous permit:

Complete Pharmacy and Medical Solutions LLC

Upon a motion by Ms. Isobe, seconded by Dr. Ma, it was voted on and unanimously carried to deny the following application for miscellaneous permit pursuant to HRS §§461-21(a)(2), (5) & (7) and 436B-19(7), (8), (12) & (13):

Absolute Veterinary Compounding Pharmacy LLC, dba NexGen Compounding Pharmacy

Next Meeting: Thursday, March 21, 2019
9:00 a.m.
Queen Liliuokalani Conference Room, First Floor
335 Merchant Street
Honolulu, Hawaii 96813

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 11:17 a.m.

Taken and recorded by:

/s/ Lee Ann Teshima
Lee Ann Teshima, Executive Officer

2/14/19

[X] Minutes approved as is.

[] Minutes approved with changes; see minutes of _____

Board of Pharmacy Ratification List for February 14, 2019

Pharmacist (PH)

PH 4403 MONIQUE R <LEWIS<

PH 4404 NOLAN N <PERSSON<

Miscellaneous Permit (PMP)

PMP	1573	2825 W ANDREW JOHNSON HWY	MORRISTOWN	TN	37814	FOUNTAIN PLAZA PHARMACY LLC
PMP	1574	250 PROGRESSIVE WAY	WESTERVILLE	OH	43082	PROGRESSIVE MEDICAL, LLC
PMP	1575	7631 EAST INDIAN SCHOOL RD	SCOTTSDALE	AZ	85251	WEDGEWOOD VILLAGE PHARMACY LLC
PMP	1576	10210 WERCH DR SUITE 202	WOODRIDGE	IL	60517	SOLEO HEALTH INC
PMP	1577	2040 W RIO SALADO PARKWAY	TEMPE	AZ	85281	ACCREDITO HEALTH GROUP, INC

SIGN-IN from the Daniel K. Inouye College of Pharmacy – (Remote Location)

722 South A'ohoku Place

Joseph M. Long Pavilion #1 (LPLH1)

Hilo, Hawaii 96720

February 14, 2019 Board Meeting

Name	
Agcaoili, Clifford	
Agochukwu, Ifeanyi	
Almogela, Alyssa-Marie	
Aluoch, Steve	
Anozie, Emmanuel	
Bui, Trang	
Bulatao, Aileen	
Cadiz, Jessica	
Chaffin, Nichole	
Chagami, Brandon	
Dinh, Thai	
Domingo, Lauren	
Domingo, Sean	
El, Angina	
Flores, Raul	
Grant, Michelle	
Guan, Tailai	
Higa, Brooke	
Hiraga, Taylor	
Hoctor, Jake	
Hosseini, Raha	
Huang, Feng Ming	
Huang, Yu Shuan	

Jetley, Patsylynn	
Jones, Matthew	
Joyce, Joseph	
Keshavarz, Melody	
Kimhan, John-Michael	
Kozima, Brandon	
Lee, Da Hai	
Lee, Kevin	
Li, QiXin	
Lin, Kimberly	
Lovesy, Noelle	
Luna, Brittany	
Macaspac, Christian	
Maldonado, Ashley	
Martin, Dario	
McDonald, Josephine	
McMillan, Ryan	
Meno, Bruce	
Min, Jiyoung	
Naeole, Shane-Earl	
Nguyen, Duy	
Nguyen, Lan Thi Hoang	
Nguyen, Nu	
Ogas, Destinee	
Okamoto, Kimo	
Oshiro, Rebecca	
Ostler, Calvin	
Oyas, Minneh	

Pae, Karen	
Palomares Layaoen, Brittney	
Pang, Jaymee-Rae	
Peguese, Jearld	
Phan, Elaine	
Quach, Henry	
Ramos, Tiana	
Ramos, Tiana	
Ranchez, Norlyn	
Salad, Habibo	
Shimizu, Sera	
Sistoza, Maysyvelle	
Siu, Johnson	
Soe, James	
Steiger, Fumiko	
Tanimoto, Deena	
Trinh, Alan	
Vasper, James Dragon	
Villalta, Christian	
Waddell, Donald	
Wong, Karmen	
Wong, Tiffany	
Yamada-Ueda, Jody	
Yi, Janelle	
Young, Tyler	

Dawn Stevens

Patricia Tusezah

Patricia Jr