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

MINUTES OF MEETING

Date: Tuesday, November 15, 2016

Time: 1:30 p.m.

Place: Queen Liliuokalani Conference Room
335 Merchant Street, First Floor
King Kalakaua Building
Honolulu, HI. 96813

Members Present: Kerri Okamura, RPh, Chair, Pharmacist
Mary Jo Keefe, RPh, Pharmacist
Carolyn Ma, PharmD., BCOP, Pharmacist
Garrett Lau, RPh, Vice Chair, Pharmacist
Ronald Weinberg, Public
Julie Takishima-Lacasa, PhD, Public

Members Excused: Marcella Chock, PharmD., Pharmacist

Staff Present: Lee Ann Teshima, Executive Officer ("EO")
Mana Moriarty, Deputy Attorney General ("DAG")

Guests: Fred Cruz, CVS Caremark
Jacqueline Moore, Foodland
Tiffany Yajima, Ashford & Wriston LLP
Pat Adams, Foodland
Stacy Pi, Kaiser Permanente
Albert Lau, Kaiser Permanente
Joe Parriott, Walmart
Andy Diep, Times Intern
Patrick Uyemoto, Times
Tad Ushijima, Aloha Care

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 present, the Chair called the meeting to order at 1:35 p.m. and excused Dr. Chock from today’s meeting.
Chair’s Report: Announcements and Introductions

The Chair asked the audience to introduce themselves.

Additions/Additional Distribution to Agenda

The Chair announced the following agenda items had additional distribution:

Additional Distribution

3. Executive Officer’s Report
d. 2017 Legislative Session
   1) Pharmacist Provider Status Bill – Amended Draft
   2) Practice of Pharmacy Bill – Amended Draft
c. Conferences/Seminars/Meetings
   1) NABP Interactive Executive Officer Forum, October 4-5, 2016, Rosemont, Illinois – EO’s written report on the EO forum that was briefly discussed at the October meeting.

Approval of the Previous Minutes – October 25, 2016 Meeting

The Chair called for a motion in regards to the minutes of the October 25, 2016 meeting.

Ms. Keefe had the following amendments:
- Page 6, last paragraph, second to the last line, insert the word “however” after “but when you report”;
- Page 8, under “Food and Drug Administration – Inter-Governmental Working Meeting, September 2021, 2016, Silver Spring, Maryland”, third line from the bottom, delete the word “So”; and
- Page 13, second paragraph under “Pharmacies Offering Prescription Drug Disposal”, insert the word “to” in the first sentence to read, “In if the Board wants to allow...”.

Upon a motion by Mr. Weinberg, seconded by Dr. Takishima-Lacasa, it was voted on and unanimously carried to approve the minutes for the October 25, 2016 meeting as amended.

Executive Officer’s Report: Controlled Substance Prescriptions

Pharmacist’s Corresponding Responsibility Guidelines – Consideration of Final Draft
The Board reviewed the final draft that included the recommendations discussed at the October meeting.

The EO reported that there was one clarification on the Pharmacist’s “Checklist” pertaining to “Quantity”.

It appears that NED is recommending “Numeric and Alphabetic” be replaced with “Words and Figures” because “numeric” can mean Arabic numbers as well as roman numerals.

The Chair stated HRS §329-38(g)(1) refers to “alphabetically and numerically”.

The EO stated that there were other recommendations that required more information.

Mr. Weinberg questioned the source of information under “Prescription Painkiller Overdoses in the U.S.” and also if the first paragraph should be amended to read as follows:

“According to the Centers for Disease Control and Prevention, unintentional overdose deaths parallel per capita sales of opioid analgesics and is now the leading cause of death among 25-65 year olds in the United States.”

Dr. Takishima-Lacasa stated that it appears the information is from the CDC and DEA.

Mr. Adams stated that the CDC information appears to come from an April 3, 2014 article by Margaret Hamburg, former Commissioner of the FDA.

The EO stated that when the language was recommended there were reference numbers but no actual references, however, she assumed it was self-explanatory when the statement refers to the CDC and DEA and therefore deleted the reference numbers.

After further discussion, the Board deferred the approval of a final draft to the December meeting.

Information from the CDC – Pharmacists: On the Front Lines
The Chair asked if this information from the CDC can be posted on the Board’s web page along with the Corresponding Responsibility document?

The EO stated that she will look into it.

Collaborative Practice Agreement (“CPA”) – Draft of Collaborative Practice Agreement for Naloxone
The EO asked the Board to defer this discussion as she believes the discussion on proposed legislation may address this issue.

Professional Development

There was no distribution for this agenda item.
Conferences/Seminars/Meetings

NABP Interactive Executive Officer Forum, October 4-5, 2016, Rosemont, Illinois
The EO asked the members if they had any questions on her report from the EO forum.

There were none.

NABP Interactive Member Forum, November 30 – December 1, 2016, Rosemont, Illinois
The EO reported that the Chair will be attending this forum.

2017 Legislative Session

Pharmacist Provider Status and Practice of Pharmacy Bills
The EO asked Mr. Adams if he could provide information on the two bills.

Mr. Adams explained that he is part of a working group that was initiated by John Pang to discuss legislation for pharmacist provider status. He explained how the practice of pharmacy bill relates to the provider status bill and how pharmacists provide more immunizations than doctors and that pharmacists should be allowed to provide certain services without a collaborative agreement. Although a collaborative agreement is necessary for certain activities, it should not be for activities such as CLIA waived tests, administration of immunizations and women’s contraception, just to name a few. Mr. Adams further stated that with HMSA moving towards capitation, more physicians may not choose to provide certain services such as women’s contraception out of their office if they are not being paid for these services.

Mr. Weinberg asked if this legislation will keep health costs down?

Mr. Adams said that it is a possibility, and the legislation would provide for more opportunity for health care initiatives to be provided by pharmacists perhaps at a lower cost. He stated that pharmacists have the professional ability and expertise to provide these services and believes that even pharmacy students are being taught assessment training.

Ms. Keefe asked if the practice of pharmacy bill provides prescriptive authority to pharmacists?

The EO explained that the intent of the legislation was to recognize pharmacists as providers so that they could be reimbursed for healthcare services they provide and at the same time recognize that the scope of practice or pharmacy practice needed to be clarified and “updated” to allow pharmacists, who have received the appropriate education and training, to provide such services, whether it is “furnishing” an immunization or women’s contraception without a prescription, making healthcare more accessible.
This bill was intended to mimic the California legislation that was recently enacted that among other things, recognize reimbursement for pharmacists (85% of the fee schedule for physician services under the Medi-Cal program) for services such as furnishing nicotine replacement products and administering immunizations. She also stated that during the legislative hearings for the women’s contraception bill that authorized pharmacists to “prescribe” certain women’s contraception, there was no testimony opposing this section of the bill, however, this bill is subject to further discussion.

Mr. Adams stated that drafts of the bills were submitted to Representative Evans who forwarded them to the Legislative Reference Bureau. The working group will be able to review and provide further recommendations, including the Board and that he hopes that a final draft can be approved in early January. He also stated that the working group will have to start speaking with the stakeholders.

Dr. Ma asked if they needed to start speaking to Legislators.

The EO stated that if any of the Board members would like to help the working group, they are more than welcome to.

Mr. Weinberg asked if other states are doing it better?

Mr. Adams replied that Idaho may have just passed legislation for pharmacist provider status.

The EO mentioned that a survey was sent to the NABP member boards asking which states had pharmacist provider status and that she will share the information/statistics with the Board at the next meeting.

The members had some recommendations to Section 1 of both bills, however, the DAG informed them that this section of the bill would not be included in the statute and is more of a justification.

After some discussion, it was the consensus of the Board that at this time, there were no concerns but that they would need to review the final draft to be sure.

Correspondence:

Intracompany Transfer of Prescription Drugs, HAR §16-95-2

The Chair asked the Vice Chair to lead the discussion on the following email inquiry:

“I am a pharmacy law attorney at Quarles & Brady in Chicago. Can you confirm that the Hawaii State Board of Pharmacy would permit an out-of-state pharmacy, (for example, a pharmacy in the continental U.S., in Guam, or in Puerto Rico), to engage in an intracompany transfer of prescription drugs by shipping the drugs to a Hawaii pharmacy under common ownership?”
That is my interpretation of Haw. Admin. Rule § 16-95-2, which excludes "intracompany sales" from the definition of "wholesale distribution." But I wanted to be sure. Are you aware of any issues if the drug being transferred is a controlled substance?"

The Vice Chair stated that for the transfer of controlled substances, that should be referred to the Department of Public Safety, Narcotics Enforcement Division ("NED"). He also mentioned that HAR §16-95-2 under the definition of “Wholesale distribution” it 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;

He stated that this section did not specify where the entity or pharmacy is located nor does it indicate any license or permit requirement.

Ms. Keefe stated we don’t know if the U.S. territories follow the same standards as the U.S. in tracking the drugs from the manufacturer.

The DAG stated that perhaps the Board does not have sufficient information and should request from the inquirer more specific information.

Mr. Adams stated that this may be a question that falls under a federal government agency as it may be addressing the USP standards.

After further discussion, it was the consensus of the Board that the pharmacy laws are not specific to where the entity is located nor does it indicate any license or permit requirement and therefore, in the interest of public safety, they determined that at this time intracompany transfer of drugs from an entity outside the U.S. is not allowed and that this matter will be referred to the Laws and Rules Committee for further discussion and research.

In addition, the Board refers the inquirer to the Department of Public Safety, Narcotics Enforcement Division for the question regarding the transfer of controlled substances.

In accordance with Hawaii Administrative Rules section 16-201-90, the above interpretation is for informational and explanatory purposes only. It is not an official opinion or decision and is therefore not binding on the Board.
Transfer of Prescriptions from U.S. Territories to Hawaii

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

“I am writing you to clarify the pharmacy law in the area of - Prescription transfers and - NEW Prescriptions from the US Territories of Puerto Rico, US Virgin Islands, Guam, Northern Mariana Islands and American Samoa.

1) Are we allowed to take new prescriptions and prescription transfers from these 5 US Territories? and
2) What rules and regulations govern the prescribing and transfers of these prescriptions to and from these territories? (for example, prescriber requirements)”

Dr. Ma stated this inquiry is similar to the previous inquiry but is asking about the transfer of prescriptions, not drugs. She stated that under HAR §16-95-84 Transfer of prescriptions, indicated below, this section refers to “pharmacies” but does not specify where the pharmacy may be located.

§16-95-84 Transfer of prescriptions. (a) Transfers of prescription information for the purpose of initial fill or refill dispensing is permissible between pharmacies provided the pharmacist transferring the prescription provides all information necessary for a valid prescription, and records on the prescription, the name and location of the pharmacy receiving the prescription, the name of the pharmacist receiving the prescription information, the date of transfer, and the name of the pharmacist transferring the prescription, or notes the pharmacist's name on the electronic files, and records that the prescription is inactivated or made void for future refills at the location from which it is being transferred.

(b) The pharmacist receiving the transferred prescription information shall indicate the name of the pharmacist transferring the prescription as well as the transferring pharmacist’s or pharmacy name, the transferring pharmacy’s name, location, and original prescription number, the original date the prescription was written, the number of refills or quantity remaining on the prescription, and the last date the prescription was filled.

(c) All records of transferred prescriptions shall be maintained for a period of five years from the date of filling or refilling.

The EO asked if the Board should be looking at the prescription to determine if it is “valid” including the prescriber/practitioner definition since the “transfer” laws and rules do not specify where the prescription is coming from?

Dr. Ma referred to the definition of “Out-of-state” practitioner under HRS 328-1 that states:

“"Out-of-state practitioner" means a physician, surgeon, osteopathic physician and surgeon, advanced practice registered nurse, dentist, podiatrist, or veterinarian authorized to prescribe drugs to patients under the applicable laws of any state of the
United States except the State of Hawaii, or a physician, surgeon, osteopathic physician and surgeon, advanced practice registered nurse, dentist, podiatrist, or veterinarian authorized to prescribe drugs under the applicable laws of Hawaii, but practicing in a state other than Hawaii."

She also referred to the following definitions under HRS 461-1:

"Practitioner" means an individual licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the person’s practice.

"Prescription" means an order or formula issued by a practitioner licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the practitioner’s practice, for the compounding or dispensing of drugs or an order or formula issued by an out-of-state practitioner in compliance with chapter 328.

Mr. Ushijima stated that pharmacy students from Guam have a prescription issued from a physician in Guam that is filled by a local pharmacy when the student relocates into this State.

Dr. Ma asked if the prescriber was also licensed in Hawaii?

Mr. Ushijima said yes.

Dr. Ma said that the prescriber may then meet the definition of “Out-of-state practitioner” so the prescription may be filled by a Hawaii pharmacy.

The DAG stated that from the discussion, it appears there is a consensus of the Board that the prescription should be “valid” and that the prescriber should meet the definition of out-of-state practitioner if he/she is practicing out-of-state.

After further discussion, it was the consensus of the Board that based on the pharmacy laws and rules and HRS Chapter 328, the Board determined that Hawaii pharmacies may accept a transfer of a “valid” prescription from an out-of-state pharmacy, regardless of where the pharmacy is located and provided the prescriber/practitioner meets the requirements as an “out-of-state practitioner” (authorized to prescribe drugs in another state of the United States but practicing in a state other than Hawaii).

In accordance with Hawaii Administrative Rules section 16-201-90, the above interpretation is for informational and explanatory purposes only. It is not an official opinion or decision and is therefore not binding on the Board.
Licensure Requirements for FDA Registered Outsourcing Facilities

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

“I am writing regarding the licensure requirements in Hawaii for non-resident FDA registered outsourcing facilities. I have reviewed the Board minutes from 09/17/15 which indicate that an outsourcing facility is not required to obtain a pharmacy license if it is not dispensing patient specific prescriptions. In addition, the minutes state that there is not specific license for outsourcing facilities. However, the description of a Miscellaneous Pharmacy would seem to include outsourcing facilities. The Hawaii website (http://cca.hawaii.gov/pvl/files/2013/06/Require-Instruct-App-for-Misc-Permit-Pharmacy_05.16R.pdf) states the following.

Miscellaneous Permits - ACTIVITIES COVERED UNDER THIS PERMIT Check Business Intended on Application:
• Sale of any prescription drugs at public auction or sale of any prescription drugs at private sale in a place where public auctions are conducted.
• Distribution or dispensing of any prescription drug samples to other than physicians, druggists, dentist, veterinarians and optometrists for use in their professional practice.
• For wholesalers to sell, distribute or dispense any prescription drug to other than pharmacists, physicians, dentists, veterinarians or optometrists.
• For any wholesale prescription drug distributor to sell or distribute medical oxygen to a physician, pharmacist, medical oxygen distributor, patient or patient's agent pursuant to a prescription or emergency medical services for administration by trained personnel for oxygen deficiency and resuscitation.
• For any medical oxygen distributor to supply medical oxygen pursuant to a prescription order.
• For any person, as principal or agent to conduct or engage in the business of preparing, manufacturing, compounding, packing, or repacking any drug.
• For any out-of-state pharmacy or entity engaging in the practice of pharmacy, in any manner to distribute, ship, mail or deliver prescription drugs or devices into the State.

Is the miscellaneous permit only applicable to an entity conducting or engaging “in the business of preparing, manufacturing, compounding, packing, or repacking any drug” within Hawaii and thus would not apply to a non-resident entity conducting or engaging “in the business of preparing, manufacturing, compounding, packing, or repacking any drug”?

Ms. Keefe stated that she read the instruction and requirements for the miscellaneous permit and that it appears only the out-of-state pharmacy category requires submission of documentation to confirm the pharmacy has a valid unencumbered license, but that the category the inquirer is referring to does not have any requirements.
The Vice Chair stated that this is similar to the DME provider issue that the Board previously addressed.

The Chair stated that without specific requirements, how can the Board determine if the compounding facility is legit?.

The EO stated that since there are no specific requirements like the ones listed for an out-of-state pharmacy, it is unlikely that the Board can require anything further if they determine that this section may be applied to outsourcing facilities.

The DAG recommended that the Board consult with their DAG to see if the promulgation of administrative rules was possible to clarify the requirements for this miscellaneous permit category.

Ms. Keefe stated this whole issue about outsourcing facilities is confusing because the federal requirements recognize non-pharmacy entities to compound but they do not consider them a manufacturer but they are required to follow the current good manufacturing practice.

After further discussion, it was the consensus of the Board that in the interest of public safety, because the miscellaneous permit category for compounding does not include any requirements, they are unable to determine if this category applies to outsourcing facilities. The Board also referred this matter to the Laws and Rules Committee for further discussion and research.

In accordance with Hawaii Administrative Rules section 16-201-90, the above interpretation is for informational and explanatory purposes only. It is not an official opinion or decision and is therefore not binding on the Board.

**Accreditation Commission for Health Care (ACHC) Compliance Solutions**

The Chair reported on an email from the ACHC asking the Board to consider accepting the ACHC Inspection Services and the Pharmacy Compounding Accreditation Board standards as proof of a pharmacy being in compliance with USP 795/797 and fulfilling the inspection required for shipping sterile and non-sterile compounds into Hawaii.

It was the consensus of the Board to take this information under advisement.

**Telepharmacy and Independent Business/Pharmacy**

The Chair reported on an email from Cardinal Health regarding the decrease in the number of independent community pharmacies over the past five years and how telepharmacy regulations can allow for more access for residents of this State.

It was the consensus of the Board to take this information under advisement.
Rx Ipsa Loquitor

The Chair reported that the September/October 2016 edition of Rx Ipsa Loquitor included the following articles:

- Legislators Make Efforts to Give Pharmacists Prescribing Authority for Oral Contraceptives in Multiple States
- Featured Case: Sorenson v. Prof'l Compounding Pharmacists of W. PA., Inc. – Florida Court of Appeals Holds Pharmacists Have a Duty Not to Fill facially Unreasonable Prescriptions

NABP News Roundup

The Chair reported that the latest NABP State News Roundup included the following articles:

- Arizona Board* Now Providing Certificate of Free Sale and Good Manufacturing Practice Certificate
- New Hampshire Board: Now Requires PIC Examination; Expands the Scope of Collaborative Practice; Updates Rule Requiring Rest Breaks for Pharmacists; Legislative Work on PDMP Data Upgrade
- North Carolina: Statewide Standing Order for Naloxone in Effect for North Carolina Pharmacist
- South Dakota: Naloxone Bill Update
- Virginia: Legislation Affecting the Practice of Pharmacy; Updates PMP laws

Executive Session:

At 3:25 p.m. upon a motion by Dr. Ma, seconded by Mr. Weinberg, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-5(a)(4), “To consult with the board’s attorney on questions and issues pertaining to the board’s powers, duties, privileges, immunities, and liabilities”.

At 3:28 p.m. upon a motion by Ms. Keefe, seconded by Mr. Weinberg, it was voted on and unanimously carried to move out of executive session.

Applications:

Ratification List

Upon a motion by Mr. Weinberg, seconded by the Vice Chair, it was voted on and unanimously carried to approve the attached ratification lists.

Miscellaneous Pharmacy Permits (PMPs)

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

- Bunch Medical, LLC dba M.D. Pharmacy – John Jones, PH
- Alliance Allergy Solutions, LLC
Next Meeting: The Chair announced the next Board meeting as December 15, 2016 and asked if everyone was available. Members present indicated they would be able to attend the December meeting.

December 15, 2016
9:00 a.m.
King Kalakaua Conference Room
King Kalakaua Building
335 Merchant Street, First Floor
Honolulu, Hawaii 96813

Adjournment: With no further business to discuss, the Chair adjourned the meeting at 3:30 p.m.

Taken and recorded by:

______________________________
Lee Ann Teshima
Lee Ann Teshima, Executive Officer

11/29/16

[ X] Minutes approved as is.
[ ] Minutes approved with changes; see minutes of ________
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Miscellaneous Permits (PMP)

Change of PIC

CA Services Inc. dba Carezone Pharmacy (PMP-1170)
860 Harbour Way S. Ste. E
Richmond, CA. 94804
New PIC: Dao Lieu
Effective: 10/13/16

Walgreens Specialty Pharmacy #16287 dba Kathleen M. Kokoski (PMP-472)
130 Enterprise Dr.
Pittsburgh, PA. 15275
New PIC: Janice Havlik
Effective: 11/1/16

Wells Pharmacy Network LLC (PMP-802)
450 US Hwy. 51 Bypass N
Dyersburg, TN. 38024
New PIC: Diane Raum
Effective: 11/1/16

Closure/Cancellation

American Custom Compounding Pharmacy LLC (PMP-994)
2607 Walnut Hill Ln. Ste. 220
Dallas, TX. 75229
Effective: 11/1/16

Pharmacy (PHY)

Change of PIC

Longs Drug Stores California LLC dba Longs Drugs #9189 (PHY-729)
3-2600 Kaumualii Hwy. Ste. 1100
Lihue, HI. 96766
New PIC: Tasha Medeiros
Effective: 7/31/16

Longs Drug Stores California LLC dba Longs Drugs #9259 (PHY-735)
94-060 Farrington Hwy. #6
Waipahu, HI. 96797
New PIC: Scott Fincham
Effective: 12/1/15

Longs Drug Stores California LLC dba Longs Drugs #9952 (PHY-740)
645 Aleka Lp.
Kapaa, HI. 96746
New PIC: Mathew Mullahy
Effective: 11/22/15
Longs Drug Stores California LLC dba Longs Drugs #9864 (PHY-730)
94-780A Meheula Pkwy.
Mililani, HI. 96789
New PIC: Erika Ruiz
Effective: 3/27/16

Longs Drug Stores California LLC dba Longs Drugs #9206 (PHY-717)
1450 Ala Moana Blvd. Ste. 2004
Honolulu, HI. 96814
New PIC: Caroline Mizo
Effective: 10/23/16

Longs Drug Stores California LLC dba Longs Drugs #7098 (PHY-790)
15-1454 Kahakai Blvd.
Pahoa, HI. 96778
New PIC: Jenna Yamashita
Effective: 10/23/16