BOARD OF PHARMACY

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

MINUTES OF MEETING

Date: Thursday, March 30, 2023

Time: 9:00 a.m.

<u>In-Person</u> Queen Liliuokalani Conference Room

MeetingKing Kalakaua BuildingLocation:335 Merchant Street, 1st Floor

Honolulu, Hawaii 96813

<u>Virtual Videoconference Meeting – Zoom Webinar (use link below)</u>

Participation: https://dcca-hawaii-gov.zoom/us/j/99192770463

Members Present: Alanna Isobe, Chairperson ("Chair")

Patrick Adams, Pharmacist, Vice Chairperson ("Vice Chair")

Mark Brown, Pharmacist Kent Kikuchi, Pharmacist Catalina Cross, Public Member Brandon Rabang, Public Member

Staff Present: James Skizewski, Executive Officer ("EO Skizewski")

Shari Wong, Deputy Attorney General ("DAG Wong")

Leanne Abe, Secretary

Mia Hoang, Tech Support Staff Johnny Li, Tech Support Staff

Excused: Sheri Tokumaru, Pharmacist

Virtual Guests: Corrie Sanders – Hawaii Pharmacists Association

Grace Sesi

Gail Elliot - Kaiser Permanente

Kellie Noguchi

Maimuna Bruce Uzzell Kekoa McClellan

In-Person Guests: Tiffany Yajima – SanHi Government Strategies (A Limited Liability Law Partnership)

on behalf of Walgreens

Cherylynn Cheng - Walgreens

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

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

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A short video was played to explain the meeting procedures and how members of the public could participate in the virtual meeting.

The Chair took a roll call to establish quorum and called the meeting to order at 9:05 a.m. All Board members confirmed that they were present and alone, with the exception of Ms. Tokumaru who was excused from the meeting.

Chair's Report: Announcements

The Chair reported that she will be attending the 119th National Association of Boards of Pharmacy (NABP) annual meeting held in Tennessee from May 10-12, 2023.

Approval of Minutes of the February 7, 2023 Meeting

The Chair asked if there were any corrections or discussion of the February 7, 2023 meeting minutes.

There being no corrections/amendments, upon a motion by the Vice Chair, seconded by the Mr. Brown, it was voted on and unanimously carried to approve the minutes of the open session of the February 7, 2023 meeting, as circulated.

Executive Officer's Report:

2023 Legislative Session

EO Skizewski provided the Board updates regarding the status of the following bills.

1) S.B. 60, Relating to Health

Report Title: Controlled Substances; Prescriptions; Out-Of-State Prescribers **Description**: Authorizes state-licensed and credentialed physicians, advanced practice registered nurses, and physician assistants, who are not physically in the State, to issue prescriptions for certain controlled substances under a limited circumstance. Authorizes pharmacies to dispense the prescriptions.

EO Skizewski stated that S.B. 60 was introduced and referred to the Health and Human Services ("HHS") Committee and Commerce and Consumer Protection ("CPN") Committee but was not heard and the bill "died".

2) S.B. 165/H.B. 1221, Relating to Pharmacists

Report Title: Insurance Coverage; Pharmacists; Reimbursement **Description**: Mandates reimbursement for services provided by participating registered pharmacists practicing within their scope of practice by private and public health plans in the State beginning January 1, 2024.

EO Skizewski stated that there are three (3) bills related to this initiative, the legislature decided to go with S.B. 693 rather than S.B. 165 or H.B. 1221. S.B. 165 and H.B. 1221 were both deferred.

Report Title: Deaf and Blind Task Force; Prescription Drug Label Information; Accessibility; Pharmacies; Board of Pharmacy; Administrative Rules Description: Requires pharmacies to provide accessible prescription drug label information to individuals who have difficulty seeing or reading standard printed

information to individuals who have difficulty seeing or reading standard printed prescription drug container labels and inform the public that prescription drug label information is available in alternate accessible formats for individuals who have difficulty seeing or reading prescription drug container labels. Requires the Board of Pharmacy to adopt certain rules by December 31, 2024.

EO Skizewski stated that S.B. 608 and H.B. 218 are companion bills. S.B. 608 crossed over from the Senate to the House but was not heard by a committee. H.B. 218 passed through both the House and Senate and currently at the conference committee. He stated that if H.B. 218 continues to move forward through legislation, the Board will have to look into adopting new rules. He further stated that he will be reaching out to technology service providers to provide information and insight to the Board.

The Chair questioned a portion of the bill that states:

3) S.B. 608/H.B. 218, Relating to Prescription Drugs

"Dispensing pharmacies shall otherwise follow the best practices as recommended by the United States Access Board for pharmacies in providing independent access to prescription drug label information."

EO Skizewski stated that he will look into that and get back to the Board. He noted that there was a recent amendment to the bill related to hardships of pharmacies with no more than two pharmacists but has not seen the committee report or the amended draft of the bill.

EO Skizewski stated that the Board submitted testimony that expressed concern regarding the mandate of pharmacies to provide accessible prescription drug label information, the types of device readers, the costs to the pharmacies, and the logistical issues with adopting these rules by December 31, 2024, and requested for an extension to December 31, 2025.

The Vice Chair left at 9:12 a.m. and returned at 9:17 a.m.

Corrie Sanders was promoted to panelist.

Ms. Sanders encouraged pharmacists to reach out to their local legislators and/or representatives to request a delay or extension to this bill if it will significantly impact their business.

Corrie Sanders returned to an attendee.

4) S.B. 602/H.B. 659, Relating to Health

Report Title: Diagnostic Testing; CLIA-Waived Tests; Pharmacists; Permit; Education Requirements

Description: Establishes permitting and education requirements for pharmacists ordering or collecting specimens for certain diagnostic tests or tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Expands the definition of "practice of pharmacy" to include the ordering of certain tests and collecting specimens for certain diagnostic or CLIA-waived tests.

EO Skizewski stated that H.B. 659 was passed by the House but did not "crossover" to the Senate. S.B. 602 is currently with the Consumer Protection and Commerce ("CPC") Committee.

Tiffany Yajima attended the meeting in-person and requested to testify on this agenda item. She introduced herself and stated that she is from SanHi Government Strategies (A Limited Liability Law Partnership) on behalf of Walgreens.

Ms. Yajima stated that they are continuing to work with the Board, Department of Health, various labs and stakeholders on amendments to the bill relating to CLIA-waived testing:

- Pharmacists to report the results of the test to a patient's "medical home" (minor patient's pediatrician or an adult patient's primary care provider)
- Pharmacists shall follow all applicable state laws and rules regarding the reporting of diseases to the Department of Health
- 5) S.B. 604, Relating to Health

Report Title: Abortion; Reproductive Health Care Services; Information; Privacy; Protection

Description: Prohibits state and county employees and officers from providing reproductive health care services patient information or expending state resources in furtherance of another state's investigation or proceeding that seeks to impose civil, criminal, or professional liability upon a person or entity related to reproductive health care services. Prohibits any person from being compelled to provide reproductive health care services patient information. Prohibits any persons from being disqualified from licensure or subject to discipline by a Hawai'i board of professional licensure for providing reproductive health care services.

EO Skizewski stated that S.B. 604 was introduced but never heard.

6) S.B. 693, Relating to Pharmacists

Report Title: Insurance Coverage; Pharmacists; Reimbursement **Description:** Mandates reimbursement for services provided by participating registered pharmacists practicing within their scope of practice by private and public health plans in the State after 7/1/2025.

EO Skizewski stated that the Board supports S.B. 693 however acknowledges that

Hawaii Revised Statutes section 23-51 and 23-52, requires a social and financial audit prior to passage of this measure, but notes that advanced practice registered nurses were similarly added as a sole provider pursuant to Act 169, Session Laws of Hawaii 2009, without such an audit.

7) S.B. 1017, Relating to Health

Report Title: Advance Health-Care Directive; Voluntary Non-Opioid Option **Description:** Adds a voluntary non-opioid option to the sample advance health-care directive form. Establishes that a prescription presented or electronically transmitted to a pharmacy shall be presumed valid and grants pharmacists immunity from civil, criminal, and professional liability for dispensing an opioid in contravention of a patient's non-opioid directive.

EO Skizewski stated that S.B. 1017 was heard by the Health and Human Services ("HHS") Committee and was deferred.

8) H.B. 218 (HD2 SD1), Relating to Prescription Drugs Report Title: Deaf and Blind Task Force; Prescription Drug Label Information; Accessibility; Pharmacies; Board of Pharmacy; Administrative Rules Description: Requires pharmacies to provide accessible prescription drug label information to individuals who have difficulty seeing or reading standard printed prescription drug container labels and inform the public that prescription drug label information is available in alternate accessible formats for individuals who have difficulty seeing or reading prescription drug container labels. Requires the Board of Pharmacy to adopt certain rules by December 31, 2024.

EO Skizewski stated that this bill was already discussed earlier in the meeting under 3) S.B. 608/H.B. 218, Relating to Prescription Drugs.

9) S.B. 473 (SD1 HD1), Relating to the Practice of Pharmacy Report Title: Practice of Pharmacy; Dialysate Drugs or Devices; Manufacturers; Wholesalers: Third-Party Logistics Providers; Exemption Description: Exempts manufacturers, wholesale distributors, and third-party logistics providers of home dialysate drugs or devices from the license, registration, and permit requirements for pharmacies, under certain conditions.

Kekoa McClellan was promoted to panelist. He introduced himself and stated that he is from The McClellan Group on behalf of Baxter.

Mr. McClellan provided testimony regarding their support for S.B. 473, as it enables the provider flexibility to not have on-site pharmacist at the licensed distribution warehouse.

The Vice Chair inquired if the provider will be dispensing dialysate drugs or devices directly from the factory to the home of the patient or would it go to a site where it will be dispensed from a warehouse to the home of the patient.

Mr. McClellan replied "the latter".

The Chair asked for clarification of "dialysate drugs" and inquired if there were more than one type of dialysate solutions.

Mr. McClellan responded that there are different sized bags of the dialysate solution. He opined that although it is a controlled substance, it is not a harmful substance.

Mr. Brown asked if the warehouse would be licensed as a wholesale distributor.

Mr. McClellan answered in the affirmative.

Mr. Brown asked if "dialysate drugs" includes just the solution or the medication that is given with the solution.

Mr. McClellan responded that their interpretation of the definition of "dialysate drugs" is specific to just the solution.

The Chair and Mr. Brown inquired if "dialysate drugs" is defined in Hawaii Revised Statutes since it is unclear that it is specific to just the solution.

Mr. McClellan opined that S.B. 473 section 1(a)(1), (2), (3), (4), and (5) of the bill defines "distribution of dialysate drugs and devices" but confirmed that he will address this inquiry in writing and provide that to the Board after the meeting.

Mr. Brown commented that Hawaii Administrative Rules section 16-95- 2, states the definition of "Wholesale distributor' means any person or entity in this State engaged in the transfer of prescription drugs to a person other than a consumer or patient..." If a business wishes to "dispense" prescription drugs or devices in this State to the end user or patient, the dispensing must occur under a permitted pharmacy and under the supervision of a licensed pharmacist. This process ensures patient safety.

The Chair asked if this bill would eliminate the on-site pharmacist at the licensed distribution warehouse.

Mr. McClellan answered in the affirmative. There would be technicians "picking the order".

The Vice Chair asked what type of training is involved for the pharmacy technicians and/or warehouse technicians "picking the order", would they be held responsible for a mistake, and would they be able to know if a product was incorrectly selected based off their knowledge of dialysis. He opined that although a mistake may not directly affect an individual, it may affect their health.

Mr. McClellan confirmed that he will address those questions in writing and provide that to the Board after the meeting.

Ms. Cross asked if the dialysate solution was a prescription drug.

The Chair answered in the affirmative.

Ms. Cross asked if this bill was proposing to bypass the final check by an on-site licensed pharmacist before dispensing this prescription drug (dialysate) to a patient.

EO Skizewski answered in the affirmative. He stated that this would potentially allow an out-of-state manufacturer to provide dialysate drugs to an in-state distributor (with a PWD license) to dispense directly to the end user. He noted the Board has concerns with the lack of safeguards to this bill. He reiterated Hawaii Administrative Rules section 16-95-2, which states the definition of "Wholesale distributor' means any person or entity in this State engaged in the transfer of prescription drugs to a person other than a consumer or patient…" If a business wishes to "dispense" prescription drugs or devices in this State to the end user or patient, the dispensing must occur under a permitted pharmacy and under the supervision of a licensed pharmacist. This process ensures patient safety.

Corrie Sanders was promoted to panelist.

Ms. Sanders asked Mr. McClellan to include the implications to a recall for these dialysate drugs or devices and who will be held responsible for contacting the patients in his written response to the Board. She expressed concern regarding who is performing the final product check of these sterile products to make sure it is temperature regulated and/or stable after the point of shipping and handling if it is going directly to the patient.

The Chair opined that the Board would like to support dialysis patients and understands the need and intent of the bill but asked Mr. McClellan to address all of the Board's concerns to ensure patient safety. She thanked Mr. McClellan for his time, and he thanked the Board for their service.

Corrie Sanders and Kekoa McClellan returned to attendee.

Hawaii Pharmacists Association

Corrie Sanders was promoted to panelist.

Ms. Sanders shared that on April 8, 2023, the Hawaii Pharmacists Association ("HPA") will hold its annual meeting at the Oahu Country Club. There will be three (3) CE ("Continuing Education") and an additional speaker, S.B. 693 and 2024 legislative initiatives open discussion, and restructuring of the HPA/current pharmacy funding for a full time State pharmacy advocacy position.

Corrie Sanders returned to an attendee.

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Board Business: Permitted Interaction Group (PIG) related to Pharmacy Technicians

Permitted Interaction Group (PIG) related to Pharmacy Miscellaneous Permits
The Chair stated that both PIGs met on February 16, 2023. She stated that the PIG
related to Pharmacy Technicians will meet via virtual videoconference meeting Zoom
webinar on April 6, 2023, at 10:00 a.m. She stated that both PIGs plan to meet again via
virtual videoconference meeting Zoom webinar on May 18, 2023. The PIG related to
Pharmacy Miscellaneous Permits will meet at 9:00 a.m., and the PIG related to
Pharmacy Technicians will meet at 10:30 a.m.

Applications:

Executive Session:

At 9:53 a.m., upon a motion by Mr. Kikuchi, seconded by Mr. Rabang, it was voted on and unanimously carried to move into Executive Session in accordance with HRS, 92-4 and 92-5(a) (1) and (4), "To consider and evaluate personal information relating to individuals applying for pharmacy licensure," and, "To consult with the board's attorney on questions and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities".

At 10:47 a.m., upon a motion by Mr. Brown, seconded by Mr. Kikuchi, it was voted on and unanimously carried to move out of executive session.

It was the Board's consensus to take the meeting out of order.

Chair's Report:

Approval of Minutes of the February 7, 2023 Meeting

It was moved by the Vice Chair, seconded by the Mr. Rabang, it was voted on and unanimously carried to approve the amended minutes of the executive session of the February 7, 2023, meeting, as circulated.

Ratification Lists

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

Applications:

Applications

Pharmacist

The Chair asked for a motion regarding the following pharmacist applications:

i. Estep, Greg

Upon a motion by Mr. Brown, seconded by the Vice Chair, it was voted on and unanimously carried to approve the application of Greg Estep.

ii. Gahm, Julie

Upon a motion by Mr. Kikuchi, seconded by Mr. Rabang, it was voted on and unanimously carried to approve the application of Julie Gahm.

iii. Saad. Batoul

The Chair stated that the application is deferred and the Board requests additional information.

iv. Truong, Dan

Upon a motion by the Vice Chair, seconded by Mr. Brown, it was voted on and unanimously carried to deny the application of Dan Truong pursuant to Hawaii Revised Statutes section 461-21(a)(2) & (5), Hawaii Administrative Rules section 16-95-110(a)(4),(9), & (12), and Hawaii Revised Statutes section 436B-19(12) & (13).

Chapter 91, HRS Adjudicatory Matters:

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

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

- a. In the Matter of the Miscellaneous Permit of **DGN Pharmacy Inc., dba Personal Rx; PHA 2022-99-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 Walgreen Pharmacy Services
 Midwest, LLC; PHA 2022-96-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 Walgreens.com, Inc, dba
 Walgreens #02445; PHA 2022-91-L, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1".
- d. In the Matter of the Miscellaneous Permit of **Healthy Options**, **Inc.**, **dba Postal Prescription Services**; **PHA 2022-84-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1",
- e. In the Matter of the Miscellaneous Permit of **Ziphealth**, **Inc.**; **PHA 2022-100-L**, Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order: Exhibits "1"-"2", &
- f. In the Matter of the Miscellaneous Permit Number 900 of **Goodhealth Inc., dba Premier Pharmacy Services; PHA-2022-89-L**, Settlement Agreement Prior to

 Filing of Petition for Disciplinary Action and Board's Final Order; Exhibits "1"-"2".

Next Meeting:

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

June 15, 2023 9:00 a.m.

In-Person: Queen Liliuokalani Conference Room

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> HRH King Kalakaua Building 335 Merchant Street, First floor Honolulu, Hawaii 96813

Virtual Participation: Virtual Videoconference Meeting

Zoom Webinar

Adjournment: There being no further business to discuss, the Chair adjourned the meeting at 10:55

a.m.

Taken by:	Reviewed and Approved by:
/s/ Leanne Abe Leanne Abe, Secretary	/s/ James Skizewski James Skizewski, Executive Officer
JS:la 4/15/23	
[X] Minutes approved as is. [] Minutes approved with changes; see minutes of	