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

MINUTES OF MEETING

Date:	February 10, 2022
Time:	9:00 a.m.
Place:	Virtual Videoconference Meeting – Zoom Webinar
Members Present:	Alanna Isobe, Chairperson Julie Takishima-Lacasa, PhD, Public Member, Vice-Chairperson Patrick Adams, Pharmacist Sheri Tokumaru, Pharmacist Kent Kikuchi, Pharmacist Mark Brown, Pharmacist
Staff Present:	James Skizewski, Executive Officer ("EO Skizewski") Lee Ann Teshima, Executive Officer ("EO Teshima") Shari Wong, Deputy Attorney General ("DAG") Kellie Teraoka, Secretary Leanne Abe, Tech Support Staff
Excused:	Catalina Cross, Public Member
Guests:	Allison Hill Cherylynn Cheng Corrie Sanders – Hawaii Pharmacists Association Grace Sesi Greg Edwards – Hawaii Dept. of Health Jessica Adams John Sisto Jonathan Ching (Kaiser Permanente) Kellie Noguchi Keith Ridley, HTH Leah Lindahl Lorri walmsley MDJohnston Patrick Uyemoto RedullaJK Stacy Pi Tiffany Yajima
Call to Order:	The agenda for this meeting was filed with the Office of the Lieutenant Governor, as required by section 92-7(b), Hawaii Revised Statutes ("HRS").

A short video regarding virtual meetings was played for the attendees and the Chair provided information on internet and phone access for today's virtual meeting.

The Chair noted that the Hawaii Medical Board's email address and P.O. Box were inadvertently listed on the agenda, instead of the Board of Pharmacy. However, prior to the meeting, staff checked with the Hawaii Medical Board to ensure that no written testimony was received. Staff will correct this information going forward.

The Chair then took roll call to establish quorum and called the meeting to order at 9:06 a.m. All Board members were in attendance, with the exception of Ms. Cross who was excused from the meeting and the Vice-Chair who joined the meeting late.

Chair's Report:

Announcements

The Chair reported she had no announcements.

Approval of Minutes of the January 20, 2022 Meeting

The Chair asked if there were any corrections or discussion of the January 20, 2022 meeting minutes.

The Vice-Chair joined the meeting at 9:08 a.m.

There being no corrections/amendments, upon a motion by Mr. Kikuchi, seconded by the Ms. Tokumaru, it was voted on and unanimously carried to approve the meeting minutes of the executive session and the minutes of the open session of the January 20, 2022 meeting, as circulated.

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

Staff reported that no one raised their hand.

Executive Officer's Report:

2022 Legislative Session

EO Skizewski reported that the following bills are moving forward in the Legislative session and that it is imperative to get the Board's positions on these bills.

1) S.B. 2030, Relating to Prescription Drugs
   Report Title: Opioids; Naloxone; Opioid Antagonist; Pharmacists; Prescribing; Dispensing
   Description: Requires a prescriber to offer a prescription of certain drugs under certain circumstances related to opioid overdose. Requires a prescriber to offer patient education under certain circumstances related to opioid overdose. Requires a pharmacist who dispenses a prescription order for an opioid to notify the individual of the potential dangers of a high dose of an opioid and to offer to dispense to the individual an opioid antagonist; provided that the individual is prescribed specific

opioids at specified doses. Exempts patients in hospice or palliative care and residents of veteran community living centers. Requires a pharmacist to notify an individual receiving an opioid antagonist of the availability of generic and brand-name opiate antagonists.

EO Skizewski stated that S.B. 2030 moved past the first committees and has been further amended to adjust the effective date and exempt pharmacists prescribing in both in-patient and out-patient settings. EO Skizewski was concerned how the Board would monitor pharmacists who did not follow this proposed law. In addition, he is unsure of which agency be responsible to take administrative action and what type of administrative action is required.

The Chair opened this agenda item up for discussion. She noted that she's unsure of what jurisdiction the Board would have over this and if an amendment should be made to recommend the administrative action be taken by the current enforcement agency, Regulated Industries Complaints Office ("RICO").

The Chair explained that S.B. 2030 states that if a prescriber prescribes an opioid or benzodiazepine medication to a patient, they must offer naloxone hydrochloride ("naloxone") if: (1) it is greater than 90 or more morphine milligram equivalents ("MME's) of an opioid medication per day; (2) if an opioid is being dispensed within 1 year from the date a prescription for benzodiazepine has been dispensed; or (3) if the patient is at increased risk for an opioid overdose.

The Chair noted that HRS chapter 329-38, states that emergency room ("ER") doctors are not required to check prescription drug monitoring programs ("PDMP"). If the bill does not carve this out specifically, she is not sure how ER doctors will know if benzodiazepine was prescribed within a 1-year period. Another concern on the prescriber side, is that the bill does not specify how often naloxone would need to be offered.

The Chair also mentioned her concern on the pharmacist side is that a prescriber must offer to the individual to whom the opioid is being dispensed, on at least an annual basis, an opiate antagonist approved by the Food and Drug Administration for the reversal of an opioid overdose if:

(1) The individual is, at the same time, prescribed benzodiazepine, a sedative drug, or carisoprodol, tramadol, or gabapentin; or
(2) The opioid prescription is at or in excess of 99 MME's as described int eh guidelines of federal Centers of Disease Control and Prevention.

She added that certain drugs are not mentioned in this list. Gabapentin is a nationally controlled substance in other states, since it can be abused. If the bill is left as is, pharmacists will not know if the patient was previously prescribed other concerning drugs, when dispensing an opioid.

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

Jared Redulla, Department of Public Safety, Narcotics Enforcement Division ("NED"), was promoted to a panelist at 9:14 a.m.

Mr. Redulla introduced himself and stated that the NED was not included in the introduction of this bill. He is not clear on what the underlying intent of this bill is. The NED provided a short supportive testimony on this bill based on the greater and wider availability of naloxone and opioid antagonists, which would ultimately result from this type of legislation.

The Chair stated that the intent of the bill is good, but she is unsure in terms of resources, if pharmacists would eventually have more visibility to gabapentin.

Mr. Redulla recognizes gabapentin's prevalence in the community, although it is not a controlled substance in Hawaii. However, the explanation of why gabapentin is included in this measure is unclear.

The Chair asked if there is any insight if the Drug Enforcement Agency ("DEA") will be controlling gabapentin.

Mr. Redulla responded that nationwide, there are several states which recognize gabapentin as a controlled substance, however Hawaii is not one of them. HRS chapter 329 creates a procedure if the state wants to act to regulate gabapentin as a controlled substance. However currently, there is no necessary rationale or motivation to move forward at this time.

Jared Redulla returned to an attendee at 9:19 a.m.

Mr. Kikuchi stated that specific drugs should not be included in this bill because it becomes difficult to manage in conjunction with morphine or any other opioid.

The Chair also added that there is no definition of sedative or hypnotic drugs in the bill.

EO Teshima left the meeting at 9:20 a.m.

Patrick Uyemoto, Times Pharmacy, was promoted to a panelist at 9:20 a.m.

Mr. Uyemoto introduced himself and offered to provide comments on this bill. He was also unaware of the introduction of this bill but feels that the intent is good. He recommended to not specifically list all drugs, because it will cause a lot of issues. He trusts a prescriber/pharmacist's judgement if the patient is at risk for overdose. Also, being sanctioned is concerning, especially since there is no outlined policy included. Mr. Uyemoto is in support of stopping the opioid epidemic and preventing overdoses, however he noted that a few things in this bill can be improved, including removing the tracking portion, as it would be difficult for pharmacists to monitor.

Patrick Uyemoto returned to an attendee at 9:23 a.m.

Mr. Adams stated that he does not understand the purpose of the bill and what it is trying to improve.

The Chair assumed that the intent of the bill is to get naloxone to the appropriate people as often as possible. Pharmacists have the ability to prescribe naloxone but now are mandated to step in and provide proper education.

Mr. Adams felt that would be a forced counseling situation.

The Chair addressed the opioid epidemic nationwide and stated that this bill would mandate pharmacists to provide counseling and education, although pharmacists are probably already following these procedures.

Mr. Adams brought up the issue that if a pharmacist counseled a patient who requested a prescription for naloxone, what would occur if the pharmacist was not a prescriber or was not trained to do so?

The Chair responded that the doctor who originally prescribed the opioid, would not be objective, and could easily be contacted to write the naloxone prescription.

Mr. Kikuchi questioned what would happen if a pharmacist is punitive in the event there was an overdose and the pharmacist was not trained to provide the appropriate counseling? There are times when a patient may have been prescribed gabapentin, which is not a controlled substance and will not show up on the PDMP.

Mr. Adams added that pharmacists currently have the obligation to counsel patients and is concerned about liability. He supports naloxone and Narcan but does not support the idea of mandating procedures that are already in place. This would put a lot of responsibility on the pharmacist as the prescriber, as they may not be able to prove that the patient was counseled.

The Chair reminded Board members that they need to think about this logistically, for the safety of the public, and the procedures will need to fall in place to make it possible to execute. The Chair stated that she is supportive of the bill, however amendments need to be made so all stakeholders will buy in, instead of being mandated to follow.

The Chair discussed the requirement to offer Narcan as it may be an obstacle if the pharmacist is not a prescriber. She suggested to change the language to educate the patient about Narcan, rather than offering it since pharmacists can't offer a drug that they don't have direct access to. The language in the bill is very vague, and pharmacists should only be required to educate the patient on the availability of Narcan and urge them to consult with their physician.

Upon a motion by the Chair, seconded by the Vice-Chair, it was voted on and

unanimously carried to support the intent of S.B. 2030, with the following concerns: (1) to request to remove the non-controlled drugs listed, including sedative hypnotic drugs and gabapentin; (2) the referral portion should be directed to RICO since the Board does not have that authority; and (3) to revise the language to offer education and availability of Narcan, instead of offering to fill the prescription, since not all pharmacists have the ability to prescribe.

2) SB 2199, Relating to Treatment of Coronavirus Disease 2019
   Report Title: Physicians; Pharmacists; Advanced Practice Registered Nurses; Coronavirus Disease 2019; Prescription
   Description: Protects physicians, advanced practice registered nurses, and pharmacists from civil and criminal liability for prescribing or administering early treatment for the coronavirus disease 2019 in good faith to prevent hospitalization and death.

EO Skizewski reviewed S.B. 2199 and shared his concerns. He stated that this bill amends HRS chapter 453, Medicine and Surgery. The Board could submit comments to include this language in HRS chapter 461, Pharmacists and Pharmacy.

Mr. Brown stated that language in S.B. 2199 does not define “early treatment” and is wide open depending on the practice.

EO Skizewski advised that the Board could request for the language to be more clearly defined.

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

Staff reported that no one raised their hand.

Upon a motion by the Chair, seconded by Mr. Kikuchi, it was voted on and unanimously carried to support the intent of S.B. 2199, with the following comments: (1) to request further clarification of the definition of early treatment; and (2) to request that this language be included in the appropriate HRS chapter 461, Pharmacists and Pharmacy.

3) SB 2592/HB 1667, Relating to Health
   Report Title: Clinical Laboratory Directors; Pharmacies; Pharmacists; Clinical Laboratory Improvement Amendments Waived Tests
   Description: Defines "clinical laboratory director" to include certain physicians, licensed clinical laboratory scientists, and pharmacists-in-charge of pharmacies. Amends the definition of "practice of pharmacy" to include the ordering and performing of certain Clinical Laboratory Improvement Amendments waived tests.

EO Skizewski reviewed S.B. 2592 and H.B. 1667 and noted that there have been revisions in the H.D. 1 draft which specifies that the pharmacist-in-charge (“PIC”), may serve as the laboratory director to sign off on CLIA waiver applications. It clarifies that a pharmacist may order and perform all CLIA waived tests that are approved and

authorized by the United States Food and Drug Administration and also adjusted the effective date to 2060.

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

Corrie Sanders, Hawaii Pharmacists Association ("HPA"), was promoted to a panelist at 9:50 a.m.

Ms. Sanders elaborated that the HPA testified in support of these bills, specifically regarding clinical lab directors on the neighbor islands, which could pose a huge barrier to accessing CLIA waived tests in a reasonable amount of time. Her suggested amendments include: (1) to remove the specific CLIA waived tests that are listed, in order to avoid going back to the Legislature if there are changes in the future; and (2) to authorize the PIC to serve as the laboratory director and/or also allow pharmacists to sign off on the CLIA waiver application.

EO Skizewski stated that there have been no changes made to S.B. 2592, however the changes Ms. Sanders previously mentioned were to H.B. 1667, which is scheduled for hearing on February 11, 2022.

Corrie Sanders returned to an attendee at 9:53 a.m.

The Chair questioned what a clinical lab director does and asked for clarification if the clinical lab director is present on-site to sign off on the waivers. In addition, how does it affect the terms of quality by having the clinical lab director sign off on the waiver versus a pharmacist.

It was noted that The Department of Health ("DOH") testified that there are 30 pharmacies in Hawaii which have CLIA waivers approved by a clinical director, however they are not physically present on-site.

The Chair explained that CLIA waived tests that do not diagnose (i.e. COVID-19 tests, pregnancy tests, etc.) and pharmacists should be qualified and educated to administer.

Tiffany Yajima, SanHi Government Strategies ("SanHi"), was promoted to a panelist at 9:56 a.m.

Ms. Yajima shared that SanHi had previous discussions about this bill with DOH. She understands the concerns that are being raised regarding patient safety and care. She knows that CLIA waived tests are being done in a formal setting however, they need additional information about the training and safe guards that in place, since they are not familiar with the pharmacies' procedures. Additional information from the pharmacies would be helpful to familiarize DOH with the safeguards that are in place. Hawaii is the only state with very strict barriers for CLIA waived testing for pharmacies, compared to the rest of the country. Ms. Yajima will continue to have further discussions with DOH and all stakeholders and requests that the Board supports of these measures.

The Chair asked if the clinical lab director has to sign off on the CLIA waiver application and if DOH also has an issue with the pharmacists administering the tests.

Ms. Yajima answered in the affirmative. Pharmacists have the training required and the pharmacy setting is acceptable. The heart of bill is just eliminating the requirement for the clinical lab director and will allow pharmacists to sign off on the waivers.

The Chair reiterated that these bills are not licensing a pharmacist or a particular person to administer the tests. The bills are requesting that the pharmacist or PIC be authorized to sign off on the form to allow the site to administer the CLIA waived tests. The pharmacists that are administering the tests will continue to follow procedures that are already in place.

Tiffany Yajima returned to an attendee at 10:02 a.m.

Keith Ridley, Department of Health ("DOH") Office of Health Care Assurance, was promoted to a panelist at 10:04 a.m.

Mr. Ridley stated that he hopes that the Board is supportive of H.B. 1667/S.B. 2592. His understanding is that several pharmacies that have already gone through the regulatory process to obtain CLIA certificates and apply for the state permit to allow pharmacies to perform these tests. Mr. Ridley asked what the Board's concerns are.

The Chair explained that it seems like an antiquated process to require the clinical lab director to sign off on the application when they are not physically present.

Mr. Ridley explained that the clinical lab director provides quality oversight in the process. It also shows that the pharmacy has a relationship with an individual who has quality oversight and can review policies and procedures on how the waived tests will be performed, who will perform them, and how the test results will be issued.

The Chair asked how other states process CLIA waived certificate applications.

Mr. Ridley responded that the Hawaii requires the CLIA certificate and a state permit which mandates that the clinical lab director must sign off on, which is in the minority.

The Chair asked if clinical lab directors are certified to meet certain criteria to sign these forms and if they hold a different license from physicians.

Mr. Ridley clarified that the DOH does not certify clinical directors, that would fall under DCCA's purview. Clinical directors must undergo training and pass a national test as part of the licensing requirement. The difference between clinical lab director and the physician is that the physician normally provides care directly to their patients. Whereas a pharmacist has the ability to service anyone.

The Chair asked if all physicians are qualified to be clinical lab directors or if they are required to complete additional training to ensure that the labs are following the correct procedures.

Mr. Ridley's understanding is that they are revising the statute to include clinical lab directors.

Mr. Adams asked how often the clinical lab director visits the pharmacy and what is their responsibility.

Mr. Ridley did not have detailed information but can pass that on at a later time. He stated that the regulatory process allows clinical lab directors, as a third party to oversee quality care and procedures.

EO Teshima joined the meeting at 10:10 a.m.

Keith Ridley returned to an attendee at 10:15 a.m.

Lorri Walmsley, Walgreens, was promoted to a panelist at 10:15 a.m.

Ms. Walmsley stated that Walgreens worked with SanHi to submit this bill. Hawaii is one of 10 states where a pharmacist cannot sign off as a clinical lab director, and the only state which requires a physician lab director and lab consultant. When the process of CLIA waived tests began during the pandemic, she reached out to the State to see how many physicians would meet these qualifications. At the time, only 2 physicians met this requirement in Hawaii which posed a significant challenge. The purpose of this bill is to make CLIA waived testing widely available.

Lorri Walmsley returned to an attendee at 10:17 a.m.

The Chair stated that she is support of these bills since pharmacists are an accessible healthcare provider which would allow patients get more convenient access, especially in rural areas where there is limited access. Pharmacists would be able to administer the tests and the community would benefit from that. CLIA waived tests have been performed by pharmacists successfully, who are properly trained, and educated on safely and accurately administering the tests.

Upon a motion by the Chair, seconded by Mr. Brown, it was voted on and unanimously carried to support both S.B. 2592 and H.B. 1667.

4) SB3382/HB 2340, Relating to Prescriptions
   Report Title: Electronic Prescription Filing Systems
   Description: Allows the utilization of post office boxes for prescriptions by amending the definition of "address" under chapter 329, Hawaii Revised Statutes.

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

Jonathan Ching and Stacy Pi, Kaiser Permanente, were promoted to panelists at 10:23 a.m.

Mr. Ching explained that pharmacists have been having issues when receiving an electronic prescription, if the address is a P.O. Box. Currently under HRS chapter 329, the definition of address is where the patient resides. Therefore, the pharmacist will need to check the patient's identification to determine where they physically reside. This bill would eliminate the extra step and streamline electronic prescriptions to save time.

The Chair understands and appreciates the intent of this bill but would like to know if the NED has concerns.

Jared Redulla, was promoted to a panelist at 10:26 a.m.

Mr. Redulla reported that the NED is aware of this bill and does not see any barriers.

The Chair confirmed that they will still require that the physical address of the patient is retrievable, however, the physical address will not be required to be on the face of the electronic prescription.

Jonathan Ching and Stacy Pi returned to attendees at 10:28 a.m.

Jared Redulla returned to an attendee at 10:28 a.m.

Upon a motion by the Mr. Adams, seconded by Mr. Brown, it was voted on and unanimously carried to support both S.B. 3382 and H.B. 2340.

Hawaii Pharmacists Association:

Corrie Sanders was promoted to a panelist at 10:29 a.m.

Ms. Sanders shared that the HPA is currently planning their annual meeting. It will be held on April 23, 2022 at the Oahu Country Club. They currently have 4 CE's lined up and are still accepting vendors or speakers who are interested. Also, the Board of Directors are accepting nominations for pharmacists that have significantly contributed to the field in 2021.

Corrie Sanders returned to an attendee at 10:31 a.m.

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

Staff reported that no one raised their hand.

Applications:

Executive Session: At 10:33 a.m., upon a motion by Mr. Brown, seconded by Mr. Adams, 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 10:37 a.m., upon a motion by the Vice-Chair, seconded by Ms. Tokumaru, it was voted on and carried by the majority, with the exception of Mr. Brown who was experiencing technical difficulties, to move out of executive session.

Ratification Lists

EO Skizewski reported that the ratification list provided was incorrect. The correct ratification list will be provided at the next meeting.

Applications

Miscellaneous Permit

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

i. Fountain Plaza Pharmacy, LLC dba FountainRx

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

Wholesale Prescription Drug Distributor

i. Medline Technologies, L.P.

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

Chapter 91, HRS Adjudicatory Matters:

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

Upon a motion by Mr. Adams, seconded by the Ms. Kikuchi, it was voted on and unanimously carried to approve the following adjudicatory matter:

a. In the Matter of the Miscellaneous Permit of **Honeybee Health, Inc.; PHA-2021-49-L,** Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order; Exhibit "1"

Next Meeting:

There being no further agenda items, the Chair announced the next meeting. All members stated that they are available, with the exception of the Vice-Chair and Mr. Adams.

March 17, 2022
9:00 a.m.
Virtual

Adjournment: There being no further business to discuss, the Chair adjourned the meeting at 10:41 a.m.

Taken by:

/s/ Kellie Teraoka
Kellie Teraoka, Secretary

Reviewed and Approved by:

/s/ James Skizewski
James Skizewski, Executive Officer

JS:kt
3/9/22

[X] Minutes approved as is.
[ ] Minutes approved with changes; see minutes of _____