

BOARD OF NATUROPATHIC MEDICINE
Professional and Vocational Licensing Division
Department of Commerce and Consumer Affairs
State of Hawaii

MINUTES OF THE MEETING

The agenda for this meeting was filed with the Office of the Lieutenant Governor as required by Hawaii Revised Statutes (“HRS”) section 92-7(b).

Date: Friday, November 15, 2024

Time: 2:00 pm

Place: PVL Exam Room, #330
King Kalakaua Building, 3rd Floor
335 Merchant Street
Honolulu, Hawaii 96813

Virtual Participation: Virtual Videoconference Meeting – Zoom Webinar
<https://dcca-hawaii-gov.zoom.us/j/87490714566>

Video Recording: <https://www.youtube.com/watch?v=1gCoVHbbK0Q>

Present: Kristen Coles, N.D., Vice Chair, Licensed Member
Corinne De Soto, N.D., Licensed Member
Joy Kimura, Public Member
Christopher Fernandez, Executive Officer (“EO”)
Rochelle Araki, Executive Officer
Christopher Leong, Esq., Deputy Attorney General (“DAG”)
Johnny Li, Tech Support
Lorna Eugenio, Secretary

Excused: None

Guest: None

Call to Order: There being a quorum present, the meeting was called to order by Chair Dr. Coles at 2:13 pm.

Approval of the April 19, 2024 Meeting Minutes: After confirming there was not testimony from the public, Chair Coles asked members if they had any comments or corrections. The Board reviewed the meeting minutes for April 19, 2024, and afterward Ms.

Kimura motioned to approve the meeting minutes as is, which seconded by Vice Chair De Soto, and unanimously approved by the Board.

Applications:

A. Ratification of Approved Applications

ND-351-0	Beau Hooker
ND-352-0	Shaye L Herndon
ND-353-0	Rainer M Fischer
ND-354-0	David J Saba
ND-355-0	Wendy Yong Shi Lin
ND-356-0	Michaela J Watts
ND-357-0	Morgan L Lucas
ND-358-0	Jene Michele Ferrante
ND-359-0	Lauren Meiko Hara
ND-360-0	Natsumi Marin Seki
ND-361-0	Marah Hodges Cannon
ND-362-0	Keani K Shirai
ND-363-0	Ilihia Lamia Herrod
ND-364-0	Elizabeth A Maly
ND-365-0	Reid S Kiyabu
ND-366-0	Brendan Courneene

After asking if members had any comments or questions, Chair Coles motioned to ratify the approved applications listed above, which was seconded by Vice Chair De Soto, and unanimously approved by the Board.

Chapter 91, HRS
Adjudicatory
Matters

In the Matter of the Naturopathic Physician's License of Allison Anne Hofmann, N.D., NAT 2024-5-L Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order.

Chair Coles noted that Board would enter recess to review the above adjudicatory matter.

RECESSED at 2:24 p.m.

RECONVENED at 2:58 p.m.

After Chair Coles took roll call of members to re-confirm quorum, she reconvened the meeting and informed the public that the Board voted to accept the settlement agreement for Dr. Allison Anne Hofmann.

Review Letter
From the State
of Hawaii, Dept.
of Health

The Board reviewed a letter from Nathan CY Tan, M.D., Deputy State Epidemiologist, Disease Outbreak Control Division regarding the sharing of relevant findings from their investigation of adverse reactions occurring after administration of intravenous nicotinamide adenine dinucleotide, oxidized (NAD⁺) solution.

Chair Coles confirmed there was not testimony from the public. She then asked members if they had read the letter and began the conversation.

Chair Coles noted there were two matters in the letter:

- 1) There was an endotoxin found in an IVNAD solution that had been dispensed by a pharmacy on Maui, and
- 2) There was also a request at the end of the letter asking the Board to notify all of our licensees about a product called BPC 157.

After members concluded that there was nothing to directly address regarding the adverse event that happened at the Maui pharmacy, members turned their focus to the request from Dr. Tam to notify its licensees of the Food and Drug Administration's (FDA) designation of BPC-157 as a category 2 bulk drug substance that cannot be used in compounding.

Members contemplated whether other Boards or Programs had been notified by the Deputy State Epidemiologist as well, or if Naturopaths were being singled out due to the circumstances of the adverse event. Members noted that practitioners such as Osteopathic Physicians, Medical Doctors, Advance Practice Nurses, and Physician Assistants can all prescribe and administer NAD⁺ solutions, and the question is whether they too were requested to notify their licensees.

It was also noted by Dr. De Soto that the issue could happen with pretty much any sterile compounded product. Vitamin C, vitamin B12, or even a steroid, for example, would be compounded could become contaminated and have elevated levels of endotoxins, which can cause harm to the patient. Pharmacies are strictly regulated to do batch testing to make sure that their products are free of endotoxins.

Chair Coles stated that she believes that it would not be an issue to provide Naturopathic Physicians a reminder of the FDA's designation of BPC-157 as a category 2 bulk drug substance that cannot be used in compounding, however she noted that the Pharmacy Board should be sending out a notice to its licensees as well, since it was in a pharmacy that the substance was compounded.

Lastly, Vice Chair De Soto noted the letter's vague description about what actually occurred with the BPC 157. The letter stated one of the four

patients who experienced an adverse event also received BPC 157, but it does not specifically state that the patient received that BPC 157 as part of the parenteral therapy or via an IV administration.

She added that if it did, then that definitely is against the FDA allowable use for that product. However, BPC 157 exists as a supplement for oral consumption that patients can even purchase online without the need of a prescription. So, it's not clear to her from the letter, that it was even being administered in a way that was not correct.

Based on its conversation, the Board chose to request additional information prior to disseminating a notice to Naturopathic Physician licensees, including if other Boards and Programs were notified, specifically, whether the Board of Pharmacy; and in what fashion the BPC 157 was administered with the NAD+ solution.

Chair Coles moved the meeting to the next agenda item.

Testosterone

Chair Coles confirmed there was not testimony from the public and then explained that the Board would be reassessing the inclusion of testosterone into the naturopathic formulary, and whether that is something the Board can pursuant to statute or rule.

Vice Chair De Soto also noted the inquiry was also coming from the state naturopathic physician association, adding that she is a member, before stating that she would like to get a summary of how and what has been discussed on this in the past, and whether there was ever any official determination as to whether the board could add testosterone to the formulary or not. Her own reading of HRS 455 was that the Board has the authority to update the formulary. When the bill passed providing prescriptive authority to naturopaths, there was an interpretation put forward by the DAG at the time, that the original intent of the legislature was to not include controlled substances, since it was removed from the version of the bill that was a finally approved. However, Vice chair De Soto felt that just because controlled substance prescriptive authority was removed from the final version of the bill did not mean that the legislature intended that naturopathic doctors should never have prescriptive authority of controlled substances. She opined that it just meant that it was not included in that bill at that time.

Vice Chair De Soto asked DAG Leong if there was a reason the Board could not updated that formulary to include testosterone.

DAG Leong confirmed that the Board does have the authority and the ability to establish a formulary and updated it. He continued that for naturopathic physicians to be able to prescribe something, it has to be on formulary. DAG Leong then added that to place controlled substances on the formulary, other applicable laws regarding controlled substances, would need to be adhered to as well. Manly, a Naturopathic Physician would need to have the authority to prescribe controlled substances, which is granted through HRS chapter 329. He stated that it is not certain that the Board would be restricted

from adding a controlled substance on the formulary, but that he was very wary of creating confusion by doing so.

Vice Chair De Soto responded that she understood that in order to prescribe testosterone, a controlled substance, a Naturopathic Physician would have to go through the appropriate channels to obtain a United States Drug Enforcement Agency (DEA) & Narcotics Enforcement Division, State of Hawaii (NED) certificate to then be able to prescribe it, which is the same for every other healthcare profession. She opined that if the other healthcare professions' formularies included testosterone, then the Narcotics Enforcement Division would then be able to issue those certificates to the individuals who are requesting them. Vice Chair De Soto added that Dr. Rachel Klein, the previous Hawaii Society of Naturopathic Physicians (HSNP) president, had conversations in the past with the head of NED, Deputy Director Jared Redulla, who said to her that if the formulary shows a Naturopathic Physician has the ability to prescribe a controlled substance, then NED would authorize prescriptive authority. She lastly noted it was very circular and still questioned if the Board has the authority to update the formulary to include testosterone.

DAG Leong cited the definition of "naturopathic formulary" in HRS 455:

means vitamins, minerals, dietary supplements, botanical medicines, homeopathic medicines, hormones, and those legend drugs consistent with naturopathic medical practice.

and "legend drugs",

means any drug falling within section 503(b)(1) of the federal Food, Drug and Cosmetic Act and which is required to be labeled with the statement "Rx only"

He then asked if testosterone fits within these definitions.

Chair Coles responded that testosterone as a medication is something that all naturopathic schools and universities are training on.

Vice Chair De Soto added that testosterone is included in the formularies of several other states, such as Oregon, Washington, and Arizona and a few others.

Chair Coles also noted that the formulary was built upon states who already had robust formularies intact prior to Hawaii Naturopaths getting a prescription rights. She stated further that all of those states that have robust formularies all do include testosterone and other controlled substances.

The big question, according to Chair Coles the question is whether there is a statute that specifically prevents the Board from considering an addition like testosterone.

DAG Leong stated that he was not certain, but that the main issue is whether it fits into the definitions.

Chair Coles opined that if a licensee attempted to prescribe testosterone to any pharmacy without DEA registration, every single pharmacy would prevent that from happening because the pharmacy end is very clear on requirements with DEA registration. So even if testosterone was listed on the formulary, there's protection still in place. Those Naturopathic Physicians would have to obtain the DEA number, registered with the state, then at that point they would be able to prescribe it.

EO Fernandez expressed his interest in learning if the states who allow for some form of prescriptive authority for controlled medications also utilize administrative rules to create their prescriptive authority. For example, do statutes or administrative rules explicitly identify scheduled drugs related to the practice of naturopathic medicine as prescribable or does it generally say legend drugs like it does in HRS chapter 455.

Vice Chair De Soto informed others that she looked it up for Oregon and for Washington. She noted that she would need additional time to find her research but added that she believed none of them required any additional provisions to be able to prescribe those medications other than obtaining ADA certificate and being registered with that state's Narcotics Enforcement Division.

EO Fernandez stated that the Board should be concerned with other statute chapters including HRS chapter 329, Uniform Controlled Substances Act, which is what the Department of Law Enforcement relies on for its direction. He noted that in HRS 329, there are definitions for certain healthcare providers who have prescriptive authority. He added his interest in knowing if these other professions, for example, like an APRN, were required to be written into HRS chapter 329 to then instigate issuance of a DEA number through the Department of Law Enforcement.

Vice Chair De Soto asked, if HRS chapter 329 has a definition of 'practitioner' that does not include naturopathic doctors, would Naturopathic Physicians have to try and get added to that definition.

EO Fernandez cited HRS chapter 329 which defines "practitioner" as:

a physician, dentist, veterinarian, scientific investigator or other person licensed and registered under Section 329-32 to distribute, dispense, or conduct research with respect to a controlled substance in the course of professional practice or research in the state.

EO Fernandez referred members to HRS section 329-32 where it says every person who proposes to engage in the manufacture or dispense or proposes dispense any controlled substances shall obtain registration

issued by the Department of Public Safety [now called the Department of Law enforcement] in accordance with the Department rules.

DAG Leong noted that the registration requirement doesn't limit registration to only those named professions, because the registration requirement statute says every person who manufactures, distributes, prescribes, dispenses or conducts reverse distribution with any controlled substance within this state, shall obtain registration. So, the statutes are not actually limited to certain professions, one is required to likely follow the administrative rules for applying.

Vice Chair De Soto stated that she found that NED shall register an applicant to manufacture, dispense, prescribe a controlled substance unless it determines that it's inconsistent with public interest. She added that according to the information she found, what would be inconsistent with public interest is that the person does not have a suspended or revoked license or, any other of those situations that would make it so that they would not be eligible to even practice and hold a license in the 1st place.

EO Fernandez referred members to HRS 329-33(c) which states:

practitioners shall be registered to dispense or to prescribe any controlled substances or conduct research with controlled substances and schedules 2 through 5, which would include three where testosterone is if they are authorized to dispense or to prescribe or conduct research under the law of this state.

Vice Chair De Soto then added that this brought the Board back to the formulary.

EO Fernandez suggested that the Board should review the process of prescribing so there is no confusion from the naturopathic side to the pharmacy side, to the patient.

He offered an example:

So if a naturopath contacts a pharmacy to request testosterone, that pharmacy, according to what members have said already, would confirm whether this person is authorized to prescribe testosterone, likely relying on the formulary.

So if they saw testosterone on the formulary, that would be one check. Another check would have to be the DEA number that the provider would have to produce.

Is there any way that that can be fraudulently done?

Chair Coles stated no. Every time a provider creates a prescription, they must provide an oral code and MPI number. The DEA number must be included on their prescription headers. If they are filling out prescriptions, the provider must write in a DEA number which must be verified and linked to their name in a database. This state is very strict on controlled

substances. Pharmacies do not allow you to even leave voicemail messages for controlled substances. You must speak directly to a pharmacist. So, in terms of public safety, as long as licensees are trained in the matter of how to prescribe testosterone, the state itself has all these other buffer systems in place regarding controlled substances that she did not feel the Board would have to worry about. Chair Coles also noted that because Naturopaths provide a lot of hormone therapy, not having testosterone in the formulary creates quite a lot of public confusion. She stated that patients assume that testosterone is prescribable only to find that currently it is not in the formulary and therefore cannot be prescribed, which requires a long conversation and supporting them finding a provider that can, to continue their therapy. She noted further that it is very unfortunate that she cannot provide continuity of care.

EO Fernandez contemplated whether obtaining a DEA number would potentially allow a provider to prescribe anything under that DEA number.

DAG Leong noted that there are limitations by scope, so a Naturopathic Physician could not prescribe everything they wanted.

EO Fernandez asked where the Board would get those restrictions.

Ms. Kimura asked if it would not be easiest to submit a bill to update the formulary for naturopathic physicians, including testosterone.

DAG Leong added that the Board already has in its statute the authority to establish a formulary.

Chair Coles clarified the agenda item was included to truly try to get the question answered, does the Board have the authority to update the formulary and include testosterone as the only controlled substance.

Ms. Kimura asked Chair how she felt about including it in the formulary.

Chair Coles stated there is a large number of naturopathic physicians in the state of Hawaii that would be very supportive of testosterone being included in the formulary, adding that Naturopaths are highly trained in hormone replacement therapy, testosterone included. She I do think that if we did include it, we should probably have further discussion regarding if we would like to require an updated training course on it. She concluded by stating that she thought there is a little bit more discussion to be had as a Board but would be supportive of including it on the formulary if the Board felt like that was a useful medication to have in the formulary.

Ms. Kimura summarized the discussion thus far, that the Board was all in agreement that it would like to include testosterone in the formulary for Naturopathic Physicians, and that the Board has the authority to update its formulary. She concluded by suggesting for future discussions, that the Board should decide if there are any other requirements to prescribe testosterone among licensees.

Chair Coles requested this agenda item be on the next meeting's agenda.

EO Fernandez stated that he could reach out to the Department of Law Enforcement to follow up on HSNP's conversation, just to make sure parties were all on the same page about what's needed. He added that he can also look into other state regulations pertaining to controlled medication prescribing, including additional training.

Vice Chair De Soto

After some further discussion that involved plans to review the structure of the formulary, specifically construction as an inclusionary formulary versus exclusionary, as well as what instructions for medications are necessary for licensees and pharmacists to review in a formulary, the Board decided to carry the conversation to the next meeting.

Next Meeting

TBD

Adjournment

Chair Coles adjourned the meeting at 4:08 p.m.

Taken, recorded, and reviewed by:

/s/ Christopher Fernandez
Christopher Fernandez
Executive Officer

CF:

- Minutes approved as is.
- Minutes approved with changes; see minutes of _____.