

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

**AGENDA**

**Date:** November 15, 2024

**Time:** 2:00 p.m.

**In-Person Meeting Location:** PVL Exam Room  
HRH King Kalakaua Building  
335 Merchant Street, Third Floor  
Honolulu, Hawaii 96813

**Agenda:** The agenda was posted to the State electronic calendar as required by Hawaii Revised Statutes (“HRS”) section 92-7(b).

**Virtual Participation:** Virtual Videoconference Meeting – Zoom Webinar  
<https://dcca-hawaii-gov.zoom.us/j/82316943945?pwd=VcNkmzN5bdy4URmK3eTbul8aUGeap6.1>

**Phone:** (669) 900-6833

**Meeting ID:** 823 1694 3945

**Passcode:** 745241

If you wish to submit written testimony on any agenda item, please email your testimony to [naturopathy@dcca.hawaii.gov](mailto:naturopathy@dcca.hawaii.gov) or by hard copy mail to: Attn: Board of Naturopathic Medicine, P.O. Box 3469, Honolulu, HI 96801. We request submission of testimony at least 24 hours prior to the meeting to ensure that it can be distributed to the Board members.

**INTERNET ACCESS:**

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The Chairperson will individually enable each testifier to unmute their microphone. When recognized by the Chairperson, please unmute your microphone before speaking and mute your microphone after you finish speaking.

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Upon dialing the number, you will be prompted to enter the Meeting ID which is also listed at the top of the agenda. After entering the Meeting ID, you will be asked to either enter your panelist number or wait to be admitted into the meeting. You will not have a panelist number. So, please wait until you are admitted into the meeting.

When the Chairperson asks for public testimony, you may indicate you want to testify by entering "\*" and then "9" on your phone's keypad. After entering "\*" and then "9", a voice prompt will let you know that the host of the meeting has been notified. When recognized by the Chairperson, you may unmute yourself by pressing "\*" and then "6" on your phone. A voice prompt will let you know that you are unmuted. Once you are finished speaking, please enter "\*" and then "6" again to mute yourself.

For both internet and phone access, when testifying, you will be asked to identify yourself and the organization, if any, that you represent. Each testifier will be limited to five minutes of testimony per agenda item. If connection to the meeting is lost for more than 30 minutes, the meeting will be continued on a specific date and time. This information can be found on the Board's website

[https://cca.hawaii.gov/pvl/boards/naturopathy/meeting\\_schedule/](https://cca.hawaii.gov/pvl/boards/naturopathy/meeting_schedule/)

Instructions to attend State of Hawaii virtual board meetings may be found online at <https://cca.hawaii.gov/pvl/files/2020/08/State-of-Hawaii-Virtual-Board-Attendee-Instructions.pdf>.

**APRIL 19, 2024, NATUROPATHIC MEDICINE BOARD MEETING**

**AGENDA ORDER**

1. Call Meeting to Order
2. Approval of Meeting Minutes

The Board to review for approval the meeting minutes from its April 19, 2024, publicly noticed meeting.

*The Board may enter into Executive Session to consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities in accordance with HRS section 92-5(a)(4).*

3. Applications

*The Board may enter into Executive Session pursuant to Hawaii Revised Statutes sections 92-5(a)(1) and 92-5(a)(4) to consider and evaluate personal information relating to individuals applying for professional or vocational licenses cited in section 26-9 or both and to consult with the board's attorney on questions and issues pertaining to the board's powers, duties, privileges, immunities, and liabilities.*

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

4. 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.

5. Review Letter from the State of Hawaii, Department of Health

*The Board may enter into Executive Session to consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities in accordance with HRS section 92-5(a)(4).*

The Board to review letter addressed to the Board 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.

6. Testosterone

*The Board may enter into Executive Session to consult with the Board's attorney on questions and issues pertaining to the Board's powers, duties, privileges, immunities, and liabilities in accordance with HRS section 92-5(a)(4).*

The Board to re-assess the inclusion of testosterone on the Boards' Naturopathic Formulary.

7. Next Meeting Date

To be announced  
Queen Liliuokalani Conference Room  
King Kalakaua Building  
335 Merchant Street, First Floor  
Honolulu, Hawaii 96813

8. Adjournment

If you need an auxiliary aid/service or other accommodation due to a disability, contact Executive Officer Christopher Fernandez at (808) 586-2708 and [naturopathy@dcca.hawaii.gov](mailto:naturopathy@dcca.hawaii.gov) as soon as possible, preferably by **November 13, 2024**. Requests made as early as possible have a greater likelihood of being fulfilled.

Upon request, this notice is available in alternate/accessible formats.

**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, April 19, 2023

Time: 2:00 pm

Place: Queen Liliuokalani Conference Room  
King Kalakaua Building, 1<sup>st</sup> 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://youtu.be/uKDOncQzp1E?si=65EYzBlpn0biXUL>

Present: David Kern, N.D., L.Ac., Chair  
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  
Mia Hoang, Office Assistant, Tech Support  
Cortnie Tanaka, Secretary  
Juliet Kalilikane, Secretary

Excused: None

Guest: None

Call to Order: There being a quorum present, the meeting was called to order by Chair Dr. Kern at 2:20 pm.

Approval of the  
December 1, 2023  
Meeting Minutes:

After the Board reviewed the meeting minutes for December 1, 2023, Vice Chair Dr. Coles noted the abbreviation "NP" was being attributed to some of her statements, stating this was confusing. She recommended being clear which term is being used and to use the full term to avoid confusion on the context for discussion.

Chair Kern noted on Page 5, the term "Naturopathic Practitioner", and subsequent abbreviation "NP" is not actually used by Naturopathic Doctors any reference to physicians or practitioner should only be abbreviated as "ND" for "Naturopathic Doctor".

Vice Chair Coles referred to her comment on page 6:

Vice Chair Coles opined that many patients will say to others, "I go to my NP for that", referring to the licensed Naturopathic Physician. This seems to be a public safety issue if it confuses the public.

She added that the point she was trying to get across in the comment was that the public may use that term "ND", or "Naturopathic Doctor" (a permitted title for licensed Naturopathic Physicians) for someone who does not hold a Naturopathic license, saying "I go see my ND" when they are referring to a practitioner that does not hold the license. The discussion was around permitted titles for certain practitioners who are not licensed (under chapter HRS 455) and that I was stating it could be a source of confusion for the public if an unlicensed person can use the term "naturopathic" combined with another term.

Chair Kern added that a person who attended an unaccredited college to study the subject of naturopathic medicine, and thus did not complete an accredited doctorate in naturopathic medicine as required by HRS chapter 455, but believes that they can use the term "NP" for "Naturopathic Practitioner", is not excused from inappropriately using a term, because the public assumes the terms "NP" or "Naturopathic Practitioner" (unlicensed) and "ND" or "Naturopathic Doctor" (licensed), are equivalent.

EO Fernandez summarized the change the meeting minutes as:

Vice Chair Coles opined that many patients will say to others, "I go to my ND for that", referring to the licensed Naturopathic Physician. This seems to be a public safety issue if it confuses the public when a unlicensed practitioner uses the same or similar term.

Vice Chair Coles agreed adding that a patient will refer to practitioner as an "ND" when they are in act not.

Referring to a comment made by EO Fernandez on page 6, Chair Kern expressed additional concern that the minutes do not reflect that the term "Naturopathic" is an unprotected term, when he opines that it is.

EO Fernandez responded that the comment below will be stricken from the minutes, page 6, first line:

Additionally, the term "Naturopathic" itself alone is not protected in the rules. It is usually attached to the term "physician" or "doctor".

Chair Kern asked for any additional changes to the minutes, hearing none from members, Vice Chair Dr. Coles made the motion to approve the meeting minutes with changes, seconded by Dr. De Soto, and unanimously carried by the Board.

Licensure  
Reciprocity  
and Professional  
Educational  
Organizations:

Chair Kern asked EO Fernandez to initiate discussion.

EO Fernandez oriented the Board.

Agenda item (3a) continued the conversation regarding titles.

Agenda item (3b) is in regard to the continuing education requirement and potential for utilizing an audit and subsequent online renewal option for the board's consideration.

**Taken out of order**

3b: The Board to consider a percentage audit of licensees for the continuing education ("CE") biennial renewal requirement.

Regarding Agenda item (3b), Chair Kern asked what the procedure is for changing the process for continuing education ("CE") requirements.

EO Fernandez explained to get an audit for Naturopathic Medicine, a statutory change would likely be a clean and straightforward way to implement change. The immediate change from the licensee perspective is submitting the renewal paperwork and fee, completing affidavit questions, and a set number of months after the closing of the renewal, you would receive a letter notifying you have been selected for CE audit. Next year, we could request an admin bill to reduce some of the administrative time constraints.

Chair Kern requested that the meeting notes and the board members be explicit about the substantive differences between statutory changes and administrative rules change processes.

EO Fernandez explained an administrative measure or bill is statutory amendments introduced on behalf of the governor whose package may include amendments to chapters such as the Board's which are considered administrative in nature. Administrative rule change process involves extensive steps and multiple entities including, the Small Business Regulatory Review Board, and the Attorney General's office to name few.

The primary difference is one is for a statutory change, and one is to amend the rules.

Any administrative rules change is dependent on what is put in the statutes. So, if there is no authority in the statute that would allow the promulgation of rules, then the rules wouldn't go anywhere. For example, regarding parenteral therapy, all the requirements for not only the applicants and licensees, but also for the non-school course providers are in the rules because the statutes provided that authority.

Chair Kern stated that in the current legislative climate that naturopathic medicine bills may not have much value since the focus is financial and on recovery from the Maui fires.

Ms. Kimura stated that if the Board were to go through the administrative rules process, it is actually quite cumbersome. The Board would have to also hold a series of public hearings, so it may be quicker and faster and easier to do it by introducing a bill and changing the statute. But it would need people to advocate for it to keep going.

Chair Kern asked if this could be done through the Board or through the state association.

EO Fernandez replied that an administrative bill ("admin bill") is typically introduced on behalf of the Governor and his departments, and represent changes to address administrative issues. If it's substantive content, like a change to names of associations in the chapter, or to change the requirements for licensure, that would be something where the association should definitely get involved and get those bills introduced. But, if it's something having to do with the submission of applications or a CE audit, there could be grounds for justifying an admin bill because it would be addressing an issue with how to basically facilitate licensure. The Board has to be very careful about how something is written, because if it comes across as 'professional development' then there is a chance it may not be administrative. That is something the Board could continue to discuss.

Chair Kern asked EO Fernandez to elaborate on the previous admin bill request.

EO Fernandez explained the amendment request regarding the definition of CE in HRS 455 was submitted on behalf of the Board to the department for consideration two or three years ago. He stated he got the response from the department stating it viewed the requested



amendment as a professional development bill and didn't include it in the admin bill package submitted to the Governor. It could have been just the way it was worded. It is not just a given that Board requests get accepted. The request still goes through an internal review process.

Chair Kern asked if there was any further discussion on agenda item 3b. With no further conversation, he moved the conversation to agenda item 3c.

3c: The Board may also address the question of whether a Naturopathic Physician can purchase IV vitamins and devices with a parenteral therapy privilege, but without the minor office procedures privilege.

Chair Kern stated that this can be answered very quickly and decided to address the question before returning to the normal order of the meeting.

He went on to reply to the question in the affirmative, stating that a licensee may hold the privileges of parenteral therapy and minor office procedures without effect on one or the other. The requirements of each are separate and therefore one can obtain IV vitamins with a parenteral therapy privilege and not a minor office procedure.

#### **Taken out of order**

3a: The Board to continue reviewing licensure requirements, Board authorities, scope of practice, reciprocity, and protected terms pursuant to chapter 465, HRS, and chapter 16-88, Hawaii Administrative Rules, and other states' regulatory chapters.

Chair Kern started by stating that the crux of the matter is how protected the terms a Naturopathic Physician may use pursuant to the laws and rules.

He then provided a history to how this issue came up, stating that there is a school on Oahu who is producing health providers under the guise of Naturopaths. And, when the Board reviewed this matter at the previous meeting the Board was discussing if it had the authority to call for the school to cease and desist from, in any way, suggesting that a graduate of the school could use the terms protected by the statute and administrative rule chapters.

Chair Kern then stated from the previous meeting EO Fernandez was concerned that the Board did not hold the authority to request that the school cease and desist based on the alleged information. He stated that historically the Board has sent cease and desist letters in such matters.

Chair Kern asked explicitly if the Board had the authority to tell the school to cease and desist. He clarified that he was referring to the Regulated Industries Complaints Office ("RICO") process wherein the Board would submit a complaint to be investigated.

EO Fernandez replied that generally speaking, anyone is capable of submitting a complaint. Therefore, it may be irrelevant whether it is a board authority. However, the question remains about terms that are protected. He noted that at the last meeting, the Board determined that there would be a higher percentage of success in enforcing the protected terms if it, was able to be protected by itself (EO Fernandez was referring to the use of "Naturopathic" by itself: see full conversation in the December 1, 2023, meeting minutes).

He asked explicitly if the Board believes the term "naturopathic" is a core term, and despite being tied to such terms as "physician", or "doctor" in §16-88-7.5. Use of titles, the term is so fundamental that it would confuse the general public if it were used in any unlicensed practice.

Chair Kern replied that yes it would confuse the public, but he added a second consideration, that to use the term not only confuses the public, but is in violation of the chapters.

Vice Chair Coles and Dr. De Soto concurred.

Vice Chair Coles added in state that licenses doctors who are trained in naturopathic medicine, anything associated with the term 'naturopathic' should be protected under the license because this is the purpose of licensure; to ensure that anyone in the public who is seeking naturopathic care is not going to be confused or bamboozled by individuals who use the term 'naturopathic' but are not medically trained the way licensed Naturopathic Physicians are. She added concern about the risks of seeking services from such a person who is not medically trained, concluding that any iteration of the term 'naturopathic' should be expected to be protected.

Dr. De Soto agreed with Dr. Coles and also added an additional perspective related to states that do not have licensure. She reminded the members that states without regulation have people who have certifications in naturopathic/holistic care, and they use the term broadly and loosely as a "holistic provider", "naturopathic provider", or a "certified naturopath". There are many online courses that people can take that will give them a "naturopathic" certification. She expressed concern that those coming from unregulated states who use the term "naturopathic" would need to understand that it is a protected term in Hawaii and cannot practice as they were in the unregulated state.

EO Fernandez added, at the recent FNMRA, or Federation of Naturopathic Medicine Regulatory Authorities, meeting, states were complaining of increases in instances of unlicensed practice.

Ms. Kimura stated as a member representing the public, it would be confusing if the term "naturopathic" were not a protected term. On face value, a public person would not know if the practitioner was a license naturopathic physician or not.

Chair Kern asked if there were any other comments for agenda item 3a.

EO Fernandez reported the following regarding research on the administrative rules in preparation for possible amendments.

Chapter 455, HRS, has a definition of naturopathic medicine. In this definition, the practice of naturopathic medicine is also defined. So, the definition is doing double duty because there is no section that talks about the practice of naturopathic medicine outside of the definition. There is a section obviously on protected terms in Hawaii Administrative Rules ("HAR") chapter 16-88, but when comparing how the practice of Naturopathic Medicine is defined and how the practice of Dentistry is done in its chapter, in his opinion, Dentistry is well written. He explained not only does the definition of practice have its own section, but it also includes the exemptions to that practice in the same section. The other thing to consider, is Dentistry has most of its language in statute. Naturopathic Medicine uses statutes and also there is a lot of work being done in the rules. EO Fernandez stated that these were merely observations of, on one hand, a piecemeal relationship between statutory chapter and administrative rules, and on the other, a chapter that houses things a little bit better, e.g., using one section, like dentistry. The board could start the process of rule amendment if it wished to include further protected terms, for example.

Chair Kern stated that over the course of the 16 years he has been fortunate to be on the board, the issues of terminology, or the issues as it relates to the rules from which the Board was speaking, have not come up in ways that have generated conflict or confusion. He contemplated if this was a "if it ain't broke, don't fix it" situation, adding he thought it might depend on whether there is a need, out of this discussion, to update the chapters stemming from the question of how comprehensive the protected terminology in the chapter needs to be. If it suits our needs in terms of anyone attempting to exploit the terms through any kind of schooling or certification (not recognized by the Board).

He asked if any members see the need to update the rules or terminology.

Ms. Kimura asked again if a RICO complaint could be made against the school whose is allegedly using the term "naturopathic" for certification.

Chair Kern stated that the Board could submit a complaint and reiterated the process asking DAG Leong if this was correct.

DAG Leong confirmed that when considering the practice of an unlicensed person, if it turns into a case where RICO is enjoining an unlicensed person from unlicensed practice, they would handle that without the Board's participation.

Dr. DeSoto stated that she is unclear whether the Board needs to update protected terms or whether they function well enough now. She admitted

that it appeared the process of amending them would be cumbersome, but that clarifying that the term "naturopathic" in and of itself is a protected term.

EO Fernandez reminded the Board that it could continue the discussion (at another meeting).

Chair Kern stated that the protected terms from the statute chapter and administrative rules chapter have served the Board well thus far, but if the need for stronger language exists to protect the practice the Board could look into that too.

Dr. De Soto asked how a complaint would be made.

EO Fernandez replied that he can do so on behalf of the Board.

Chair Kern called for a motion to instruct EO Fernandez to submit a complaint to RICO on behalf of the Board.

Vice Chair Coles motioned to instruct EO Fernandez to submit a complaint to RICO on behalf of the Board regarding the alleged use by a training school in Hawaii of the protected term "naturopathic" or in certification training which purports to certify students in naturopathic medicine. The motion was seconded by Ms. Kimura, and the Board voted unanimously to approve the motion.

Ms. Kimura brought up another subject related to the agenda item, mainly the existence of practitioners who do something called functional medicine.

EO Fernandez asked Ms. Kimura if she felt this was another instance of skirting around protected terms.

Ms. Kimura replied that she would assume someone was trained in naturopathic medicine if they are trained in functional medicine and are using holistic modalities.

Dr. Kern replied to Ms. Kimura stating he could provide a history of the term. One of the most well-known people in holistic medicine was a biochemist by education and training, who was trained at the Linus Pauling Institute, and who was a mentor of his in naturopathic medicine when he was starting out; that person's name was Jeffrey Bland. Dr. Bland laid out a framework of naturopathic medicine through a series of works and talks coining the term Functional Medicine. He added that this term is used by medical doctors practicing naturopathic medicine, but who do not want to use the term naturopath. He added that there is more to functional medicine than that.

Applications:

- a. Applications Review for Approval Request for Approval of Qualifying Course on Parenteral Therapy

1. Request by Dr. Virginia Osborne for course from March 7th to 10th, 2024: San Diego, CA.
2. Request by Dr. Virginia Osborne for course from September 7th-10th, 2024: Dallas, TX.

Chair Kern asked EO Fernandez if there were any issues to be concerned about with the applications.

EO Fernandez noted that the applications had no updated course content or instructor information, just change of date and location of facilitation. He added though, that the requestor, Dr. Virginia Osborne submitted a letter to the Board requesting that the approval of course content and instructors be approved for a 2-year period. EO Fernandez reminded the Board that based on previous discussions and determinations, each facilitation of the course (i.e., the date and location of the course) needed to be approved. He recommended that the Board not approve course content and instructors of Dr. Osborne's courses for a 2-year period based on the aforementioned.

Chair Kern agreed.

Vice Chair Coles echoed Dr. Kern adding that to approve multiple courses at once would require a rule change and that she believes the Board should not pursue that. She stated that unfortunately the Board will just need to inform Dr. Osborne that will not be possible.

EO Fernandez asked DAG Leong if the Board could consider approving an Executive Officer delegation to approve courses from Dr. Osborne, provided that the course content and instructors have not changed since the last Board approved course.

DAG Leong answered that the Board could provide the delegation, but would need to be posted on a future agenda.

Chair Kern expressed interest in creating such a delegation for EO Fernandez.

Chair Kern called for a motion to approve the courses listed above under numbers 1 and 2.

Dr. De Soto motioned to approve the courses facilitated by Dr. Osborne and her group: March 7-10, 2024 in San Diego, CA; and September 7-10, 2024 in Dallas, Tx. The motion was seconded by Vice Chair Coles, and the Board voted unanimously to approve the courses.

Officer  
Elections:

Dr. Kern noted that his term on the Board was coming to a close in June, based on term limits. He added that the Board would be voting to choose a new Chairperson and Vice Chair. He opened the floor for nominations to the Chair position and also offered the nomination of Dr. Coles to the Chairperson position.

On a motion by Chair Kern, seconded by Ms. Kimura, the Board voted unanimously to make Dr. Coles the new Chair of the Board of Naturopathic Medicine.

Vice Chair and Chairperson-Elect Coles thanked and accepted the nomination.

On a motion by Chair Kern, seconded by Ms. Kimura, the Board voted unanimously to make Dr. De Soto the Vice Chair of the Board of Naturopathic Medicine.

Dr. Kern provided some closing remarks stating that he was thrilled to have such an incredible group of colleagues, in addition to Ms. Kimura on the Board. He felt the Board would be in good hands with the level of professionalism, competence, intelligence and articulation is exceptional. He congratulated the new Chairperson and Vice Chair.

Next Meeting

Friday, July 26, 2:00 p.m.  
Queen Liliuokalani Conference Room  
King Kalakaua Building  
335 Merchant Street, First Floor  
Honolulu, Hawaii 96813

Adjournment

After thanking the staff of the Board for support during his tenure, Chair Kern adjourned the meeting.



**STATE OF HAWAII  
DEPARTMENT OF HEALTH  
KA 'OIHANA OLAKINO  
P. O. BOX 3378  
HONOLULU, HI 96801-3378**

In reply, please refer to

September 23, 2024

Dear Board of Naturopathic Medicine,

We are writing in follow up to share relevant findings from our investigation of adverse reactions occurring after administration of intravenous nicotinamide adenine dinucleotide, oxidized (NAD+) solution.

Between December 13 – 15, 2023 four persons experienced adverse events following intravenous (IV) administration of NAD+ solution Lot 11242023@4 Expiration 1/20/24 at Maui Longevity RX clinic. The NAD+ solution was compounded at the Wailea People and Paws Pharmacy and prescribed by naturopathic physician Dr Emily Loren.

### **Findings / Test Results**

#### Endotoxin Detection in NAD+ Samples

The FDA conducted qualitative endotoxin testing and reported to Hawaii Department of Health (DOH) on reports dated between 3/18/24 and 4/18/24 that endotoxin was found in the following specimens:

- The used and unused multiuse vials of NAD+ solution lot 11242023@4 compounded by Wailea People and Paws Pharmacy obtained by DOH from Maui Longevity RX clinic.
- Samples from Wailea People and Paws Pharmacy of the left-over NAD+ compounded solution lot 11242023@4, bulk NAD+ powder used to make compounded lot 11242023@4, and newly compounded NAD+ solution.

Quantitative endotoxin testing reported to DOH on reports dated 4/5/24 showed levels of endotoxin that would be objectionable for the intended eventual use of IV administration in the following specimens:

- The unused multiuse vials of NAD+ solution, and
- Bulk NAD+ powder, and compounded NAD+ solution made at the pharmacy.

Because endotoxin testing on the compounded NAD+ solution was performed after the labeled beyond use dates it is not possible to determine whether the endotoxin found in these samples contributed to the adverse effects experienced by patients treated at the

clinic. However, the results also do not provide any reassurance as to quality or consistency of compounded NAD+ solution dispensed and eventually administered to the four patients who experienced adverse events.

BPC-157, a 503A Category 2 Bulk Drug Substance was Administered

One of the four patients who experienced an adverse event also received BPC-157 that was obtained from the Wailea People and Paws Pharmacy and administered by Maui Longevity Rx.

On September 29, 2023, the FDA designated BPC-157 as a category 2 bulk drug substance and noted the following safety risk: "compounded drugs containing BPC-157 may pose risk for immunogenicity for certain routes of administration and may have complexities with regard to peptide-related impurities and API characterization. FDA has identified no, or only limited, safety-related information for proposed routes of administration; thus, we lack sufficient information to know whether the drug would cause harm when administered to humans." <https://www.fda.gov/drugs/human-drug-compounding/safety-risks-associated-certain-bulk-drug-substances-nominated-use-compounding>

Regarding category 2 bulk drug substance, of which BPC-157 was designated, the FDA states, "These are bulk drug substances that were nominated with sufficient supporting information for FDA to evaluate them, but raise significant safety concerns, and are not eligible for the policy that applies to substances in Category 1. These bulk drug substances cannot be used in compounding unless FDA publishes a final rule (section 503A (b)(1)(A)(i)(III)) or final Federal Register notice (section 503B(a)(2)(A)) authorizing the particular substance's use in compounding." <https://www.fda.gov/drugs/drug-safety-and-availability/update-fda-revises-final-guidances-interim-policy-certain-bulk-drug-substances-used-compounding>

**Additional Actions**

NAD+ bulk powder lot 200264/G exp 3/2025 used as a component in NAD+ compounded solution lot 11242023@4, held by Wailea People and Paws Pharmacy under embargo by DOH was found to have levels of endotoxin that would be objectionable for IV administration. Given the sole intended use of the powder is for eventual intravenous administration, all NAD+ bulk powder lot 200264/G exp 3/2025 in the possession of Wailea People and Paws Pharmacy is to be disposed of according to industry best practices and relevant regulations after being released from embargo by DOH for the sole purpose of destruction. With this understanding, NAD+ bulk powder lot 200264/G exp 3/2025 was released from embargo on 6/24/24.



Board of Naturopathic Medicine  
September 23, 2024  
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Finally, at the time of these recommendations BPC-157 should not be compounded as a human drug product based upon current information from the FDA, and as a result also should not be administered as a human drug product. DOH requests that, if feasible, the Board of Naturopathic Medicine notify its licensees of the FDA's designation of BPC-157 as a category 2 bulk drug substance that cannot be used in compounding.

Sincerely,

A handwritten signature in black ink that reads "Nathan Tan". The signature is written in a cursive style with a long horizontal line extending from the end of the name.

Nathan CY Tan M.D.  
Deputy State Epidemiologist  
Disease Outbreak Control Division  
Hawaii State Department of Health

# NATUROPATHIC FORMULARY

(Effective August 4, 2023)

## Introduction

Pursuant to Hawaii Revised Statutes §455-6(7), the Board of Naturopathic Medicine ("Board") may annually establish and publish a naturopathic formulary that has been approved by the Board for prescription, administration, or dispensing by naturopathic physicians.

Be advised, that naturopathic physicians **shall only** prescribe, administer, or dispense vitamins, minerals, dietary supplements, botanical medicines, homeopathic medicines, hormones (except for testosterone), and legend drugs consistent with naturopathic medical practice **that are included in this formulary.**

Be further advised, that naturopathic physicians **cannot** prescribe, administer, or dispense any item included in the formulary in the injectable form or by injection unless the naturopathic physician is specifically authorized by the Board pursuant to Hawaii Administrative Rules §16-88-56. To determine if a naturopathic physician is licensed and possesses a "parenteral therapy" special privilege issued by the Board, please visit <https://pvl.ehawaii.gov/pvlsearch/> or you may call our Licensing Branch at (808) 586-3000.

If you have any other questions, please contact the Board's office at (808) 586-2708 or visit the Board's website at <http://hawaii.gov/dcca/pvl/boards/naturopathy/>.

## List of Formulary Items

**ATTENTION:** *New entries in the formulary are identified by bold italicization.*

1. **ALL non-prescription and prescription** vitamins, minerals, nutritional/dietary supplements, botanical medicines, homeopathic medicines, and all biological substances including extracts and/or their products and residues.
2. **ALL HORMONES** with the exception of testosterone.
3. **ANTIBIOTICS**
  - Amebecides
  - Antifungal agents
  - Anthelmintics
  - Antimalarial preparations (includes artemisinin, derived from *Artemisia annua*)
  - Antiprotozoal agents
  - Antituberculosis agents
  - Antiviral agents

# NATUROPATHIC FORMULARY

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Bacitracin

### 3. **ANTIBIOTICS** (continued)

Cephalosporins and related antibiotics

Fluroquinolones

Macrolides

Nitrofurantoin

Metronidazole

Neomycin

Nitrofurans

Penicillins

Quinolones

Sulfonamides

Tetracyclines

### 4. **PAIN CONTROL AGENTS**

Anti-gout agents

Antimigraine agents

Antirheumatics

Cyclobenzaprine

Naltrexone

Non-opiate analgesics

NSAIDS

Salicylates

### 5. **DERMATOLOGICALS**

Anti-fungals, topical and oral

Anti-infectives, topical only

Anti-inflammatory agents

Anti-psoriatic agents, excluding methotrexate

Antihistamine preparations, topical and oral

Antiseborrheic products

Counterirritants

Destructive agents

Dressings and granules

Drying agents

Eflornithine HCl

Enzyme preparations

Finasteride

Hemostatics, topical only

Immunomodulators, topical only

Irrigating solutions

Keratolytic agents

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Local anesthetics

Topical, IM, and SQ Bupivacaine, Lidocaine, and Procaine

### 5. **DERMATOLOGICALS** (continued)

IM and SQ Epinephrine

Minoxidil

Photochemotherapy

Pigment agents

Protectants

Pyrrhione zinc

Retinoids

Rexinoids

Scabicides/pediculicides

Oral and topical steroids

### 6. **OPHTHALMIC AGENTS**

Antibiotics

Antivirals

Mast cell stabilizers

Ophthalmic antihistamines

### 7. **OTIC AGENTS**

Antibiotics and combination preparations

Otic anesthetics

Otic steroids

### 8. **RESPIRATORY AGENTS**

Antitussives and combined antitussives

Bronchodilators

Expectorants

Antihistamines

Leukotriene formation inhibitors

Leukotriene receptor antagonists

Nasal steroids

### 9. **GASTROINTESTINAL AGENTS**

Antidiarrheals

Anti-emetic/antivertigo agents

Bile acid sequestrants

Functional bowel disorder agents

Cholelitholytic agents

H. pylori agents

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Proton pump inhibitors  
Sodium phenyl butyrate

## 10. **CARDIOVASCULAR AGENTS**

Anti-lipemic agents  
Anti-thrombotic/anti-coagulant agents  
Hypotensive agents  
Digoxin  
Pentoxifylline  
Vasodilating agents

## 11. **RENAL AND GENITOURINARY AGENTS**

Alpha-reductase inhibitors  
Diuretics  
Impotence agents  
Phenylbutyrate  
Uricosuric agents  
Urinary antispasmodics  
Vaginal Preparations

## 12. **PSYCHOTHERAPEUTIC AGENTS**

Acetylcholinesterase Inhibitors  
Antidepressants  
Smoking cessation agent  
**Antipsychotics** (effective August 4, 2023)

## 13. **ENDOCRINE AND METABOLIC AGENTS**

Anti-diabetic agents  
Anti-thyroid agents  
Bisphosphonates  
Uterine-active agents

## 14. **DIAGNOSTIC AGENTS**

In vitro Diagnostic Aids  
In vivo Diagnostic Biologicals

## 15. **VACCINES (all)**

Anti-toxins and antivenins  
Immune globulins

**NATUROPATHIC FORMULARY**

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**16. CENTRAL NERVOUS SYSTEM DRUGS**

Anticonvulsants

**17. CHELATING AGENTS (all)**

**18. MEDICAL GAS**

**19. ADDITIONAL PARENTERAL FORMULARY ITEMS**

**I. Category: Amino Acids and Glutathione**

**II. Category: Electrolytes, Sugars, and Diluents**

**III. Category: Glandulars**

**IV. Category: Total Parenteral Nutrition**

**V. Category: All biological substances including extracts and/or their products and residues except for testosterone.**

**VI. Category: Other: alpha lipoic acid; intraarticular agents; sclerosing agents; fish oil; hydrochloric acid; phosphatidyl choline**

**V. Category: Cosmetic Treatments and Dermatological Fillers**