



Oregon

Tina Kotek, Governor

Board of Naturopathic Medicine
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WHO: **Formulary Council - Oregon Board of Naturopathic Medicine**
TELEPHONE CONFERENCE / Zoom

WHEN: **March 15, 2023 at 9:30 am**

In order to limit the exposure of the COVID-19 virus and adhere to the Governor's social distancing measures the Health Licensing Office (Office) is prohibiting attendance at the Board meeting. All audience members may attend the public session portion of the meeting by telephone conference call. Executive Session will be held according to ORS 192.660 (2)(f) (information or records exempt from public disclosure), and 192.660(2)(k) (information obtained as part of an investigation of licensee or applicant conduct).

What is the purpose of the meeting?

Bi-Annual Meeting of the Formulary Council of the Board of Naturopathic Medicine, see agenda attached.

May the public attend the public session via teleconference?

Yes, however, for the courtesy of all participants on the call all non-board members are asked to **mute** the call.

Approximately five minutes prior to the 9:30 start of the meeting please follow the directions listed below:

- Dial 1(866)528-2256 and enter the following participants pass code: 8467947 to be connected to the meeting. This phone line will stay connected for the duration of the meeting.
- The teleconference system will notify you that you are connected.
- No final actions or final decisions will be made in executive session portion of the meeting. The board will take any final action and / or make any final decisions in the public session portion of the meeting.

Oregon Board of Naturopathic Medicine

◆ Formulary Council Biannual Meeting ◆

DRAFT MINUTES

Conference Call/Zoom

March 15, 2023 @ 9:30 am

1. Members Present: Natalie Gustafson; Adam Alani; Carmen Ionescu
Members Excused: Bill Walter
Members Absent: Lara Williams, Will McClatchy, Stephanie Culver
Present: Mary-Beth Baptista, JD – Executive Director Board of Naturopathic Medicine
2. (TABLED – NO QUORUM) Review and Approval Public Formulary Council Meeting Minutes – September 21, 2022
3. DTE compounding Update –FDA has been active in reclassification of what types of drugs are permitted to be compounded. Biologics are prohibited from being compounded. The Sept 2022 compounding pharmacists got a “surprise” FDA letter announcing (without process) that thyroid extracts are biologic and may not be used in compounding medication. Letter asserts that thyroid was always classified as a biologic and the letter served as notice will now enforce the prohibition. FDA sent a second letter that softens their stance – but still strong on enforcement.

Compounding pharmacists are concerned about patient safety because compounded thyroid medication is different from the commercial medication and patients with hypothyroidism find relief / wellness from compounded thyroid medication that they do not with manufactured medication. Patients will also now have limited / eliminated access to the medication. Compounding pharmacists are concerned and speculating about the motive for FDA to make this move, theories include pharmaceutical companies pressuring FDA to make the change to increase manufactured product sales.

Additional concern is that FDA may be setting a precedent / path for prohibiting compounding of hormones. Hormones are currently “under review” meaning currently researching whether to allow compounding of hormones, the review report could recommend prohibiting compounding hormones. This would have a devastating effect because hormones are widely used in compounding a whole spectrum of medication. Additionally, unlike thyroid where there are some manufactured commercially available thyroid medication, most / many compounded hormones are not available commercially. Prices will rise dramatically and much more restricted patient access. All are concerned if FDA eliminates / whittles away these two categories, this will signal the end to many compounding pharmacies.

Major rule changes around compounding are going into effect in 2023. US Federal standards for compounding are also going to drastically change as of Nov. 1, 2023. The Oregon Board of Pharmacy has a compounding workgroup to finalize Board rules by October to comply with the new federal rules.

ACTION ITEM: Council Chair Natalie Gustafson invited to speak with the Board at the October meeting to discuss the new pharmacy rules.

4. Suboxone and elimination of the X-waiver – Federal Government eliminated the X waiver in January. Board filed an emergency temporary rule to strike the recent formulary rule excluding prescribing Buprenorphine in combination for use in addition treatment. Board filed notice of permanent rulemaking earlier this month, open for public comment until May. Board will vote to adopt by June before the temporary rule expires at the 6-month deadline. Federal government lifted the waiver without instituting rules, guidelines or training. Per HHS, they are developing training requirements and guidelines, projected completion June of 23. Concern regarding ND's being able to prescribe and engage in this treatment without training. Inquiries to pharmacists regarding use. Discussion regarding wanting to wait to see what the federal requirements will be prior to making OAR. Carmen Ionescu suggested Board reach out to OHSU department of addiction – which includes addiction therapy psychiatrists; because they have a robust hands on training program for addiction therapy that is available to all general practitioners.

ACTION ITEM: MB – to contact OHSU psychiatry to learn more about the training to bring to the Board / licensees to encourage licensees to take the training while waiting for the federal rules to be adopted.

5. Oregon Psilocybin Services begins approving worker permit, license applications. Dr. Zelfand, Dr. Hicks and Sam Chapman, head of the Healing Advocacy Fund, will attend the April Board meeting to discuss / explain the facilitator certification program and detail for the Board what is required to be certified. Formulary Council members questions?
- What is the relationship b/w the service center and the facilitator?
 - How is the psilocybin administered – plant or extract? Who and how is appropriate dosage assessed? Who makes those recommendations? What study was done around dosage, are there dosage guidelines?
 - How is psilocybin ordered / distributed? Who administers the psilocybin? What is the “chain of custody” to ensure the right dosage is ordered and administered to the right participant? What amount if any is permitted to be on site? Does it have to be ordered specifically for a patient or is a service center allowed to have some on hand?
 - What medical intake is conducted before administering psilocybin?
6. Discussion regarding criteria for pharmacy CE credit approval. Continuing education requirements are getting more specific based on area of practice. Board has criteria for approval for certain required CE subject areas. Baptista shared CA board requirements for pharmacology approval. Baptista asked for recommendations for criteria for approval for pharmacology CE.
- Dosing / administration / side effects – something about the drug itself.
 - Presentation on new or experimental medication
 - When how to recognize when dosing adjustments are necessary, identifying drug to drug interactions / drug to condition presented interactions
 - Contraindications and prescribing safety
 - Case presentation – Dr. describes prescribing / condition / treatment and evidence based outcome of treatment

ACTION ITEM: Nurse Practitioners have clear requirements of what is required for a presenter to be approved as pharmacy CE. MB to contact the nursing board regarding nursing board CE approval

criteria.

7. (TABLED – NO QUORUM) Board approved on February 13, 2023, Dr. Carmen Ionescu & Dr. Adam Alani to appointed for 2 more years on the Formulary Council. However, per OAR, Council must approve their applications.
8. Formulary Meeting Schedule – Third Wednesday – September / March – Via Zoom. Next meeting September 20, 2023. Suggested providing more reminders throughout the six-month period to remind members of the meeting date and time.

ACTION ITEM: MB to send formulary council meeting reminder June and August.

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UPCOMING BOARD MEETINGS:

All are invited to attend the Public Session of any Board meeting.

OBNM Public meetings are tentatively scheduled for the second Monday of every even-numbered month

◆ Council Chair reserves the right to revise the agenda and to limit public discussion