

**MARYLAND BOARD OF PHYSICIANS
NATUROPATHIC DOCTORS FORMULARY COUNCIL (NDFC)
OPEN MEETING MINUTES
May 4, 2017**

MEMBERS PRESENT: Christina G. Marrongelli, OTA, BScPH, PharmD.; Brenda Baker; Melissa A. Clark, M.D.; Paul Faust, N.D.; Joylene John-Sowah, M.D., MPH; Carrie A. Runde, N.D.; and Mariana Marques, Department of Health and Mental Hygiene.

STAFF PRESENT: Yemisi Koya, Director, Communication, Education and Policy Unit; David Finkler, Board Counsel; Sandi Van Horn, Health Policy Analyst; and David Chijioke, Health Policy Analyst Associate.

ABSENT: None

GUEST: Rachel Burch

CALL TO ORDER

Dr. Marrongelli called the meeting to order at 10:10 a.m.

INTRODUCTIONS

NDFC members and Board staff introduced themselves.

ADMINISTRATIVE MATTERS

Dr. Koya discussed the Open Meetings Act, noting that members of the public are welcome to attend NDFC meetings and that agendas are posted on the Board's Website. Dr. Koya also reviewed administrative matters related to the NDFC. Board staff will be assisting the NDFC with agenda development and meeting preparation. NDFC members will vote on decisions.

MARYLAND'S STATUTE AND REGULATIONS REGARDING NATUROPATHIC DOCTORS / STATUTORY AUTHORITY OF THE NDFC / DUTIES AND OBJECTIVES

Mr. Finkler read from statute (§14-5F-4.1 of the Health Occupations Article) about the membership of the NDFC, duties of the NDFC, and the required contents of a formulary. The role of the NDFC is to develop a formulary and recommend a formulary to the Board. The Board has the final authority to accept or modify recommendations from the NDFC. Mr. Finkler also noted, per statute, what is excluded from a formulary.

EXAMPLES OF OTHER STATES' FORMULARIES

Ms. Van Horn provided examples of categories utilized in formularies of other states and the District of Columbia. She also reviewed the formats of the various formularies, noting that most are presented via a chart or a list with categories or classifications. Some formularies also include an introduction, exclusions, or information on types of permitted administration.

FORMULARY FOR MARYLAND

Dr. Marrongelli opened a discussion regarding a formulary for Maryland. Dr. Runde inquired if the NDFC has authority to make recommendations for statutory changes regarding prescribing.

NATUROPATHIC DOCTORS FORMULARY COUNCIL
OPEN MEETING MINUTES
May 4, 2017
Page 2 of 4

Mr. Finkler opined that he did not think the NDFC, at this time, could go beyond the scope of duties mandated in statute. Mr. Finkler discussed what naturopathic doctors (NDs) are permitted to order, dispense, and administer, and which routes of administration are allowed by statute.

Dr. Marrongelli inquired if NDs in Maryland have a DEA registration, and Dr. Runde responded that they do not. Dr. Marrongelli asked whether NDs can “prescribe” epinephrine because statute states that administering (auto-injectable) epinephrine is permitted. *See §14-5F-14(a)(5)*. Mr. Finkler noted that statute allows NDs to prescribe epinephrine, as it is an item to be listed on the formulary. *See §14-5F-04.1(d)(1)(ii)*. He added that if there is confusion about certain statutory language, the NDFC can refer that matter to the Naturopathic Medicine Advisory Committee (NMAC) to consider a regulatory change for clarification. Board staff and Mr. Finkler are to conduct further research into pharmacy law and regulations, DEA registration requirements, and how the formulary interacts with statutory language in §14-5F-14.

Dr. Marrongelli suggested a formulary with notations about dosing. She added that the statute does not allow for certain routes of administration. Mr. Finkler said that adding routes to statute would be a legislative matter.

Dr. Faust added that another gray area is nebulization, which is not mentioned at all.

Dr. Marrongelli noted that statute specifically states (under §14-5F-14) that NDs can administer auto-injectable epinephrine; however, clarification is needed as to whether NDs can prescribe auto-injectable epinephrine for patients’ use.

Mr. Finkler stated he would look into the matter regarding administering vs. prescribing epinephrine. He noted that statute does not specifically state (under §14-5F-14) that NDs can “administer” oxygen; however, prescription oxygen is to be on the formulary. *See §14-5F-04.1*. The other prescription items (in §14-5F-04.1) are not listed in routes of administration or items permitted for dispensing and ordering. *See §14-5F-14(a)(3) and (4)*. The NDFC may not have authority to include “method” in a formulary beyond what statute states.

Dr. John-Sowah said she would like to see the routes defined. Dr. Koya suggested a preamble or introduction to the formulary utilizing statutory language about routes of administration. Mr. Finkler added that the preamble could contain a notice stating nothing on the formulary restricts NDs from dispensing, ordering, or administering the items listed in statute, as long as they are not prescription drugs. Those items in the statutory language [of §14-5F-14(a)(3) and (4)] do not have to be included in the formulary list, but NDs should be aware of what they are permitted to do per statute.

Dr. Clark directed a question to the ND members about the use of vaccines. Dr. Runde noted that vaccines are part of ND training but currently are not in the scope of practice for NDs in Maryland.

NATUROPATHIC DOCTORS FORMULARY COUNCIL
OPEN MEETING MINUTES
May 4, 2017
Page 3 of 4

Dr. Faust advocated for retaining statutory language to avoid the potential for misinterpretation that unintentionally could limit what NDs are permitted to do.

Dr. Marrongelli again mentioned inclusion of dosing limits so that NDs don't go beyond an amount that would fall into a prescriptive dose.

Mr. Finkler opined that there would be no conflict if statutory language was included in a preamble about permitted items to be dispensed or ordered, despite the formulary.

Dr. Clark inquired about local anesthetics and minor office procedures. Dr. Runde noted that NDs are trained in minor office procedures but such procedures currently are not in the scope of practice for NDs in Maryland.

Dr. Runde brought up two topics: medical foods and natural substances. She noted that natural substances are permitted in the NDs' scope; however, when NDs need to obtain them from a compounding pharmacy it falls into a prescription category (for example, a B-12 shot). This limits the ability of NDs to utilize natural substances.

Mr. Finkler discussed the term "medical foods," which he has been researching, and said the Food and Drug Administration (FDA) considers medical foods to be non-drugs and not prescription drugs. Medical foods could be added to a formulary preamble.

Dr. Clark proposed a list (to follow a preamble) for a formulary, utilizing certain categories in Colorado's formulary as an example: epinephrine, oxygen, FDA regulated non-prescription medications, barrier contraceptives, and FDA-regulated non-prescription devices. There was further discussion about organization of the preamble (with the language about routes of administration) and formulary. Dr. Clark made a motion to direct staff to draft a formulary with a list of the five items with methods and to add "medical foods" to the language (from statute) that will go into a preamble.

Dr. Faust suggested that the routes be addressed only in the preamble.

Dr. John-Sowah inquired about the process regarding NDFC recommendations. Mr. Finkler explained that staff will prepare a draft, which will be presented at the next NDFC meeting. Staff also should have information regarding the topics that will be researched. Then, the NDFC will review the draft, will revise it if necessary, and will vote to approve a recommendation to the Board.

Dr. Marrongelli raised a concern about listing medical foods in a preamble because that term is not in the naturopath statute. The term in statute - "food" - is broader.

Mr. Finkler explained that, based on his research, medical foods are not prescription drugs and therefore would not be excluded.

NATUROPATHIC DOCTORS FORMULARY COUNCIL
OPEN MEETING MINUTES
May 4, 2017
Page 4 of 4

Dr. Clark explained her understanding of medical foods and their preparation for a specific effect for the body; she suggested that the term be used in a preamble.

Mr. Finkler read a definition of medical food: A food which is “formulated to be consumed or administered, enterally under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” Mr. Finkler noted that the FDA guidance document specifically mentions that the FDA does not regulate medical foods as drugs.¹

Discussion turned to voting on the motion (for staff to draft a formulary). Dr. Marrongelli made a motion to add medical foods to the preamble language (as stated in Dr. Clark’s original motion).

Ms. Baker seconded. The vote was unanimous in favor.

FUTURE NDFC MEETINGS

NDFC members discussed their availability for the next meeting and agreed upon August 14, 2017 from 10 a.m. - noon.

ADJOURNMENT

Dr. Marrongelli adjourned the meeting at 11:31 a.m.

Respectfully Submitted by,



Dr. Yemisi Koya
Director, Communication, Education and Policy Unit

¹ The FDA document is “Frequently Asked Questions About Medical Foods; Second Edition Guidance for Industry” (May 2016) available from the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, FDA.