Naturopathic Doctors Formulary Workgroup

Report to the Senate Education, Health, and
Environmental Affairs Committee
and the House Health and
Government Operations Committee
July 1, 2015

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Maryland Board of Physicians
Baltimore, Maryland
July 1, 2015

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STATE OF MARYLAND

DHMH Board of Physicians

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

July 1, 2015

The Honorable Joan Carter Conway, Chair
Senate Education, Health and
Environmental Affairs Committee
2 West Miller Senate Building
11 Bladen Street
Annapolis, MD 21401-1991

The Honorable Peter A. Hammen, Chair
House Health and
Government Operations Committee
241 House Office Building
6 Bladen Street
Annapolis, MD 21401-1991

RE: CH 153 and 399 of the Acts of 2014 (HB 402),
State Board of Physicians and Allied Health Advisory Committees –
Naturopathic Doctors Formulary Workgroup Report

Dear Chair Carter Conway and Chair Hammen:

Attached please find a report of the Naturopathic Doctors Formulary Workgroup; the report has been prepared pursuant to Chapter law.

The Maryland Board of Physicians (the "Board") was legislatively mandated by the General Assembly (Section 3, Chapter 153 and Chapter 399, Acts of 2014) to convene a workgroup to study the development of a naturopathic formulary to regulate pharmaceuticals in the State of Maryland. The workgroup consisted of stakeholders representing various health organizations or health professions in Maryland and had the following charge:

1) Review the naturopathic formularies developed in other states;
2) Make recommendations regarding the establishment of a naturopathic formulary, including the types of drugs, medicines, and devices to be included in the formulary and the methods by which the drugs, medicines, and devices will be included on the formulary; and
3) Make recommendations regarding the routes of administration to be used by naturopathic doctors when administering natural medicines.

The workgroup met its first objective by reviewing information regarding 21 states or jurisdictions that license or regulate naturopaths. Meetings held between January and May 2015 resulted in key decisions by the workgroup, including the following:

- To recommend the establishment of a formulary in Maryland;
- To recommend that all over-the-counter medications and devices be included in a formulary; and
- To recommend that all controlled substances and legend drugs (except for epinephrine and oxygen) be excluded from a formulary.

All of the workgroup's findings and recommendations are discussed in the report.

On behalf of the Board, thank you for your consideration of this report. Should you have questions about the report, please contact Wynee E. Hawk at 410-764-3786.

Sincerely,

Christine A. Farrelly

Christine A. Farrelly, Executive Director
Maryland Board of Physicians

Attachment: Naturopathic Doctors Formulary Workgroup Report

cc: Van Mitchell, Secretary
Allison Taylor, Director of Governmental Affairs
Sara Fidler, Department of Legislative Services
Lisa Simpson, Department of Legislative Services

Maryland Naturopathic Doctors Formulary Workgroup
2015 Membership Roster

Members (in alphabetical order)

Claire Bode, R.N., M.S., CRNP

Jennifer French, R.Ph

Mona Gahunia, D.O.

David H. Jones, R.Ph, FASCP

Andrea Mathias, M.D., MPH

Kristaps Paddock, N.D.

Jean Prevas, PA-C

Devinder Singh, M.D.

H. Russell Wright, M.D.

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Other documents referenced in this report are available upon request.

REPORT SUMMARY

In 2016, the Maryland Board of Physicians (the "Board") will begin licensing and regulating naturopathic doctors ("NDs"). As required by law, the Board convened a Naturopathic Doctors Formulary Workgroup (the "workgroup"), which began meeting in January 2015. The workgroup had the following charge:

- To study naturopathic formularies in other states;
- Make recommendations regarding the establishment of a naturopathic formulary, including the types of drugs, medicines, and devices to be included in the formulary and the methods by which the drugs, medicines, and devices will be included on the formulary; and
- Make recommendations regarding the routes of administration that may be used by a naturopathic doctor when administering natural medicines.

The workgroup included representatives of the Board, NDs, the State Medical Society, the State Nurse Practitioner Association, the Maryland Pharmacists Association, the Department of Health and Mental Hygiene ("DHMH"), and the Board of Pharmacy. The workgroup met a total of seven times; the final meeting was held in early May 2015.

The workgroup was convened separately from the Naturopathic Medicine Advisory Committee ("NMAC"), which is developing regulations to recommend to the Board for the licensure of NDs and the practice of naturopathic medicine.

Workgroup's Key Recommendations:

- The workgroup reviewed formularies in other states and recommends that a formulary be established for NDs in Maryland;
- The workgroup recommends that controlled substances should *not* be included in a formulary;
- The workgroup recommends that legend drugs (most prescription drugs fall under legend categories) should *not* be included in a formulary, except for the following two exclusions: epinephrine (such as EpiPen for anaphylaxis) and oxygen;
- The workgroup recommends that a Maryland formulary include all Over-The-Counter ("OTC") medications and devices. It also recommends the inclusion of two prescription barrier contraceptive devices: diaphragms and cervical caps;
- The workgroup recommends expanding the routes of administration that may be used by NDs when administering natural medicines;
- The workgroup recommends that drugs or devices on the formulary should *not* be used for cosmetic purposes; and
- The workgroup recommends the establishment of a Formulary Council, to meet at least once a year, to review and recommend changes to the formulary.

INTRODUCTION

The Naturopathic Doctors Formulary Workgroup (the "workgroup") is an ad hoc workgroup established by Chapter 153 (SB 314)/Chapter 399 (HB 402), Acts of 2014. Section 3 of the legislation provides that the Maryland Board of Physicians (the "Board") shall convene a workgroup to study the development of a naturopathic formulary in the State and the routes of administration that may be used by a naturopathic doctor ("ND") when administering natural medicines.

The Annotated Code of Maryland, Health Occupations Article, Title 14-5F, defines naturopathic medicine as "the prevention, diagnosis, and treatment of human health conditions, injury, and disease using only patient education and naturopathic therapies and therapeutic substances recognized by the Council of Naturopathic Medical Education." The Naturopathic Medicine Advisory Committee ("NMAC") is currently developing regulations to prepare for ND licensing, which is to begin in March 2016.

The 2014 legislation outlined specific stakeholders to be members of the workgroup, as well as an "any other stakeholder" category. Nominations were solicited from the named stakeholder groups, and the following members were selected by nomination:

1	Maryland Association of Naturopathic Physicians (Maryland Naturopathic Doctors Association)	Kristaps Paddock, N.D.
2	MedChi, the Maryland State Medical Society	H. Russell Wright, M.D.
3	Nurse Practitioner Association of Maryland	Claire Bode, R.N., M.S., CRNP
4	Maryland Pharmacists Association	Jennifer French, R.Ph
5	DHMH/Maryland Medical Assistance Program	Mona Gahunia, D.O.
6	Maryland Board of Physicians	Devinder Singh, M.D.
7	Maryland Board of Pharmacy	David H. Jones, R.Ph, FASCP
8	Any Other Stakeholder: Physician Assistant Association Other (local health department)	Jean E. Prevas, PA-C Andrea Mathias, M.D., MPH

The legislation delineated the charge of the workgroup to:

1. Review the naturopathic formularies developed in other states;
2. Make recommendations regarding the establishment of a naturopathic formulary, including the types of drugs, medicines, and devices to be included on the formulary and the method by which the drugs, medicines, and devices will be included on the formulary; and
3. Make recommendations regarding the routes of administration that may be used by a naturopathic doctor when administering natural medicines.

The workgroup is to report its findings and recommendations to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee on or before July 1, 2015. The legislation stated that further action by the Maryland General Assembly would be required to authorize the establishment of a naturopathic formulary to regulate pharmaceuticals.

SUMMARY OF THE WORKGROUP'S MEETINGS

The workgroup met seven times at the Board's offices in Baltimore between January 12, 2015 and May 4, 2015.[1] All meetings were open to the public; the meeting dates and agendas were posted on the Board's Web site.

Throughout the meeting period, members were permitted to submit items for consideration for each agenda, following a process they agreed upon at the first meeting.

Prior to the first meeting, Board staff gathered or prepared background information and various resources for the workgroup:

- A document outlining the workgroup's objectives;
- Annotated Code of Maryland, Health Occupations Article, Title 14, Subtitle 5F – Naturopathic Doctors (the Maryland Naturopathic Medicine Act);
- A binder containing the statute and regulations of 21 states (including Maryland) or other jurisdictions, such as the District of Columbia, that license or regulate naturopaths;
- A "State by State Comparison Chart" (the "comparison chart"), organizing information from the statutes and regulations gathered for the binder; and
- A document summarizing the comparison chart.

Following is a summary of the major topics addressed at each meeting; discussion of issues and workgroup decisions can be found in the section "Recommendations of the Workgroup and Discussion of Decisions."

First Meeting

The five items noted above were reviewed by Board staff at the first meeting of the workgroup members on January 12, 2015. David Finkler, Assistant Attorney General (Board Counsel), commented on the workgroup's charge.

Dr. Paddock summarized education, curricula, and training of naturopathic doctors ("NDs")[2], and there was discussion regarding the Naturopathic Physicians Licensing Exam (the "NPLEX") and continuing education ("CE"), especially as they related to pharmacology.

There was discussion of the 2014 legislative session (during which Dr. Mathias was Board Chair) and circumstances that led to the statute. The topic of utilizing clear terminology was introduced.

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[1] The workgroup cost the Board approximately $30,000. This dollar amount does not reflect the impact of staff hours spent on the workgroup that otherwise could have been applied to routine Board mission-related tasks.

[2] Per Maryland's statute, licensed NDs may not use the term "physician." The titles "doctor of naturopathic medicine", "doctor of naturopathy", "naturopathic doctor", or "naturopath" are allowed. In addition, licensed NDs may use the initials "N.D.", "ND", "NMD", or "N.M.D." after the name of the individual.

Second Meeting

At the second meeting, Dr. Paddock responded to questions raised by Dr. Singh, Dr. Gahunia, and Mr. Jones on January 12, 2015.[3] Mr. Jones offered a definition of "legend drug" and reviewed the classes of controlled substances. There was a request for further information regarding legend drugs that may be over-the-counter ("OTC") in lower strengths.[4]

This meeting also marked the beginning of discussions regarding the role of the Food and Drug Administration (the "FDA") in the regulation of legend drugs and its monitoring of statements made about other products.

In addition, the workgroup held a more in-depth discussion of the formularies of other states which generated some questions from members regarding devices. The workgroup also was provided with a report prepared by the Society for Science-Based Medicine. *(See Appendix 3)*

Third Meeting

Discussion of NDs' CE and the validity of the NPLEX resumed during the third meeting. Mr. Jones provided additional information regarding legend drugs, controlled substances, dual category drugs, and OTC medications. Dr. Mathias requested a chart that would include the substances (and class or definition of the substances) that NDs in Maryland are seeking to have included in a formulary.

Dr. Mathias submitted for the workgroup's review warning letters sent by the FDA to three companies regarding the FDA's concerns about advertising and claims of certain products.

Dr. Mathias also submitted a *New York Times* article describing a study that found adulteration of natural substances and noncompliance of companies to adhere to the FDA's "good manufacturing practices" ("GMPs").

The items aided the workgroup in a discussion about how therapeutic claims about herbals and dietary supplements can be a violation of federal law. Specifically, there was concern about statements in advertising regarding intended use, potency, and efficacy of substances used in naturopathic practice without adequate evidence and the obligation to protect the public. Ms. Prevas posed a question regarding the responsible party should a patient be harmed when taking certain herbs and nutritional supplements.

Based upon discussion of the letters and news article, the concept of developing a notice regarding the intent of the formulary, or a mission statement, was introduced.

The workgroup voted that it had met its objective of reviewing the formularies of other states, and it voted that it would recommend that there be an ND formulary in Maryland.

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[3] In addition to responding to inquiries during the workgroup meetings, Dr. Paddock submitted formal letters addressed to the workgroup (or a specific member) with question responses.

[4] OTC drugs also may be referred to as "non-legend" drugs, which do not require a prescription for patient use.

Fourth Meeting

On March 9, 2015, Dr. Paddock provided responses to questions regarding substances utilized in naturopathic practice and quality control of dietary supplements. Mr. Jones discussed a draft of a mission statement to accompany the formulary, and he provided additional information regarding legend drugs: a cross reference of categories and drug types.

A journal article regarding complementary and integrative medical therapies was provided to the workgroup.[5]

The workgroup voted on a motion to qualify that the formulary be categorized as complementary and not alternative. In addition, the workgroup voted on a motion to prohibit any medicines, drugs, or devices on the formulary from being applied for cosmetic purposes.

The workgroup also agreed on a working definition of legend drugs, as follows:

> *A legend drug means any agent that is approved by the U.S. Food and Drug Administration and that is required by federal or state law to be dispensed to the public only on prescription of a licensed physician or other licensed provider. These are sometimes called prescription drugs even though that phrase may be confusing since prescriptions (can) be written for drugs that do not legally require a prescription.*

The workgroup also voted to exclude controlled substances from a formulary.[6]

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[5] Cohen, Michael H. Complementary and integrative medical therapies, the FDA, and the NIH: definitions and regulation. Dermatologic Therapy 2003: 16: 77-84.

[6] An exception was made for the controlled substance testosterone, which was to be discussed at a future date by the workgroup. The workgroup later declined to add testosterone to the formulary.

Fifth meeting

At the fifth meeting, there was extensive discussion of the draft mission statement. The workgroup, which had concerns about false statements made about certain products, felt that additional language in the mission statement would be beneficial.

It was noted that a PowerPoint regarding dietary supplements (provided by Dr. Mathias) and information on the FDA's current GMPs (provided by Dr. Gahunia) had been e-mailed to the workgroup.

Dr. Wright read a letter from the Maryland Medical Society ("MedChi"), which stated that MedChi did not support the inclusion of any legend or prescription drugs in a formulary. *(See Appendix 4)*

Mr. Jones conveyed the Board of Pharmacy's position: limited exceptions of legend drugs.

Dr. Singh noted that only physicians would be allowed to prescribe medical marijuana; therefore, medical marijuana is not an issue for NDs.[7]

The workgroup voted on a motion to include all OTC (non-legend) medications in the formulary, then began reviewing medications by category to carve out possible exceptions of legend drugs. There was a motion to exclude anti-depressants from a formulary. The workgroup also voted on a motion to grant an exception for epinephrine (including EpiPen for anaphylaxis) and oxygen. The last motion of the meeting was to recommend a continuing formulary council.

[7] Per the Maryland General Assembly Website, Chapter 403 of 2013 established a medical marijuana commission to implement and administer a medical marijuana program in Maryland. Chapters in 2014 and 2015 included revisions regarding the commission and program. Chapter 251 of 2015 renamed the commission to the Natalie M. LaPrade Medical Cannabis Commission. Under the program, only physicians can become certified by the commission to provide medical cannabis. In addition, marijuana is a controlled substance; the workgroup voted to exclude controlled substances from a formulary.

Sixth meeting

On April 20, 2015, the workgroup revisited the draft mission/vision statement, discussing specific language about the FDA in regard to false claims and whether the mission/vision statement would have any force of law.

The workgroup also considered issues regarding the use of anti-infectives, referring to a chart prepared by Dr. Gahunia.

The workgroup again discussed other states that regulate or license naturopaths, clarifying which states permit a certain level of independent prescriptive practice versus those that require supervision or a special license endorsement.[8]

The workgroup also discussed several topics related to formularies: those in other states, those of other health professions in Maryland, the role of formulary councils, maintenance of formularies, and the membership of Maryland's formulary council. The workgroup voted on a motion to define the membership of the council and how often it should meet.

Final meeting

At the workgroup's May 4, 2015 meeting, discussion continued in regard to the goal of the mission/vision statement. The workgroup remained concerned about false statements; the matter was referred to the NMAC for consideration of inclusion of language in either regulations or the code of ethics.[9] *(See Appendix 1)*

The workgroup voted on a motion to include all OTC devices, plus two prescription barrier contraceptive devices, in a formulary.[10]

The workgroup revisited the statute language pertaining to NDs' scope of practice and routes of administration. Following discussion of the routes regarding ordering and dispensing that are in the Health Occupations Article, §14–5F–14 (a)(3), the workgroup voted on a motion to expand the routes for administering [amend §14–5F–14 (a)(4)].

The workgroup also received copies of communication submitted by members of the public. *(See Appendix 4)*

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[8] For example, Vermont requires a special license endorsement ("SLE") that authorizes a naturopathic physician to prescribe, administer, and dispense prescription medicines. Per Vermont's administrative rules, to obtain an SLE, a naturopathic physician first must pass a naturopathic pharmacology exam. After receiving Vermont's SLE, a naturopathic physician is subject to certain requirements, such as prescription review by a supervising physician.

[9] The NMAC was established within the Board, pursuant to the Maryland Naturopathic Medicine Act. It is developing regulations (to be recommended to the Board) for the licensure of NDs and the practice of naturopathic medicine. At this writing, NMAC is reviewing the workgroup's request.

[10] All OTC barrier contraceptive devices, including but not limited to condoms, also would be included in a formulary.

RECOMMENDATIONS OF THE WORKGROUP AND DISCUSSION OF DECISIONS

The workgroup met its mandate by taking action on the three objectives that were part of its official charge under Section 3 of Chapter 153 and Chapter 399 (Acts of 2014).

I. Review the naturopathic formularies developed in other states.

The following action was taken in regard to this topic:

- On February 23, 2015, on a motion made by Dr. Paddock and seconded by Ms. Prevas, the workgroup members present voted unanimously that it met its objective to review the formularies of other states.[11]

Discussion

Board staff provided to each workgroup member a binder that contained the statute and/or regulations of 21 states and jurisdictions that licensed or regulated naturopaths. When available online, related documents, such as naturopath license application packets, were retrieved by Board staff for inclusion in the binder. For states and jurisdictions with formularies (or lists of substances), that information rounded out the binder entries.

To accompany the binders, Board staff compiled a summary document and a comparison chart with key information, including: the licensing body; whether there was prescriptive authority and, if so, what were the limitations; whether devices were allowed and, if so, what were the limitations; scope of practice variations; supervision or collaboration requirements, if any; additional license certification or endorsement requirements, if any; and CE requirements.

[11] Dr. Singh and Dr. Wright were not present at the February 23, 2015 meeting.

II. Make recommendations regarding the establishment of a naturopathic formulary, including the types of drugs, medicines, and devices to be included on the formulary and the method by which the drugs, medicines, and devices will be included on the formulary.

Establishment of a Naturopathic Formulary

The following actions were taken in regard to this topic:

- On February 23, 2015, on a motion made by Mr. Jones and seconded by Dr. Mathias, the workgroup members present voted unanimously to recommend the establishment of a naturopathic doctors formulary in Maryland.

- On March 9, 2015, Dr. Wright made a motion that a formulary include a qualifying statement that it be categorized as complementary and not alternative. Dr. Mathias seconded the motion and suggested the term "integrative." The workgroup members present voted unanimously in favor of the motion.

Discussion

As previously noted, workgroup members were given information, in various formats, about 21 states or jurisdictions that licensed or regulated naturopaths. During the February 9, 2015 meeting, Board staff reviewed those states or jurisdictions specifically with formularies, which ranged from being broad to limited. Workgroup members found Maine's formulary to be a possible template, based on its structure with cross-referencing.

Drugs and Medicines to be included on the Formulary

The following actions were taken in regard to this topic:

- On March 9, 2015, Dr. Singh made a motion that the formulary including medicines, drugs, or devices shall not be applied for cosmetic purposes or indications for patients. Ms. French seconded the motion, and the workgroup members present voted unanimously in favor of the motion.

- On March 9, 2015, Dr. Paddock made a motion to accept the definition of legend drugs (as drafted by Mr. Jones). Dr. Singh seconded the motion, and the workgroup members present voted unanimously in favor of the motion.

- On March 9, 2015, Dr. Singh made a motion to exclude controlled substances (categories I-V) from the formulary. Ms. Bode seconded the motion, and the workgroup voted unanimously in favor of the motion. Dr. Singh then amended the motion to set aside testosterone for a later discussion. Dr. Wright seconded the motion, and the workgroup members present voted unanimously in favor of the motion.

- On April 6, 2015, Dr. Singh made a motion that a formulary should include no legend drugs with limited exceptions to be discussed by class. Dr. Paddock seconded the motion, and the workgroup members present voted unanimously in favor.[12]

- On April 6, 2015, Dr. Paddock made a motion that all OTC medications be included in the formulary; Dr. Wright seconded the motion, and there was a unanimous vote in favor by the members present.

- On April 6, 2015, Dr. Wright made a motion to exclude anti-depressants from a formulary; Dr. Singh seconded the motion. Dr. Paddock abstained. There was a unanimous vote in favor by the workgroup members present.

- On April 6, 2015, Dr. Paddock made a motion for an exception to be granted for epinephrine (including EpiPen) and oxygen; Dr. Wright seconded the motion; the workgroup members present voted unanimously in favor of the motion.

Discussion

The naturopathic association, represented by Dr. Paddock, was seeking a broad formulary, requesting that NDs be able to utilize substances for which they receive training, medications for which natural substances are not an effective substitute, prescription strengths of OTC (non-legend) medications, and medications that address conditions commonly seen in naturopathic practice.

Much discussion in early meetings was dedicated to the education and training of NDs, especially when it pertained to pharmacology. To aid deliberations, the workgroup reached consensus on the definition of a legend drug (see page 4).

The workgroup also considered the categories of legend drugs, with members sometimes asking Dr. Paddock for a specific diagnosis to warrant the use of a certain legend drug in the naturopathic scope of practice. Ms. French noted that a diagnosis should be an *approved* diagnosis.

The workgroup also reviewed the classes of controlled substances.

Ms. Prevas prompted a discussion of the role of NDs and the role of primary care physicians; the workgroup again consulted statutory language about the ND scope of practice.

Mr. Jones conveyed the Board of Pharmacy's position: no legend drugs to be included in a formulary, except for limited exceptions. Dr. Wright represented MedChi, which did not support the inclusion of any legend drugs. Dr. Gahunia, on behalf of DHMH, was especially concerned about the overutilization of anti-infectives in the context of the growing issue of multi-drug resistant organisms.

[12] Dr. Mathias was not present for the April 6, 2015 meeting.

Dr. Singh discussed his position concerning legend drugs. At the beginning of his comments, Dr. Singh noted that he is chair of the Board of Physicians but was not speaking for the Board of Physicians. He stated he would agree with MedChi in that legend drugs should not be included but perhaps with limited exceptions in light of the Board of Pharmacy's comments. He explained the basis for his position that legend drugs should be excluded from a formulary. First, naturopathic medicine is complementary and not alternative. In addition, allopathic standards of medicine rely on the rigorous training and residency of practitioners. Without residency, there's risk in allowing naturopathic doctors to prescribe legend drugs. Dr. Singh also noted that the NPLEX only has ten percent of questions (according to Dr. Paddock) related to pharmacology. And he stated he still had reservations about whether the NPLEX meets psychometric standards, although he appreciated prior comments by Dr. Paddock.

Dr. Singh said he also based his position on the fact that there is precedent that legend drugs are not available or prescriptive authority is not available in every state that licenses naturopaths. He added that, although there are some states that do, it is not unanimous.

Dr. Singh also noted again MedChi's objection, adding that MedChi represents 30,000 licensed physicians in the State of Maryland. Finally, he noted the position of the Board of Pharmacy, which was to recommend non-legend drugs with limited exceptions. For those reasons, he personally would vote that legend drugs not be included, although he would be amenable to limited exceptions.

Though the workgroup decided to recommend that no legend drugs be included in a formulary, it reached consensus on allowing the basic emergency agents epinephrine and oxygen.

Devices to be included on the Formulary

The following action was taken in regard to this topic:

- On May 4, 2015, Dr. Paddock made a motion to include in the formulary OTC devices and two prescription barrier contraceptives: diaphragms and cervical caps. Ms. Bode seconded the motion, and there was a vote in favor by the members present.[13]

Discussion

At the May 4 meeting, Dr. Paddock reiterated his association's position regarding devices – adding non-prescription, OTC devices, including certain therapeutic devices, such as those involved in pain relief. He added that the only prescription devices for consideration would be barrier contraceptives.

[13] Dr. Gahunia, Dr. Mathias, and Dr. Wright were not present for the May 4, 2015 meeting.

Method by which Drugs, Medicines, and Devices will be included on the Formulary

The following actions were taken in regard to this topic:

- On April 6, 2015, Dr. Wright made a motion for a recommendation of a continuing formulary council. Dr. Paddock seconded. All members present were in agreement.

- On April 20, 2015, Dr. Wright made a motion that the vote from the prior week be referenced and the formulary council be formed with the ability or power to recommend adjustments to the formulary, methods of administration, and devices. Ms. Bode seconded the motion. Dr. Paddock asked for clarification on the motion and requested that the workgroup reconcile routes of administration. Dr. Wright clarified that the motion would be that the formulary council will have the ability to recommend future changes and devices. There was a unanimous vote in favor by the members present.[14]

- On April 20, 2015, Dr. Wright made a motion that the formulary council include two NDs, two MDs – allopathy or osteopathy, one pharmacist, one public health representative, and one consumer representative. Mr. Jones seconded the motion. Discussion continued, and language was added to the motion. It was suggested that the council meet at least annually or at the discretion of the council. In addition, it was suggested that recommendations of the council are to be brought before the Board, and the Board would retain the discretion to accept or reject council recommendations. The vote was unanimous in favor by the members present.

- On May 4, 2015, Dr. Paddock made a motion that devices be added by the formulary council. Dr. Singh clarified that the council is external to the Board, but the Board would consider adopting recommendations by the council. Mr. Jones seconded the motion, and there was a unanimous vote in favor by the members present.

[14] Ms. Prevas was not present for the April 20, 2015 meeting.

Discussion

The workgroup was tasked with recommending a method by which drugs, medicines and devices will be included on the formulary. While the workgroup was not required to recommend the creation of a formulary council, the workgroup did recommend creating such a formulary council to recommend to the Board all future changes to the formulary.

During the April 20, 2015 meeting, Dr. Singh questioned whether the topic of escalating supervision or collaborative agreements should be considered before the workgroup discussed further legend drug exceptions.[15]

Ms. Bode suggested that the workgroup make no further recommendations regarding exceptions of legend drugs for a formulary, which led to the motions regarding the ability of the council to make future changes.

[15] Some states reviewed by the workgroup had certain supervision or collaboration requirements. Per Maryland's statute, to apply for licensure as an ND, an applicant is required to submit certain items to the Board, including an application and a Board–approved written attestation that states, in part, that the applicant has a collaboration and consultation agreement with a Maryland licensed physician. The attestation also is required to state that the applicant:

- will refer patients to and consult with physicians and other health care providers licensed or certified under the Health Occupations Article "as needed," and
- will require patients to sign a consent form that states that the applicant's practice of naturopathic medicine is limited to the scope of practice identified in §14–5F–14.

III. Make recommendations regarding the routes of administration that may be used by a naturopathic doctor when administering natural medicines.

The following action was taken in regard to this topic:

- On May 4, 2015, Dr. Singh made a motion to reconcile the routes for ordering and dispensing with administering, but to exclude "intramuscular" as a route for administration. Ms. Bode seconded the motion, and the members present voted in favor. [The recommendation is that §14–5F–14 (a)(4) be amended to add oral, nasal, auricular, ocular, rectal, and vaginal routes of administration; §14–5F–14 (a)(4) already includes transdermal.]

Discussion

At the final meeting, the workgroup members considered statutory language regarding routes of administration. Dr. Paddock read from the statute and suggested the routes of administration mirror language that appears in §14–5F–14 (a)(3) regarding dispensing ("...that use various routes of administration, including oral, nasal, auricular, ocular, rectal, vaginal, transdermal, and intramuscular...") instead of limiting the means by which an N.D. may administer (natural medicines) to just transdermal [§14–5F–14 (a)(4)].

Mr. Finkler read from §14–5F–14 (a)(4) to clarify the substances an N.D. may administer: "...natural medicines of mineral, animal, or botanical origin, including food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, and all dietary supplements and nonprescription drugs as defined by the federal Food, Drug, and Cosmetic Act using transdermal routes of administration."

Mr. Jones commented from the perspective of the Board of Pharmacy, stating that if a practitioner is going to recommend or order something, part of that practice is education and may require actual administration to make sure the patient understands.

Dr. Paddock noted which routes are excluded: subcutaneous, intradermal, and intravenous. He added that most of the substances will be administered orally, and he provided examples of some items applied externally.

After considering the types of substances and medications the workgroup was recommending for the formulary and how those substances and medications are administered, the workgroup decided on the following routes of administration: oral, nasal, auricular, ocular, rectal, vaginal, and transdermal. The workgroup did not include *intramuscular* as a route for the administration of natural medicines.

Appendix 1

Naturopathic Formulary Work Group

Formulary Mission/Vision Statements

Mission:

The Maryland State Naturopathic Formulary (the "Formulary") serves to provide an approved listing of agents used by naturopathic doctors within the scope of naturopathic practice to enhance the health of patients throughout Maryland. Acceptance of any agent for Formulary inclusion and subsequent use by practitioners shall be based on the best possible evidence-based, clinically relevant data.

Vision:

Medications that are listed on the Formulary shall meet standards established in accepted compendia including, but not limited to, the United States Pharmacopoeia, the National Formulary, and the Homeopathic Pharmacopoeia of the United States.

A drug shall be understood to mean any agent intended to prevent, cure, treat, or diagnose people or mitigate symptoms. It may also include any article other than food that can affect the structure or function of the body. All drugs are approved by the FDA for specific indications. As is true for all authorized prescribers, naturopathic doctors shall be aware of and adhere to these indications.

Herbals and nutritional supplements are generally excluded from the above definition of a drug. The Dietary Supplement Health and Education Act (DSHEA) of 1994 defines herbals as dietary supplements and allows the FDA to regulate dietary supplements under regulations that differ from those for drugs or food. Manufacturers and distributors must evaluate the safety and labeling of such agents prior to marketing and are prohibited from providing products that are mislabeled or adulterated. Similarly, manufacturers of herbal supplements are responsible for assuring that any claims made about products are not false or misleading. Claims made must be backed up by adequate evidence. DSHEA makes the FDA responsible for taking action against any misbranded or adulterated product after marketing.

Naturopathic doctors shall recommend and use those products that maintain assurance of a pedigree equivalent to that expected for drugs. This assurance must include good manufacturing practices that include ongoing quality control measures. Among these are verification of raw source material, batch testing for

potency, screening for contaminants, and full shipping and handling protection through to the consumer. Final product labeling must assure full patient understanding for appropriate use and awareness of risk. As with standards of professional practice for drugs, naturopathic doctors shall be aware of and comply with FDA regulations regarding herbal product benefit and safety claims.

A process shall be provided to assure ongoing review of the Formulary to assure that the listing remains current and appropriate.

Appendix 2

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Wynee Hawk, RN, JD
Chief, Legislation and Policy Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215

November 19, 2014

Dear Ms. Hawk,

Thank you for contacting me regarding the scope of naturopathic pharmaceutical privileges in other states that license the practice of naturopathic medicine. I am attaching several appendices, including the formularies of the States of Hawaii, New Hampshire, and Oregon, as well as a reference document indicating where you will be able to find naturopathic formularies or the statutes and regulations relating to naturopathic pharmaceutical privileges in the states that currently license naturopathic doctors.

Before discussing the formularies I have included, I should explain our goals in crafting a naturopathic formulary. Our long-term goal is to create a formulary that allows for licensed naturopathic doctors to treat their patients safely, effectively, and efficiently, using pharmaceutical medications when necessary and appropriate.

As you will see from the attached documents, naturopathic doctors in many states have access to a broad formulary that permits them to serve their patients' needs. The MNDA recognizes that the establishment of a formulary in Maryland is part of a process, and that the initial formulary may not have the breadth of what has been established in other states and what naturopathic doctors are trained to safely use in practice. Nonetheless, we believe that through partnership and education, a functional initial formulary will be achieved that can ultimately modernize to align with clinical need and naturopathic education.

Of the naturopathic formularies included, you will note a range of content and breadth. Naturopathic doctors in Oregon have broad pharmaceutical privileges which are suitable to the practice of primary care medicine, which is the role NDs occupy in Oregon and how NDs are trained in naturopathic medical school. Likewise, NDs in Vermont will soon have access to an open formulary, which is also reflective of their primary care role. The formularies of New Hampshire and Hawaii, which I have also included, are typical of states where naturopathic doctors have a broad scope of practice, but do not serve a primary care role.

Included as an appendix is a chart indicating the continuing education requirements for naturopathic doctors around the country, including information on the number of continuing education hours to be devoted to pharmaceutical education. While we have not recommended that naturopathic doctors in Maryland be required to complete continuing education hours in pharmacy in order to practice at their current scope, such requirements may be considered as part of legislation creating a naturopathic formulary.

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

The formulary work group is also charged with examining the routes of administration by which naturopathic doctors may administer medicines and the therapeutic devices that naturopathic doctors may prescribe in practice.

Regarding routes of administration, under the current law, naturopathic doctors will be permitted to administer medicines transdermally only. On the other hand, naturopathic doctors are permitted to prescribe substances that may be administered orally, nasally, auricularly, ocularly, rectally, vaginally, transdermally, and intramuscularly. Though the MNDA believes that naturopathic doctors should be able to administer substances and medicines via intravenous, subcutaneous, and intradermal routes, we would currently seek only to have the rights of naturopathic doctors to administer substances be congruent with their rights to prescribe substances.

Regarding medical devices, the MNDA has taken the position that the naturopathic formulary should include devices which are commonly used and recommended in office-based clinic settings. This list could include, but would not be limited to, items such equipment necessary for physical examination, for collection of specimens for laboratory examination, for treatment under the scope of naturopathic medicine, as well as blood sugar monitors, blood pressure monitors, pedometers, TENS units, crutches, canes, and similar devices.

Sincerely,

K, ND

Kristaps Paddock, ND
President, MNDA

NATUROPATHIC FORMULARY
(Effective February 7, 2014)

Introduction

Pursuant to Act 22 (2009), the Board of Naturopathic Medicine ("**Board**") hereby establishes this naturopathic formulary that specifies the vitamins, minerals, dietary supplements, botanical medicines, homeopathic medicines, hormones, and legend drugs consistent with naturopathic medical practice that naturopathic physicians can prescribe, administer, or dispense; provided that naturopathic physicians **cannot** prescribe, administer, or dispense any of these items in the injectable form or by injection unless the naturopathic physician is specifically authorized by the Board. **Controlled substances are excluded from this formulary.**

Effective February 14, 2011, only naturopathic physicians who possess a "parenteral therapy" special privilege issued by the Board may prescribe, administer, or dispense any of these items in the injectable form or by injection. To find out if a naturopathic physician is licensed and possesses a "parenteral therapy" special privilege issued by the Board, please visit http://pvl.ehawaii.gov/pvlsearch/app 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) 586-2704 or visit the Board's website at http://hawaii.gov/dcca/pvl/boards/naturopathy/.

List of Formulary Items

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 those that are controlled substances (e.g. testosterone).

3. **ANTIBIOTICS**

   Amebecides
   Antifungal agents
   Antihelminthics
   Antimalarial preparations (includes artemesin, derived from Artemesia annua)
   Antiprotozoal agents
   Antituberculosis agents
   Antiviral agents
   Bacitracin
   Cephalosporins and related antibiotics
   Fluroquinolones

3. **ANTIBIOTICS** (continued)

Macrolides
Nitrofurantoins
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
Local anesthetics
Topical, IM, and SQ Bupivacaine, Lidocaine, and Procaine
IM and SQ Epinephrine
Minoxidil

5. **DERMATOLOGICALS** (continued)

Photochemotherapy
Pigment agents
Protectants
Pyrithione 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
Proton pump inhibitors
Sodium phenyl butyrate

10. **CARDIOVASCULAR AGENTS**

Anti-lipemic agents

10. **CARDIOVASCULAR AGENTS** (continued)

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

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

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

STATE OF NEW HAMPSHIRE
BOARD OF NATUROPATHIC EXAMINERS
Department of Health and Human Services
Office of Operations Support
129 Pleasant St, Concord, New Hampshire 03301
603-271-0853 Fax: 603-271-5590 TDD Access: 1-800-735-2964

April 2, 2010

Board of Pharmacy
57 Regional Drive
Concord, NH 03301-8518

The following Naturopathic Formulary was approved by the New Hampshire Council on Doctors of Naturopathic Medicine Formulary on June 9, 2009 pursuant to RSA 328-E:16, III and Nat 103.03. Licensed Naturopathic Doctors may prescribe the following categories of substances in all forms within their scope of practice. A current list of Naturopathic Doctors licensed in New Hampshire is available from the New Hampshire Board of Naturopathic Examiners, 129 Pleasant Street, Brown Building Concord, NH 03301, (603) 271-0277.

Sincerely,

Brian J. Paterson ND, CNHC

Chair of the New Hampshire
Board of Naturopathic Examiners

BJP/clb
Enclosure

Naturopathic Formulary by Classification

The following are classifications for substances listed in RSA 328-E:16, III revised and adopted on June 09, 2009 by the Board of Naturopathic Examiners Formulary Council established by the New Hampshire Legislature. Substances listed on the formulary compendium can be prescribed in any dosage or any dosage form. Products marked with an asterisk (*) may be used by Naturopathic Doctors, but may not be prescribed. A double asterisk (**) indicates examples included and are not limited to the substances listed within the category.

1) **Amino Acids**;**
   - A) Acetyl Carnitine
   - B) EDTA
   - C) GABA
   - D) Glutathione
   - E) Levocarnitine
   - F) Succinic Acid (DMSA)
   - G) Tryptophan

2) **Animal Preparation and their derivatives**;**
   - A) Adrenal
   - B) Thymus
   - C) Thyroid (See Hormones section 15)

3) **Antigout Agents;**
   - A) Allopurinol;
   - B) Colchicine;
   - C) Probenecid;

4) **Antihistamines;**
   - A) 1st generation, ethanolamines (aminoalkyl ether);
     - i) Diphenhydramine
   - B) 1st generation, piperazine-derived;
     - i) Meclizine

5) **Anti-Hyperglycemic Agents (Diabetic);**
   - A) Alpha Glucosidase Inhibitors
     - i) Acarbose;
   - B) Biguanides
     - i) Metformin;
   - C) Insulin – synthetic and human

6) **Anti-infective Agents;**
   - A) Antibacterial Agents;
     - i) Aminoglycosides**;
       - (1) Gentamicin;
       - (2) Kanamycin Sulfate;
       - (3) Tobramycin;
     - ii) Beta-lactam antibiotics;
       - (1) Cephalosporins**;
         - (a) Cefaclor;
         - (b) Cefadroxil;

(c) Cefdinir;
(d) Cefditoren;
(e) Cefibuten;
(f) Cefixime;
(g) Cefonicid Sodium;
(h) Cefpodoxime Proxetil;
(i) Cefprozil;
(j) Ceftibuten;
(k) Cefuroxime;
(l) Cephalexin;
(m) Cephradine;

(2) Penicillins**;
(a) Amoxicillin and Clavulanate;
(b) Amoxicillin;
(c) Ampicillin and Sulbactam;
(d) Ampicillin;
(e) Bacampicillin;
(f) Cloxacillin;
(g) Dicloxacillin;
(h) Oxacillin;
(i) Penicillin;

iii) Macrolides and Ketolides**;
(1) Azithromycin;
(2) Clarithromycin;
(3) Dirithromycin;
(4) Erythromycins;
(5) Telithromycin;
(6) Troleandomycin;

iv) Quinolones**;
(1) Fluoroquinolines;

v) Sulfonamides;
(1) Sulfonamide/Trimethoprim/Sulfones;

vi) Tetracyclines**;
(1) Demeclocycline Hydrochloride;
(2) Doxycycline;
(3) Minocycline;
(4) Oxytetracycline;
(5) Tetracycline;

vii) Miscellaneous antibacterials;
(1) Bacitracin;
(2) Clindamycin;
(3) Colistimethate;
(4) Lincomycin;
(5) Novobiocin;
(6) Polymyxin B Sulfate;
(7) Spectinomycin;
(8) Vancomycin;

B) Antifungals;

i) Polyene;
(1) Amphotericin B;
(2) Nystatin;
ii) Gentian Violet;
iii) Griseofulvin;

C) Antihelmintics;
i) Mebendazole;
ii) Thiabendazole;

D) Antitubercular and antimycobacterial agents;
i) Aminosalicylic Acid;
ii) Cycloserine;
iii) Pyrazinamide;
iv) Rifabutin;
v) Rifampin;

E) Antiprotozoal and antiparasitic agents;
i) Halogenated 8-hydroxyquinolines
(1) Iodoquinol;
ii) Nitroimidazoles;
(1) Metronidazole;
(2) Tinidazole
iii) Quinolines;
(1) Chloroquine;
(2) Hydroxychloroquine;
(3) Mefloquine;
(4) Quinine Sulfate;
iv) Hydroxynaphthoquinones
(1) Atovaquone

F) Miscellaneous;
i) Immune Globulins **
ii) Mupirocin;
iii) Permethrin;
iv) Pyrethrins;

7) **Anti-thyroid Agents;**
A) Thionamides (thioureylenes);
i) Methimazole
ii) Propylthiouracil

8) **Autonomic Drugs;**
A) Anticholinergic agents;
i) Antimuscarinic agents
(1) Atropine;
(2) Atropine Sulfate;
(3) Belladonna;
(4) Flavoxate;
(5) Homatropine Hydrobromide;
(6) Hyoscyamine;
(7) Methscopolamine;

(8) Scopolamine;
ii) Muscarinic receptor agonists (cholinomimetics)
(1) Pilocarpine;
B) Ergot derivatives
i) Ergonovine Maleate
ii) Methergine
C) Sympathomimetic;
i) Ephedrine;
ii) Epinephrine, including auto-inject forms;
iii) Psuedoephedrine;
D) Sympatholytic (adrenergic blocking) agents;
i) Alpha adrenergic blocking agents;
(1) Yohimbine;
ii) Beta adrenergic blocking agents**
(1) Propranolol;
E) Miscellaneous;
i) Nicotine;

9) **Barrier Contraceptives**
A) Cervical Caps
B) Diaphrams
C) Exclusion: IUD

10) **Biologicals;**
A) Biological Response Modifiers
i) Candida and Tricophyton Extracts
ii) Rho(D) Immune Globulins
iii) Skin test antigens
iv) Tuberculin Tests
B) Blood Typing Serum
C) Enzymes**;
i) Collagenase;
ii) Desoxyribonuclease (deoxyribonuclease, multiple other synonyms);
iii) Fibrinolysin;.
iv) Hyaluronidase;
v) Pancrelipase;
vi) Papain;
D) Electrolytes and Fluid Replacement **
i) Saline solutions
ii) Sterile water
iii) D5W
iv) Lactated Ringers Solution
v) Sodium Bicarbonate
E) Hormones – see Hormones (section 13)
F) Immune globulins - see anti-infective, misc;
G) Prostaglandins and prostaglandin analogs**;
i) Alprostadil;
ii) Bimatoprost;

iii) Dinoprostone;
iv) Iloprost;
v) Misoprostal;

11) **Blood Formation and Coagulation;**
i) Heparin; subcutaneous, sublingual and heparin locks;

12) **Botanicals ****
i) Non-legend or controlled Vinca species derivatives
ii) Exclusions
(1) Digitalis
(2) Cocaine
(3) Legend or controlled Vinca species derivatives
(4) Papaver somniferum derivatives
(a) Codeine
(b) Morphine
(c) Opiates
(d) Paclitaxel

13) **Cardiovascular Drugs;**
A) Antilipemic;
i) HMG CoA Reductase Inhibitors**;
(1) Atorvastatin;
(2) Fluvastatin;
(3) Lovastatin;
(4) Pravastatin;
(5) Simvastatin;
B) Anti-angina agents;
i) Piperazine derivatives
(1) Metabolism modifiers (p-FOX Inhibitors);
(a) Ranolazine;
(b) Trimetazidine;
C) Rauwolfia Alkaloids;

10) Central Nervous System Agents;
A) Anticonvulsants
i) Agents that enhance GABA (gamma amino benzoic acid) Activity**;
(1) GABA Analogs and analog derivatives
(a) Gabapentin;
(b) Nipecotic Acid Derivatives
(i) Tigabine;
(c) Pregabalin;
B) Psychotherapeutic;
i) Anxiolytics, Sedatives and Hypnotics;
(1) Benzodiazepines**;
(2) Non-benzodiazepine sedative-hypnotic agents;
(a) Imidazopyridine agents;
(i) Zolpidem;

(b) Cyclopyrrolone agents;
(i) Eszopiclone;
(3) Anti-Manic;
(a) Lithium;

12) **Childbirth preparations**
A) Triple Dye

13) **Homeopathic preparations and their derivatives****

14) **Hormones**;**
A) Adrenal
i) Aldosterone
ii) Cortisone acetate
iii) DHEA
iv) Epinephrine
v) Hydrocortisone
vi) Pregnenalone
B) Agents acting at estrogen receptors;
i) Selective Estrogen-Receptor Modulators (SERMs) and anti-estrogens (estrogen antagonists)**;
(1) Clomiphene;
(2) Tamoxifen;
(3) Toremifene;
(4) Raloxifene;
ii) Agents with mixed activity at steroidal receptors**;
(1) Tibolone;
C) Gonadal
i) Conjugated Estrogens
ii) Estrogen
iii) Estradiol
iv) Estriol
v) Estrone
vi) Estropipate
vii) Ethinyl Estradiol
viii) HCG
ix) Quinestrol
x) Progesterone
xi) Testosterone
D) Thyroid (See also Animal preparations section 2)
E) Pituitary
i) ACTH
ii) Growth Hormone
iii) Oxytocin
F) Parathyroid
i) Calcitonin

15) Local anesthetics**;
- A) Amino Esters
  - i) Procaine*;
  - ii) Chloroprocaine*;
  - iii) Tetracaine*;
  - iv) Benzocaine*;
- B) Amino Amides
  - i) Lidocaine * (injectable and non-injectable dosage forms);
  - ii) Mepivocaine*;
  - iii) Bupivacaine*;
  - iv) Levobupacaine (Chirocaine)*;
  - v) Etidocaine*;
  - vi) Prilocaine*;
- C) Other topical anesthetics
  - i) Ketones
    - (1) Dyclonine*;
  - ii) Ethers
    - (1) Pramoxine;
  - iii) Skin refrigerants
    - (1) Ethyl Chloride (chloroethane);
- D) Methyl Group Donors
  - i) Betaine;
- E) Sclerosing Agents
  - i) Laureth 4 (Polidocanol, hydroxyl polyethoxy dodecane, lauromacroglolum 400)*;

16) **Mineral, Trace Minerals, and their derivatives** **
- A) Super Saturated Potassium Iodine (SSKI);

17) **Miscellaneous**
- A) Bee Venom;
- B) DMSO;
- C) Ethyl Chloride Spray;
- D) Fluro-Ethyl Spray;
- E) Fluro-Methane Spray;
- F) Hydrogen Peroxide;
- G) Hydrochloric Acid;
- H) MSM;
- I) Oxygen;
- J) Salicylic Acid – topical application;
- K) Urea;

18) **Periphenalia**
- A) Needles*;
- B) Syringes*;
- C) IV Tubing*;
- D) Filters*;

19) **Respiratory Anti-inflammatory Agents**
   A) Cromolyn sodium

20) **Vaccinations****
   A) BCG*;
   B) Cholera*;
   C) Diphtheria*;
   D) DPT*;
   E) Haemophilus b Conjugate*;
   F) Hepatitus A Virus*;
   G) Hepatitus B*;
   H) Influenza Virus*;
   I) Japanese Encephalitis Virus*;
   J) Measles Virus*;
   K) Mumps Virus*;
   L) Pertussis*;
   M) Plague*;
   N) Pneumococcal*;
   O) Poliovirus - Inactivated*;
   P) Poliovirus - Live Oral*;
   Q) Rabies*;
   R) Rubella*;
   S) Smallpox*;
   T) Tetanus IG*;
   U) Tetanus Toxoid*;
   V) Typhoid*;
   W) Varicella*;
   X) Yellow Fever*;

21) **Vitamin – all forms of prescription and non-prescription vitamin preparations and their derivatives**
   A) Exclusion;
      i) Isotretinoin;

850-060-0226 Formulary Compendium Classifications June 13, 2011

The Formulary Council has approved the following pharmacologic-therapeutic classifications in addition to drugs previously approved by the Formulary Council and listed in 850-060-0225. This listing does not supersede the education and training requirement established in 850-060-0212 for administration of IV agents. The Formulary Council may consider new agents, substances and pharmacologic-therapeutic classifications for addition to this list.

(1) **Antihistamine Drugs**
- (a) First Generation Antihistamine Drugs
  - (A)Ethanolamine Derivatives
  - (B) Ethylenediamine Derivatives
  - (C) Phenothiazine Derivatives
  - (D) Piperazine Derivatives
  - (E) Propylamine Derivatives
  - (F) Miscellaneous Derivatives
- (b) Second Generation Antihistamines

(2) **Anti-Infective Agents**
- (a) Antihelmintics
- (b) Antibacterials
  - (A) Aminoglycosides
  - (B) Cephalosporins
    - (i) *First Generation Cephalosporins*
    - (ii) *Second Generation Cephalosporins*
    - (iii) *Third Generation Cephalosporins*
    - (iv) *Fourth Generation Cephalosporins*
  - (C) Miscellaneous β-Lactams
    - (i) *Carbacephems*
    - (ii) *Carbapenems*
    - (iii) *Cephamycins*
    - (iv) *Monobactams*
  - (D) Chloramphenicol
  - (E) Macrolides
    - (i) *Erythromycins*
    - (ii) *Ketolides*
    - (iii) *Other Macrolides*
  - (F) Penicillins
    - (i) *Natural Penicillins*
    - (ii) *Aminopenicillins*
    - (iii) *Penicillinase-resistant Penicillins*
    - (iv) *Extended-spectrum Penicillins*
  - (G) Quinolones
  - (H) Sulfonamides
  - (I) Tetracyclines
    - (i) *Glycylcyclines*
  - (J) Antibacterials, Miscellaneous
    - (i) *Aminocyclitols*
    - (ii) *Bacitracins*
    - (iii) *Cyclic Lipopeptides*
    - (iv) *Glycopeptides*
    - (v) *Lincomycins*
    - (vi) *Oxazolidinones*
    - (vii) *Polymyxins*
    - (viii) *Rifamycins*
    - (ix) *Streptogramins*
- (c) Antifungals
  - (A) Allylamines
  - (B) Azoles
  - (C) Echinocandins
  - (D) Polyenes
  - (E) Pyrimidines
  - (F) Antifungals, Miscellaneous
- (d) Antimycobacterials
  - (A) Antituberculosis Agents
  - (B) Antimycobacterials, Miscellaneous
- (e) Antivirals
  - (A) Adamantanes
  - (B) Antiretrovirals
    - (i) *HIV Fusion Inhibitors*
    - (ii) *HIV Protease Inhibitors*
    - (iii) *Integrase Inhibitors*
    - (iv) *Nonnucleoside Reverse Transcriptase Inhibitors*
    - (v) *Nucleoside and Nucleotide Reverse Transcriptase Inhibitors*
  - (C) Interferons
  - (D) Monoclonal Antibodies
  - (E) Neuraminidase Inhibitors
  - (F) Nucleosides and Nucleotides
  - (G) Antivirals, Miscellaneous
- (f) Antiprotozoals
  - (A) Amebicides
  - (B) Antimalarials
  - (C) Antiprotozoals, Miscellaneous

(3) **Antineoplastic Agents** (oral and topical only) limited to the following:
- (a) 5FU
- (b) Anastrozole

(c) Letrozole
(d) Megestrol
(e) Mercaptopunne
(f) Methotrexate
(g) Tamoxifen
(h) Tretinoin
(4) Autonomic Drugs
(a) Parasympathomimetic (Cholinergic) Agents
(b) Anticholinergic Agents
(A) Antimuscarinics/ Antispasmodics
(c) Sympathomimetic (Adrenergic) Agents
(A) α-Adrenergic Agonists
(B) β- Adrenergic Agonists
(i) *Non-selective β- Adrenergic Agonists*
(ii) *Selective β_1- Adrenergic Agonists*
(iii) *Selective β_2- Adrenergic Agonists*
(C) α-And β-Adrenergic Agonists
(d) Sympatholytic (Adrenergic Blocking) Agents
(e) Skeletal Muscle Relaxants
(A) Centrally Acting Skeletal Muscle Relaxants
(B) Direct-acting Skeletal Muscle Relaxants
(C) GABA-derivative Skeletal Muscle Relaxants
(D) Neuromuscular Blocking Agents
(E) Skeletal Muscle Relaxants, Miscellaneous
(f) Autonomic Drugs, Miscellaneous
(5) **Blood Derivatives**
(6) **Blood Formation, Coagulation, and Thrombosis**
(a) Antianemia Drugs
(A) Iron Preparations
(b) Antithrombotic Agents
(A) Anticoagulants
(i) *Coumarin Derivatives*
(ii) *Direct Thrombin Inhibitors*
(iii) *Heparins*
(iv) *Anticoagulants, Miscellaneous*
(c) Platelet-reducing Agents
(d) Platelet-aggregation Inhibitors
(e) Thrombolytic Agents
(f) Hematopoietic Agents
(g) Hemorrheologic Agents
(h) Antihemorrhagic Agents
(A) Antiheparin Agents
(B) Hemostatics
(7) **Cardiovascular Drugs**
(a) Cardiac Drugs
(A) Antiarrhythmic Agents
(i) *Class Ia Antiarrhythmics*
(ii) *Class Ib Antiarrhythmics*
(iii) *Class Ic Antiarrhythmics*
(iv) *Class III Antiarrhythmics*
(v) *Class IV Antiarrhythmics*
(B) Cardiotonic Agents
(C) Cardiac Drugs, Miscellaneous
(b) Antilipemic Agents
(A) Bile Acid Sequestrants
(B) Cholesterol Absorption Inhibitors
(C) Fibric Acid Derivatives
(D) HMG-CoA Reductase Inhibitors
(E) Antilipemic Agents, Miscellaneous
(c) Hypotensive Agents
(A) Calcium-Channel Blocking Agents
(B) Central a-Agonists
(C) Direct Vasodilators
(D) Peripheral Adrenergic Inhibitors
(d) Vasodilating Agents
(A) Nitrates and Nitrites
(B) Phosphodiesterase Inhibitors
(C) Vasodilating Agents, Miscellaneous
(e) Sclerosing Agents
(f) α-Adrenergic Blocking Agents
(g) β-Adrenergic Blocking Agents
(h) Calcium-Channel Blocking Agents
(A) Dihydropyridines
(B) Calcium-Channel Blocking Agents, Miscellaneous
(i) Renin-Angiotensin-Aldosterone System Inhibitors
(A) Angiotensin-Converting Enzyme Inhibitors
(B) Angiotensin II Receptor Antagonists
(C) Mineralocorticoid (Aldosterone) Receptor Antagonists
(D) Renin Inhibitors
(8) **Central Nervous System Agents**
(a) Analgesics and Antipyretics
(A) Nonsteroidal Anti-inflammatory Agents
(i) *Cyclooxygenase-2 (COX-2) Inhibitors*
(ii) *Salicylates*
(iii) *Other Nonsteroidal Anti-inflammatory Agents*
(B) Opiate Agonists
(C) Opiate Partial Agonists

(D) Analgesics and Antipyretics, Miscellaneous
(b) Opiate Antagonists
(c) Anticonvulsants, does not include Barbiturates
(A) Benzodiazepines
(B) Hydantoins
(C) Succinimides
(D) Anticonvulsants, Miscellaneous
(d) Psychotherapeutic Agents
(A) Antidepressants
(i) *Monoamine Oxidase Inhibitors*
(ii) *Selective Serotonin- and Norepinephrine-reuptake Inhibitors*
(iii) *Selective Serotonin- Reuptake Inhibitors*
(iv) *Serotonin Modulators*
(v) *Tricyclics and Other Norepinephrine-reuptake Inhibitors*
(vi) *Antidepressants, Miscellaneous*
(B) Antipsychotics, to include only the following:
(i) *Atypical antipsychotics*
(e) Anorexigenic Agents and Respiratory and Cerebral Stimulants
(A)Amphetamines
(B) Anorexigenic Agents and Respiratory and Cerebral Stimulants, Miscellaneous
(f) Anxiolytics, Sedatives, and Hypnotics, does not include Barbiturates
(A)Benzodiazepines
(B) Anxiolytics, Seditives, and Hypnotics; Miscellaneous
(g) Antimanic Agents
(h) Antimigraine Agents
(A) Selective Serotonin Agonists
(i) Antiparkinsonian Agents
(A) Adamantanes
(B) Anticholinergic Agents
(C) Catechol-*O*-Methyltransferase (COMT) Inhibitors
(D) Dopamine Precursors
(E) Dopamine Receptor Agonists
(i) *Ergot-derivative Dopamine Receptor Agonists*
(ii) *Non-ergot-derivative Dopamine Receptor Agonists*
(F) Monoamine Oxidase B Inhibitors
(G) Central Nervous System Agents, Miscellaneous

(9) **Contraceptives** (foams, devices)
(10) **Diagnostic Agents**
(11) **Disinfectants** (for Agents used on objects other than skin)
(12) **Electrolytic, Caloric, and Water Balance**
(a) Acidifying Agents
(b) Alkalinizing Agents
(c) Ammonia Detoxicants
(d) Replacements Preparations
(e) Ion-Removing Agents
(A) Calcium-removing Agents
(B) Potassium-removing Agents
(C) Phosphate-removing Agents
(D) Other Ion-removing Agents
(f) Caloric Agents
(g) Diuretics
(A) Loop Diuretics
(B) Osmotic Diuretics
(C) Potassium-sparing Diuretics
(D) Thiazide Diuretics
(E) Thiazide-like Diuretics
(F) Diuretics, Miscellaneous
(h) Irrigation Solutions
(i) Uricosuric Agents
(13) **Enzymes**
(14) **Respiratory Tract Agents**
(a) Antihistamines
(b) Antitussives
(c) Anti-inflammatory Agents
(A) Leukotriene Modifiers
(B) Mast-cell Stabilizers
(d) Expectorants
(e) Pulmonary Surfactants
(f) Respiratory Agents, Miscellaneous
(15) **Eye, Ear, Nose, and Throat (EENT) Preparations**
(a) Antiallergic Agents
(b) Anti-infectives
(A) Antibacterials
(B) Antifungals
(C) Antivirals
(D) Anti-infectives, Miscellaneous
(c) Anti-inflammatory Agents
(A) Corticosteroids
(B) Nonsteroidal Anti-inflammatory Agents
(C) Anti-inflammatory Agents, Miscellaneous
(d) Local Anesthetics
(e) Mydriatics

(f) Mouthwashes and Gargles
(g) Vasoconstrictors
(h) Antiglaucoma Agents
(A) α-Adrenergic Agonists
(B) β-Adrenergic Agents
(C) Carbonic Anhydrase Inhibitors
(D) Miotics
(E) Prostaglandin Analogs
(i) *EENT Drugs, Miscellaneous*

(16) **Gastrointestinal Drugs**
(a) Antacids and Adsorbents
(b) Antidiarrhea Agents
(c) Antiflatulents
(d) Cathartics and Laxatives
(e) Cholelitholytic Agents
(f) Emetics
(g) Antiemetics
(A) Antihistamines
(B) 5-HT_3 Receptor Antagonists
(C) Antiemetics, Miscellaneous
(h) Antiulcer Agents and Acid Suppressants
(A) Histamine H_2-Antogonists
(B) Prostaglandins
(C) Protectants
(D) Proton-pump Inhibitors
(i) Prokinetic Agents
(j) Anti-inflammatory Agents
(k) GI Drugs, Miscellaneous

(17) **Gold Compounds**

(18) **Heavy Metal Antagonists** (NOTE: IVadministration requires education and training compliance with 850-060-0212)

(19) **Hormones and Synthetic Substitutes**
(a) Adrenals
(b) Androgens
(c) Contraceptives
(d) Estrogens and Antiestrogens
(A) Estrogens
(B) Estrogen Agonists-Antiagonists
(e) Gonadotropins
(f) Antidiabetic Agents
(A) α-Glucosidase Inhibitors
(B) Amylinomimetics
(C) Biguanides
(D) Dipeptidyl Peptidase (DDP-4) Inhibitors
(E) Incretin Mimetics
(F) Insulins
(G) Meglitinides
(H) Sulfonylureas
(I) Thiazolidinediones
(g) Antihypoglycemic Agents
(A) Glycogenolytic Agents
(h) Parathyroid
(i) Pituitary
(j) Somatotropin Agonists and Antagonists
(A) Somatotropin Agonists
(B) Somatotropin Antagonists
(k) Progestins
(l) Thyroid and Antithyroid Agents
(A) Thyroid Agents
(B) Antithyroid Agents

(20) **Local Anesthetics**

(21) **Oxytocics, except for Mifepristone**

(22) **Serums, Toxoids, and Vaccines**
(a) Serums
(b) Toxoids
(c) Vaccines

(23) **Skin and Mucous Membrane Agents**
(a) Anti-infectives
(A) Antibacterials
(B) Antivirals
(C) Antifungals
(i) *Allylamines*
(ii) *Azoles*
(iii) *Benzylamines*
(iv) *Hydroxypyridones*
(v) *Polyenes*
(vi) *Thiocarbamates*
(vii) *Antifungals, Miscellaneous*
(D) Scabicides and Pediculicides
(E) Local Anti-infectives, Miscellaneous
(b) Anti-inflammatory Agents
(c) Antipruritics and Local Anesthetics
(d) Astringents
(e) Cell Stimulants and Proliferants
(f) Detergents
(g) Emollients, Demulcents, and Protectants
(h) Keratolytic Agents
(i) Keratoplastic Agents
(j) Depigmenting and Pigmenting Agents
(A) Depigmenting Agents
(B) Pigmenting Agents
(k) Sunscreen Agents
(l) Skin and Mucous Membrane Agents, Miscellaneous

(24) **Smooth Muscle Relaxants**
(a) Gastrointestinal Smooth Muscle Relaxants

(b) Genitourinary Smooth Muscle Relaxants
(c) Respiratory Smooth Muscle Relaxants
(25) **Vitamins**
(26) **Miscellaneous Therapeutic Agents**
(a) Alcohol Deterrents limited to the following:
(A) Acamprosate;
(B) Disulfiram;
(C) Naltrexone
(b) 5-α Reductase Inhibitors
(c) Antidotes
(d) Antigout Agents
(e) Biologic Response Modifiers, limited to Interferons
(f) Bone Resorption Inhibitors
(g) Cariostatic Agents
(h) Complement Inhibitors
(i) Disease-Modifying Antirheumatic Agents
(j) Gonadotropin-releasing Hormone Antagonists
(k) Immunosuppressive Agents
(l) Other Miscellaneous Therapeutic Agents limited to the following:
(A) Alfuzosin Hydrochloride;
(B) Drotrecogin Alfa (Activated);
(C) Lanreoytide Acetate;
(D) Rilonacept;
(E) Sapropterin Dihydrochloride;
(F) Tamsulosin Hydrochloride

Stat. Auth.: ORS 685.125
Stats. Implemented: ORS 681.145
Hist.: BNE 1-2002, f. & cert. ef. 2-19-02; BNE 4-2002, f. & cert. ef. 8-8-02; BNE 3-2003, f. & cert. ef. 6-9-03; BNE 5-2003, f. & cert. ef. 12-5-03; BNE 5-2004, f. & cert. ef. 6-10-04; Renumbered from 850-010-0226, BNE 8-2005, f. & cert. ef. 10-27-05; BNE 9-2005, f. & cert. ef 12-12-05; BNE 4-2006, f. & cert. ef. 12-11-06; BNE 3-2007, f. & cert. ef. 6-12-07; BNE 1-2008, f. & cert. ef. 2-19-08; BNE 2-2008, f. & cert. ef. 3-21-08; BNE 6-2008, f. & cert. ef. 6-11-08; BNE 7-2008, f. & cert. ef. 12-8-08; BNE 2-2009, f. & cert. ef. 6-17-09; BNE 7-2009, f. 12-14-09, cert. ef. 1-1-10; OBNM 5-2010, f. & cert. ef. 6-30-10; OBNM 7-2010, f. & cert. ef. 12-13-10

References for State Naturopathic Formularies or Laws Related to Naturopathic Pharmaceutical Privileges

Alaska:
http://commerce.state.ak.us/dnn/portals/5/pub/NaturopathyStatutes.pdf

Arizona:
http://www.azleg.state.az.us/FormatDocument.asp?inDoc=/ars/32/01501.htm&Title=32&DocType=ARS

California:
http://www.leginfo.ca.gov/cgi-bin/displaycode?section=bpc&group=03001-04000&file=3640-3645

Colorado:
http://cdn.colorado.gov/cs/Satellite/DORA-Reg/CBON/DORA/1251648073084

Connecticut:
http://www.ct.gov/dph/lib/dph/practitioner_licensing_and_investigations/plis/naturo/nat_statute.pdf

District of Columbia:
http://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/Naturopathic%20Physician%20Formulary.pdf

Hawaii:
http://hawaii.gov/dcca/pvl/news-releases/naturopathy_announcements/NaturopathicFormulary010110.pdf

Kansas:
http://www.ksbha.org/statutes/booklets/naturopathy.pdf

Maine:
http://www.maine.gov/sos/cec/rules/02/502/502c006.doc

Minnesota:
https://www.revisor.leg.state.mn.us/statutes/?id=147E.05

Montana:
http://www.mtrules.org/gateway/ruleno.asp?RN=24%2E111%2E511

New Hampshire:
https://www.nh.gov/pharmacy/documents/naturo-form.pdf

North Dakota:
http://legis.nd.gov/cencode/t43c58.pdf?20140812103528

Appendix D – References for Naturopathic Formularies

Oregon:
http://www.oregon.gov/obnm/rules/850-060-0226_1.pdf

Utah:
http://www.dopl.utah.gov/laws/R156-71.pdf

Vermont:
http://healthvermont.gov/regs/naturopath_rules.pdf

Washington:
http://apps.leg.wa.gov/WAC/default.aspx?cite=246-836-210

Appendix E

ND Pharmacy Educational Requirements

	AK	AZ	CA	CO	CT	DC	HI	KS	ME	MN	MT	NH	ND	OR	UT	VT	WA
Yearly Pharmacy CE Credits		10	10				7.5		7	5	5	3	2.5	10	10	5	
Yearly Total CE Credits	0	30	30	TBD	15	25	17.5	25	25	25	15	15	20	50	24	15	20

Documented 10/31/14
K. Paddock, ND

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Devinder Singh, MD
Chair, Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Dr. Singh,

At the first meeting of the Board of Physicians Naturopathic Formulary Work Group, you'd raised two questions which I was not able to answer at the time, and I have since spoken to both the North American Board of Naturopathic Examiners (NABNE) and the Council on Naturopathic Medical Education (CNME) regarding these questions. You had asked about the Naturopathic Physicians Licensing Examination (NPLEX) licensing examination and it's adherence to validated testing methods, as well as the role of the U.S. Department of Education and the Council on Naturopathic Medical Education (CNME) in accreditation. I'm happy to report that I have complete answers to these questions, as well as references, should you require further information. I hope that this information is useful to you in the naturopathic formulary work group process.

Regarding the NPLEX examination, I have spoken to Teresa Vanderkin, Communications Coordinator for NABNE, who indicated that the NPLEX examination does adhere to validated testing standards. This adherence is overseen by Dr. Christa Louise, M.S., Ph.D., the executive director for NABNE, who unfortunately was not available when I called. Dr. Louise has a background in psychometrics and research design. The following is taken from their website (www.nabne.org) regarding NCME standards:

> Since 1990, NPLEX has focused on developing procedures to ensure that national testing standards are followed. NPLEX follows AERA/APA/NCME standards for test development and administration. Extensive analyses of exam performance and passing scores have led to refinement of systems. NPLEX has completed two criterion-related validity studies of the Part II – Clinical Science and Clinical Elective Examinations and has twice redone the original job analysis.

Dr. Louise has previously testified before the House Health and Government Operations Committee in support of naturopathic licensure in Maryland, and has served as a reference for the Board of Physicians in the past. If you have further questions about the application of validated standards to the NPLEX examination, I can provide her contact information on request.

Regarding the CNME, I have spoke with Dr. Daniel Seitz, J.D., Ed.D., the executive director of the organization. Dr. Seitz clarified that indeed, the U.S. Department of Education recognizes the CNME as the accrediting body for naturopathic medical schools based on its having met the Department's criteria for such a role. The CNME then in turn establishes requirements for naturopathic schools' programs of study, including didactic and clinical curricula, rather than the Department establishing or overseeing curricula. The CNME does monitor the curricula of

MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

accredited schools to ensure the quality of education provided and does respond to concerns when they arise. Dr. Seitz has offered to serve as a resource if necessary, and I can provide his information on request. Additionally, should it be helpful, I can provide the CNME's Handbook of Accreditation for Naturopathic Medicine Programs or more detailed curricula for naturopathic medical programs including course descriptions and book lists.

I hope this is helpful to you in the work of the naturopathic formulary work group, and our association is appreciative of the efforts made by yourself and the Board in this matter. If you have any other questions, or would like to contact the above references, please don't hesitate to ask.

Sincerely,

Kristaps Paddock, N.D.
President, MNDA

cc:
Wynee Hawk, R.N., J.D., Chief, Legislation and Policy Maryland Board of Physicians
Yemisi Koya, Director, Communications Education and Policy
Sandi Van Horn, Health Policy Analyst
Mark Woodard, J.D., Health Policy Analyst
Hayley Evans, J.D.

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Devinder Singh, MD
Chair, Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Dr. Singh,

The uncodified language that laid out the charge before the naturopathic formulary workgroup was clear: the workgroup should make recommendations for the types of drugs and medicines to be included in the naturopathic formulary, the types of devices to be included in the formulary, and the routes of administration by which naturopathic doctors may be permitted to administer medicines. Though the language was clear, there will certainly be differences of opinion on what the committee should ultimately recommend. In the interest of clarity, these are our primary expectations for the workgroup process and our goals.

Regarding drugs and medicines, the MNDA will advocate for a broad formulary. While many states have very broad formularies, and in the case of Vermont an open formulary, we acknowledge that this is likely to be a stepwise process that will proceed as the Board and the various stakeholders gain familiarity with and confidence in the naturopathic profession, and the formulary work group's recommendations will lay the ground for future developments in the naturopathic formulary. Nonetheless, the workgroup recommendations regarding formulary should represent the role pharmaceutical medications play in the core of naturopathic practice, and should permit naturopathic doctors to treat patients effectively and efficiently through the use of pharmaceutical medications. Through examination of the formularies of the other states, it will become clear which drugs represent the core of naturopathic prescribing.

Also regarding drugs and medicines, concerns have been raised as to delineating those natural substances which will be included in the formulary. While these substances are not prescription-only medications, are included within the naturopathic scope of practice according to statute, are indeed are available to the lay public, we are not opposed to enumerating these substances if it becomes necessary.

Our association will also advocate for development of education standards to ensure that naturopathic doctors attain and maintain competency in the prescription of pharmaceuticals that may be listed in the naturopathic formulary. The formulary work group should examine the content of the Naturopathic Physicians Licensing Examination as regards pharmacy, as well as standards required in other states which permit NDs to prescribe pharmaceuticals. Those standards form a strong precedent upon which the formulary work group may make recommendations.

Regarding devices, the MNDA will advocate for the inclusion of durable medical equipment and therapeutic devices such as might be used in primary care outpatient settings. Such a list may include durable medical equipment such as crutches, canes, or glucometers, as well as

MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

therapeutic devices such as transcutaneous electrical nerve stimulation devices ("TENS units"), therapeutic ultrasound devices, or similar devices used in the practice of physical medicine. The use of all of these devices is consistent with the practice of naturopathic medicine.

Finally, regarding routes of administration, the MNDA will advocate that naturopathic doctors be permitted to administer medicines via those same routes which they are currently permitted to order medicines to be administered, including oral, nasal, auricular, ocular, rectal, vaginal, transdermal, and intramuscular. We will not be advocating for subcutaneous, intradermal, or intravenous routes of administration, as we have noted the concerns voiced by several stakeholders regarding these routes of administration.

The MNDA believes that through cooperation, the naturopathic formulary workgroup can create a set of recommendations that will provide naturopathic doctors with the necessary tools to effectively treat patients and promote public health while simultaneously maintaining standards and protecting public safety. In advocating for the naturopathic profession, we advocate ultimately for our patients and their health.

Sincerely,

K[illegible], ND

Kristaps Paddock, N.D.
President, MNDA

cc:
Wynee Hawk, R.N., J.D., Chief, Legislation and Policy Maryland Board of Physicians
Yemisi Koya, Director, Communications Education and Policy
Sandi Van Horn, Health Policy Analyst
Mark Woodard, J.D., Health Policy Analyst
Hayley Evans, J.D.

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Devinder Singh, MD
Chair, Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Dr. Singh,

At the most recent meeting of the Naturopathic Formulary Workgroup, you had requested a information regarding naturopathic continuing medical education. Please find attached two documents related to that question.

The first is a document outlining continuing education requirements in states that currently license naturopathic doctors. You'll note that typical annual CE requirements range from 20 to 30 hours, and that typical annual pharmacy CE requirements are 5 to 7 hours.

The second document is the American Association of Naturopathic Physicians' Continuing Education Application. You'll note that the AANP implements the guidelines put forth by the Accreditation Council for Continuing Medical Education in their approval process. Please also note that in order to be approved for pharmacy credit, at least 40% of a session's content must be pertain to pharmacology, prescribing, pharmaceutical research, or drug safety.

Sincerely,

K Paddock, ND

Kristaps Paddock, N.D.
President, MNDA

cc:
Wynee Hawk, R.N., J.D., Chief, Legislation and Policy Maryland Board of Physicians
Yemisi Koya, Director, Communications Education and Policy
Sandi Van Horn, Health Policy Analyst
Hayley Evans, J.D.

Appendix E

ND Pharmacy Educational Requirements

	AK	AZ	CA	CO	CT	DC	HI	KS	ME	MN	MT	NH	ND	OR	UT	VT	WA
Yearly Pharmacy CE Credits		10	10				7.5		7	5	5	3	2.5	10	10	5	
Yearly Total CE Credits	0	30	30	TBD	15	25	17.5	25	25	25	15	15	20	50	24	15	20

Documented 10/31/14
K. Paddock, ND

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

2014 Continuing Education Application

2014 Naturopathic Continuing Education Application

The American Association of Naturopathic Physicians (AANP) is an accredited provider of Naturopathic Continuing Education. As such, we can approve your course for Naturopathic CE in all states excluding Oregon (which requires a direct application). The following pages contain the full application for this process. We have developed this application process using guidelines put forth by the ACCME for PRA Category 1 CME. The AANP believes that Continuing Naturopathic Education should be held to as high a standard as Continuing Medical Education.

The AANP will approve courses presented by qualified, unbiased professionals who fill all of the requirements and guidelines put forth in this document and the application forms.

Commercial Bias
The following requirements are minimum standards set forth by the AANP for approval of Naturopathic Continuing Education:

- Educational activities should be free from commercial bias
- No company logos or names may be printed on any presentation slides or handouts. In other words – CONTENT must be free from any commercial mention, though the event as a whole may be listed as sponsored by or organized by a commercial entity
- Presenters must be licensed health care professionals or experts in their fields.
- Educational topics should promote improvements in the quality of healthcare or the management of healthcare practices and businesses.
- All speakers must complete Financial Disclosure and Presenter Compliance Agreement

Please review the application carefully. Incomplete applications will not be reviewed. Complete applications are due at least 45 days prior to the educational activity. Applications should be submitted either electronically (scan/email) or by fax. Complete applications should be sent to Rebecca Takemoto at rtakemoto@sync-opate.com or fax 703-991-9133. Questions should be addressed to Ms. Takemoto at the above email or at 410-590-7900.

Credit Hours
1 credit hour will be assigned for each hour spent in lecture. It is the responsibility of the applicant to indicate specialty credits such as pharmacy, OB or ethics. To be approved for pharmacy credit, at least 40% of a session's content must be pharmacological in nature. Approved pharmacy topics include:

- pharmaceuticals and their application in patient care
- pharmacology
- research of pharmaceuticals and formulary substances in naturopathic care
- drug interactions and contraindications

Fees
The fee for AANP credit approval is $180 per credit hour. As part of this fee, the AANP will distribute certificates following your activity. At least 50% of the fee is due with application. If application is rejected, full payment will be refunded. Any remaining balance will be invoiced prior to distribution of certificates.

The American Association of Naturopathic Physicians
Continuing Education Application

A. General Activity Information

Activity Host: _____

Activity/Meeting Title: _____

Activity Date(s): _____ Location: _____

Activity Contact Information:

Contact Name	
Position	
Phone	
Email	
Fax	

B. Educational Objectives
Please describe the Purpose/Educational Objectives of this activity: (attach additional if necessary)

C. Program Development
Please describe the method used to choose speakers: (i.e. invitation, call for papers)

D. Speaker Payment
Will faculty honoraria or reimbursement be provided for this activity? ☐Yes ☐No
If yes, please attach a list of faculty and the honoraria/reimbursements provided.

E. Commercial Support
Will commercial support be solicited for this activity? ☐Yes ☐No
If yes, please attach an accounting of all commercial support (company, amount, type of support).

F. Session Information
Please attach the following to this application:
Full meeting schedule
Session Information Documents (for each session)
Session Outline (for each session)
Disclosure Form for each speaker *as well as each planning committee member*
CE Compliance Form for each speaker

The American Association of Naturopathic Physicians
Continuing Education - Session Information Form

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Date/Time: _____ CE Requested: _____

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Session Description (<350 words)

Speaker(s) Biography

Session Learning Objectives

Session Outline

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(to be completed by each speaker AND each planning committee member)

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I have nothing to disclose in relation to this activity.

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The American Association of Naturopathic Physicians
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(to be completed by each speaker)

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Activity/Meeting Dates: _____

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Naturopathic Formulary Workgroup
Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Fellow Committee Members,

Having reviewed the naturopathic formularies of other states, as well as other states' laws related to naturopathic doctors' prescriptive rights, our association feels it is appropriate to discuss the categories of legend drugs which are of interest to us, and it is important that all stakeholders understand our efforts in the context of our ultimate goals for a naturopathic formulary.

The categories of medications for which naturopathic doctors are seeking prescriptive rights meet several criteria. First, they must be within the scope of naturopathic training as taught at accredited naturopathic medical schools. Secondly, they must be pertinent to the practice of naturopathic medicine in the state of Maryland, in that they must address conditions commonly seen in naturopathic practice. Finally, the formulary must permit naturopathic doctors to adequately respond to emergency situations while working in concert with emergency medical services.

The categories of legend drugs of most interest to naturopathic doctors, and which comprise the vast bulk of medications prescribed by naturopathic doctors, are these:

- Analgesics and topical anesthetics
- Antidepressants
- Antihistamines
- Anti-infective agents, including antibacterials, antifungals, antiparasitics, and antivirals
- Anti-inflammatory agents, including corticosteroids, NSAIDs and other pain control agents
- Basic emergency agents, including epinephrine and oxygen
- Cardiovascular medications including antihypertensives and antilipidemics
- EENT preparations of analgesics, antihistamines, anti-infectives, anti-inflammatories, and other miscellaneous EENT preparations
- Hormones, both natural and synthetic
- Topical medications and preparations, including anti-infectives, anti-inflammatories, and miscellaneous topic medications

Please also reference this table, which indicates those other states which permit naturopathic doctors to independently prescribe these types of legend drugs:

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MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Category	AZ	CA	CO	DC	HI	ME	MT	NH	OR	UT	VT	WA
Analgesics/ Anesthetics	X				X	X	X	X	X	X	X	X
Antidepressants	X				X				X	X		X
Antihistamines	X				X			X	X	X		X
Anti-infectives	X			X	X	X	X	X	X	X	X	X
Anti-inflammatories	X				X		X	X	X	X	X	X
Basic Emergency Medications	X	X	X	X	X	X	X	X	X	X	X	X
CV Medications	X				X		X	X	X	X	X	X
EENT Preparations	X				X	X			X	X		X
Hormones	X	X		X	X	X	X	X	X	X	X	X
Topical Medicines	X			X	X	X	X	X	X	X	X	X

The categories of legend drugs which our association is seeking all have precedent in multiple states. Our goal in proposing a formulary of this type is to provide clarity in areas that need clarity, and to provide naturopathic doctors with the tools that permit them to safely and effectively treat patients in a timely manner.

In addition, it is important to note that all of the formularies that the committee has reviewed have included full access to amino acids, botanicals, dietary supplements, enzymes, homeopathics, minerals, and vitamins. While not legend drugs, these substances are included in the scope of practice outlined in the statute governing naturopathic medicine, and unrestricted access to these items should be included in the formulary.

Finally, for clarity's sake, all nonprescription drugs and OTC preparations of drugs should be included in the naturopathic formulary in order to permit naturopathic doctors to properly counsel patients on the safe and effective use of these substances, and recommend their use when appropriate. These drugs are included in the scope of practice outlined in the statute covering the practice of naturopathic medicine.

Sincerely,

K. Paddock, ND

Kristaps Paddock, N.D.
President, MNDA

cc:

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Andrea Mathias, M.D.
Naturopathic Formulary Workgroup
Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Dr. Mathias,

At the February 23rd meeting of the naturopathic formulary workgroup, you had made two requests. The first was regarding supplements; you had requested that I supply information about a "naturopathic materia medica" that provides an outline of all substances used by naturopathic doctors. The second was regarding methods that naturopathic doctors use to maintain quality control regarding herbs, vitamins, and other substances, given the nature of the oversight the FDA exerts over dietary supplements.

Regarding the first question, I have not found any reference to an all-inclusive "naturopathic materia medica" that encompasses all herbs, vitamins, supplements, etc., that a naturopathic doctor might use or is educated in using. The term "materia medica" may be used to title smaller works that encompass a more limited area of practice, however; a naturopathic doctor writing a book for a given condition or group of conditions might include a "materia medica" of herbs and nutrients that are indicated in that condition, along with those items' contraindications, interactions, and potential side effects. It was perhaps in reference to such a work that the term came up. As stated in the meeting, most states have opted to include non-exclusive lists of examples in the categories of amino acids, botanicals, enzymes, minerals, and vitamins in their naturopathic formularies. Homeopathics are often defined in accordance with the Homeopathic Pharmacopoeia of the United States, and other dietary supplements may or may not be listed at all. Our association recommends that the workgroup follow the lead of these other states in including these substances in the formulary.

The second question raised was regarding the methods naturopathic doctors use to ensure quality control of dietary supplements they recommend. As stated in the meeting, naturopathic doctors are educated regarding quality control during didactic classes and clinical rotations, and are educated on the importance of verification of raw materials, good manufacturing practices, testing for contaminants and adulterants, potency testing, and a host of other procedures put in place by manufacturers of high quality dietary supplements. As I mentioned in the meeting, because naturopathic doctors are using these substances for therapeutic effect, it is important that the supplements they recommend to patients are accurately labelled as regards identity and potency, and that they are free from contaminants. These steps are taken not only by naturopathic doctors, but by other healthcare professionals who may recommend supplements. Most manufacturers make this information available to providers and the public, and indeed it becomes a selling point for these brands, as healthcare providers seek high quality products to recommend to their patients.

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There was also discussion at the meeting of a mission statement being written for the naturopathic formulary that would include language encouraging naturopathic doctors to act to ensure that their patients utilize substances that meet quality control standards. We anticipate that it will address the committee's concerns regarding supplements.

Sincerely,

K, ND

Kristaps Paddock, N.D.
President, MNDA

cc:
Wynee Hawk, R.N., J.D., Chief, Legislation and Policy Maryland Board of Physicians
Yemisi Koya, Director, Communications Education and Policy
Sandi Van Horn, Health Policy Analyst
Hayley Evans, J.D.

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MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Naturopathic Formulary Workgroup
Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Fellow Committee Members,

The Maryland Naturopathic Doctors Association has reviewed the regulation of therapeutic devices and their place in the formularies of other states that license naturopathic doctors, and while other states are variable in the way they deal with the issue of devices, and indeed there is not a strong precedent in this regard, we have developed a policy that the committee members should find agreeable.

We have noted that in their naturopathic formulary, the state of Colorado permits naturopathic doctors to use "Any nonprescription ... devices appropriate within naturopathic medicine for treating patients." While this statement may require some crafting to the specific language used in Maryland statute, this approach will prove fruitful in our work regarding devices.

It is important to note that our emphasis in the selected text is on the term "nonprescription." The association seeks to have included those nonprescription devices which are available to the general public. Inclusion of nonprescription devices in the formulary should not be controversial.

The term "appropriate within naturopathic medicine for treating patients" is less defined. As we've stated before, our association seeks only those devices used in the practice of naturopathic medicine as defined in statute. Such devices include those used for physical and laboratory examination (including otoscopes, blood pressure cuffs, phlebotomy needles, etc.), the performance of naturopathic physical medicine treatments (including hydrotherapy, therapeutic ultrasound, phototherapy, etc.), and devices needed for the administration of medicines via approved routes of administration. This list would not include imaging devices, as our association has clarified in the past.

Among prescription devices, we are seeking only the inclusion of barrier contraceptive devices, excluding intrauterine devices. Barrier contraceptives are permitted in the scope of nearly all states that license naturopathic doctors, and prescription barrier contraceptives are included in the naturopathic formularies of those states that include devices in those formularies.

Finally, I must admit an omission from the list of necessary drug categories I had previously submitted to the work group. Our association seeks inclusion of gastrointestinal agents, such as proton pump inhibitors, antacids, and antidiarrheal agents. Please consult the following chart of the states which currently permit the use of gastrointestinal agents by naturopathic doctors.

MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Category	AZ	CA	CO	DC	HI	ME	MT	NH	OR	UT	VT	WA
Gastrointestinal agents	X			X	X	X	X	X	X	X	X	X

Sincerely,

Kristaps Paddock, N.D.
President, MNDA

cc:
Wynee Hawk, R.N., J.D., Chief, Legislation and Policy Maryland Board of Physicians
Yemisi Koya, Director, Communications Education and Policy
Sandi Van Horn, Health Policy Analyst
Hayley Evans, J.D.

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MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Naturopathic Formulary Workgroup
Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Fellow Workgroup Members,

As we gear up for a longer, hopefully very productive meeting at our next session, I've written a longer letter than usual, which answers the several questions which came up at the last meeting, and also addresses some other important topics which may come up in the coming meeting. I've numbered this topics for easy reference during conversation, and I hope the information to helpful to you.

1. Dr. Gahunia had requested information about the Good Manufacturing Practices followed by high quality supplement manufacturers of the type recommended by naturopathic doctors. These supplement companies follow the Current Good Manufacturing Practices (CGMP) standards set by the FDA, and submit to third party or agency audit. These audits are in some cases carried out by the FDA, NSF International, the United States Pharmacopeia, the Natural Products Association, or other organizations. Many of these same organizations also provide CGMP auditing to pharmaceutical or medical device manufacturers. Some vendors/distributors which are used extensively by naturopathic doctors and other healthcare providers require that brands whose products they carry comply with CGMP guidelines and submit to audits. Our association supports recommendations that naturopathic doctors utilize and recommend supplements produced by manufacturers that follow CGMP guidelines.

2. Ms. Bode had requested more detailed information regarding priorities and context as regards categories of drugs. You will find below a chart of the categories of drugs our association is seeking to have included in the Maryland Naturopathic Formulary. The list is cross referenced with the formularies of those states that also have naturopathic formularies or prescriptive rights for naturopathic doctors.

Category	AZ	CA	CO	DC	HI	ME	MT	NH	OR	UT	VT	WA
Analgesics/Anesthetics	X				X	X	X	X	X	X	X	X
Antidepressants	X				X				X	X		X
Antihistamines	X				X			X	X	X		X
Anti-infectives	X			X	X	X	X	X	X	X	X	X
Barrier Contraceptives	X	X	X	X	X	X	X	X	X	X	X	X
Basic Emergency Medications	X	X	X	X	X	X	X	X	X	X	X	X
CV Medications	X				X		X	X	X	X	X	X
EENT Preparations	X				X	X			X	X		X
Gastrointestinal agents	X			X	X	X	X	X	X	X	X	X

MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Hormones	X	X		X	X	X	X	X	X	X	X	X
Topical Medicines	X			X	X	X	X	X	X	X	X	X

Our association believes that a broad formulary including drugs from all of these categories are necessary for the practice of naturopathic medicine in Maryland as a complementary and integrative medical practice. You can see that some categories are nearly universally permitted, such as emergency medications, barrier contraceptives, hormones, topical medicines, analgesics, gastrointestinal agents and anti-infectives. Other categories, such as antihistamines and EENT preparations are slightly less common, but are important to clinical practice. Finally, cardiovascular medications and antidepressants are more potent medications, though not controlled substances, but they are commonly prescribed to treat conditions which are very responsive to dietary and lifestyle therapies, and are therefore important to the practice of naturopathic medicine.

3. Dr. Singh had requested additional information regarding naturopathic doctors' use of testosterone. Our association is aware that this would be the sole controlled substance to be included in a naturopathic formulary, and that it thus requires some additional scrutiny. To begin with, I'll remind the committee that testosterone was included on the NPLEX blueprint list of pharmaceuticals which I had submitted for the workgroup's first meeting in January, and that naturopathic doctors are expected to be competent in the use of testosterone in order to be considered competent to practice. The use of testosterone is taught in naturopathic schools, naturopathic students are exposed to it as part of their clinical training, and continuing education does address the issue as well.

As a large portion of naturopathic prescriptions are related to the use of hormones, it is important that testosterone be included in the formulary. Naturopathic doctors will typically use testosterone therapy as indicated by lab testing and clinical symptoms to address low testosterone levels in men, and also where indicated by clinical symptoms and lab testing in women to address conditions such as low libido or vulvodynia.

In order that workgroup members might be able to see the decisions that other states have made, the chart below documents the states where naturopathic doctors are permitted to prescribe testosterone. You'll note that the majority of states that permit NDs to prescribe drugs permit them to prescribe testosterone.

Category	AZ	CA	CO	DC	HI	ME	MT	NH	OR	UT	VT	WA
Testosterone	X	X		X			X	X	X	X	X	X

4. Regarding the questions that arose over the term "miscellaneous" as applied to EENT and Topical applications, the following clarifications will be helpful. As Mr. Jones noted, miscellaneous EENT preparations would include cough, cold and sore throat remedies, including expectorants, antipyretics and local anesthetics. This list would also include mouthwashes and gargles. The category of miscellaneous topical applications is broader, and would include

antipruritics, topical anesthetics, astringents, detergents, emollients, demulcents, protectants, and sunscreens, all of which would fall outside the prohibition against cosmetic medications.

5. It is important to discuss many of the issues attendant to pharmaceutical privileges, such as limitations or prohibitions, supervision/collaboration, endorsements or certificates, and continuing education.

The committee has already voted on important limitations, including a prohibition against controlled substances (with the possible exception of testosterone), and a prohibition against the use of devices and substances for cosmetic purposes. Our association accepts these prohibitions, though additional prohibitions or limitations are not necessary. Statute already clearly limits naturopathic practice, and regulations will reinforce those limits. For example, statute clearly prohibits the practice of surgery by naturopathic doctors, and therefore this workgroup need not recommend prohibitions against the use of devices and medications associated with surgery. As the formulary is to be an inclusive formulary, naturopathic doctors will only be permitted to use those substances and devices included in that formulary, so prohibitions beyond those already included are not necessary.

Regarding supervision/collaboration, our association is firmly opposed to additional collaborative requirements. Though it has not been discussed at length in this workgroup, the licensing statute requires naturopathic doctors to submit attestation statements comparable to those currently in place for nurse practitioners. The collaborative relationships which naturopathic doctors will already be required to attest to are more than adequate to ensure oversight of pharmaceutical prescriptions for the limited formulary our workgroup is considering. Though the state of Maine requires a one-year collaborative relationship in order to gain full access to prescriptive authority, no other states require oversight for the prescriptive authority described in the charts above. In requiring an attestation statement, Maryland has already created oversight requirements greater than any other state, and additional oversight for prescriptive authority is not necessary.

Regarding additional certification or endorsement, our association is likewise opposed for a recommendation of this type at this time. A precedent does exist for additional testing in both Oregon and Vermont; however, naturopathic doctors in both of those states have access to extremely large formularies appropriate for primary care medicine, well in excess of the limited formulary our association is seeking. Our association is not opposed to discussing additional pharmaceutical testing at some point in the future, but this should be considered at a separate time as part of greater pharmaceutical privileges for naturopathic doctors.

Regarding continuing education, our association will again underline its recommendation that approximately one quarter of required continuing education hours be devoted to pharmacy and that guidelines comparable to those established by the American Association of Naturopathic Physicians be utilized to ensure freedom from commercial influence and sufficient quantity of content being devoted to pharmaceutical prescription, management and safety issues. This recommendation would be in line with standards established by other states.

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6. Finally, the committee may have time to discuss both those devices which will be included in the formulary, and the routes of administration which will be permitted to naturopathic doctors. As stated in the last meeting, our association proposes that naturopathic doctors be permitted to use those nonprescription devices which are necessary to the practice of naturopathic medicine as defined in statute. Elements of naturopathic practice which would require the use of devices includes physical and laboratory examination, naturopathic physical medicine, and the application of medicines via approved routes of administration.

Regarding routes of administration, at this time, our association seeks only that naturopathic doctors themselves be permitted to administer medications in office via those same routes of administration which they are permitted to prescribe patients to administer medications to themselves. The law currently permits naturopathic doctors to administer medications transdermally only, whereas they can prescribe medicines which are administered orally, nasally, auricularly, ocularly, rectally, vaginally, transdermally, and intramuscularly. These should be brought into alignment.

Sincerely,

KP, ND

Kristaps Paddock, N.D.
President, MNDA

cc:
Wynee Hawk, R.N., J.D., Chief, Legislation and Policy Maryland Board of Physicians
Yemisi Koya, Director, Communications Education and Policy
Sandi Van Horn, Health Policy Analyst
Hayley Evans, J.D.

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MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Naturopathic Formulary Workgroup
Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Fellow Workgroup Members,

In the forthcoming meeting, it is the MNDA's hope that the workgroup will be able to vote on a number of issues. These include: the recommendation that anti-infective agents and hormones be exempted from the general ban on legend drugs; a recommendation on the types of devices to be included on the formulary; a recommendation on the composition of the formulary council; a recommendation on the routes of administration which naturopathic doctors will be able to utilize; and a recommendation for pharmacy continuing education hours.

1. Regarding drugs, it is important that naturopathic doctors be permitted prescribe to anti-infective agents and hormones. As stated in a prior letter, and reaffirmed in the meeting on April 6th, our association used several criteria in determining which drugs should be included in a naturopathic formulary at the present time. They include: that the drugs be within the scope of naturopathic training, as taught at accredited schools of naturopathic medicine; that the drugs be used to treat conditions which commonly present in naturopathic practice; and that the drugs occupy a clinical role not covered by natural substances.

The two categories of drugs being considered for inclusion in a naturopathic formulary are anti-infective agents and hormones, as they are among the most common prescriptions for most naturopathic doctors operating in a specialist capacity. The use of these types of drugs is taught in naturopathic medical school and tested as part of the NPLEX licensing examination, as has been documented in past weeks.

Additionally, they are used to treat conditions which present commonly in naturopathic practice. The majority of patients presenting in typical naturopathic practices are women, and very commonly, these women are suffering from symptoms related to menopause, menstrual irregularities, or hypothyroidism. Among men, the majority of patients presenting in naturopathic practice are in middle age and beyond, and may be suffering from conditions related to age-related decline in testosterone levels. Both of these patient populations suffer from conditions which are treated using hormones.

Regarding anti-infective agents, a certain portion of paients present with acute infections in naturopathic practice, and naturopathic doctors may utilize antibiotics to treat these acute infections. However, more commonly, patients present in naturopathic practice with recurring infections, such as recurring urinary tract infections, sinus infections, bacterial vaginosis, or vaginal candidiasis. Antimicrobials are of important clinical use in treating these conditions.

These drugs occupy a place in naturopathic practice not otherwise occupied by natural substances and therapies. In naturopathic practice, prescription hormones are used to influence or replace the body's normal processes when the patient's own body is failing to do so. As these substances are identical to or very similar to the body's own hormones, their use is in keeping with the principles of naturopathic medicine. They are rarely used as monotherapy, and are often used as temporary measures to relieve symptoms in the process of bringing the body back to normal functioning via dietary and lifestyle measures.

Anti-infectives also occupy an important role in naturopathic practice. I previously mentioned, acute or recurring infections are a common presentation in naturopathic practice. In the case of acute infections, naturopathic doctors will often utilize natural therapeutics as a first line therapy, and also send a patient home with instructions to follow up within 24-48 hours, at which point an antibiotic may be prescribed if indicated. The prescription would be based on the results of a culture and sensitivity if available; if not, the patient would either be prescribed a broad-acting antimicrobial or referred to and urgent care facility, depending on the particular presentation. With recurring infections, naturopathic doctors typically view these in terms of both host and organism, so will institute natural therapies to decrease host susceptibility, as well as utilize an antimicrobial to eliminate the organism; in chronic infections, where a patient may have been subject to several rounds of incompletely effective antimicrobials, culture and sensitivity are essential to successful elimination of the infection. Dr. Gahunia mentioned the problem of antibiotic resistance, and certainly this is a question of primary importance to naturopathic doctors; antibiotics are rarely prescribed as monotherapy, and for the reasons stated above, are prescribed in response to culture and sensitivity results.

I am including an attachment which delineates those categories of antimicrobials and hormones which should be included in a naturopathic formulary. I have also included several examples of specific drugs within those categories (drawn from the naturopathic formularies of other states), all of which are administered via approved routes of administration (e.g. orally, topically, vaginally, but not intravenously). Though I am sensitive to the work group members' desire for specifics as regards those drugs which would be included in a formulary, responsible antibiotic prescriptions should incorporate the results of culture and sensitivity testing, and a broad formulary is necessary to act on test results, and these lists are intended to serve primarily as examples. Similarly, there are a variety of forms which these hormones take in prescriptions, and I have included several examples.

These substances are not without hazards. Estrogens carry risk of blood clotting, not to mention the hazards associated with unopposed estrogen. The issues with testosterone are well known and there exists a risk for abuse, though these hazards are lower in the low dose testosterone therapy common to naturopathic practice. Antibiotics carry a number of hazards as well, including toxicities and potential of promotion of antibiotic resistance. In order to ensure that naturopathic doctors maintain the competencies they demonstrated in passing the NPLEX, we recommend the adoption of continuing education requirements in pharmacy. As has been noted in the past, we recommend that approximately one quarter of required CE hours be devoted to pharmacy.

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As further reference, I'm again including the table below, which indicates those states that permit access to hormones (testosterone is listed separately) and anti-infective agents.

Category	AZ	CA	CO	DC	HI	ME	MT	NH	OR	UT	VT	WA
Anti-infectives	X			X	X	X	X	X	X	X	X	X
Hormones	X	X		X	X	X	X	X	X	X	X	X
Testosterone	X	X		X			X	X	X	X	X	X

2. Regarding the devices to be included in the formulary, I will restate that naturopathic doctors should have access to all non-prescription devices (just as naturopathic doctors will have access to non-prescription drugs), and that naturopathic doctors have access to one type of prescription device – barrier contraceptives.

The non-prescription devices we are seeking are those that are necessary to practice naturopathic medicine as defined in statute, including physical examination, laboratory examination, naturopathic physical medicine, and the application of medicines via approved routes of administration; such items include stethoscopes, needles for phlebotomy, transcutaneous electrical nerve stimulation, and other comparable devices. These devices are available to the general public, and their inclusion should not be controversial.

Regarding barrier contraceptives, all states that license naturopathic doctors permit them access to barrier contraceptive devices. The application and use of contraceptive devices is taught in naturopathic medical school, and these devices are a core part of naturopathic practice, which as I noted consists of a majority of female patients. Of course, there are no substitutes for barrier contraceptives among natural therapeutics.

3. Regarding the naturopathic formulary council, the work group voted at the last session to recommend creating such a body. Dr. Singh expressed concern that the composition and structure of a formulary council had not been discussed, and we agree that this warrants conversation. The table below indicates the composition of the bodies that determine the naturopathic formularies with some exceptions; in Arizona, California, the District of Columbia, and Washington, prescriptive authority is described in statute. In some states, it is the board or a committee of the board which determines the formulary, whereas in others, it is a formulary council which determines the formulary.

State	ND	MD/DO	RPh/DPh	APD*	Public	Other
Hawaii	3				2	
Kansas	2	2	1	1		
Maine	2	1	1			
Montana	2	1	1		1	
New Hampshire	2	1	1	1		
Oregon	2	1	2	2		

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Utah	4		1			
Vermont	2					1**

(The abbreviation APD is used to mean "holder of advanced degree in pharmacology or pharmacognosy"*
*** In Vermont, two NDs advise the Commissioner of Health regarding the naturopathic formulary.)*

Our association is open to discussion of the composition of a formulary council, but we would recommend that the council be comprised of at least two licensed naturopathic doctors, one licensed physician or allied healthcare provider, one licensed pharmacist, and one member of the public. This model is in holding with precedent in other states. We also recommend that the work group consider that these positions may be filled by members of the Naturopatic Medicine Advisory Committee and other regulatory bodies. Regarding the operations of a formulary council vis a vis the writing of regulations and the adding of drugs to the formulary, we await the Board staff's report regarding standard procedure for other professions in Maryland.

4. **Regarding routes of administration**, the work group should recommend that naturopathic doctors be permitted to administer medicines via the same routes of administration which they are permitted to prescribe. Currently, naturopathic doctors are permitted to prescribe medicines to be administered orally, nasally, auricularly, ocularly, rectally, vaginally, transdermally, and intramuscularly. At the same time, naturopathic doctors themselves are permitted to administer medicines only transdermally. This is not the result of legislative intention, but is a function of the drafting and discussion process; in order to achieve of passage of a naturopathic licensure bill in the 2014 session, the House Health and Government Operations committee recommended that this error be corrected as part of the formulary work group process. As this discrepency places naturopathic doctors in a situation in which patients, who have not received medical training, can self-administer medications which their trained and licensed naturopathic doctor cannot themselves administer, it should be corrected.

Finally, there has been considerable discussion regarding supplement safety, and at the last meeting there were also concerns voiced regarding proper prescribing of legend drugs. I am sensitive to these concerns, and have worked with Mr. Jones to craft a vision statement which recommends the creation of a formulary that conforms to standards utilized by other professions. I do not take these concerns lightly, but also want to ensure that the workgroup is able to achieve the task set out to it by the legislature within the alloted time frame. The work done on the mission/vision statement adequately addresses these concerns in as much as they need to be addressed at the present moment, and further elaboration of these concerns should be voiced in the writing of regulations related to a formulary council. For the present, it is important that the work group complete its assigned task and report to the legislature in a timely fashion.

Sincerely,

KP, ND

Kristaps Paddock, N.D.
President, MNDA

MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

cc:
Wynee Hawk, R.N., J.D., Chief, Legislation and Policy Maryland Board of Physicians
Yemisi Koya, Director, Communications Education and Policy
Sandi Van Horn, Health Policy Analyst
Hayley Evans, J.D.

Category	Class	Indication	Examples
Antimicrobial Agents	Aminoglycosides	bacterial infection	Neomycin
	Azole antifungals	fungal infection	Clotrimazole
			Fluconazole
			Itraconazole
			Ketoconazole
	Cephalosporins	bacterial infection	Cefaclor
			Cefadroxil
			Cefdinir
			Cefditoren
			Cefixime
			Cefpodoxime
			Cefprozil
			Ceftibuten
			Ceftriaxone
			Cephalexin
	Fluoroquinolones	bacterial infection	Cirprofloxacin
			Levofloxacin
	Macrolides	bacterial infection	Azithromycin
			Clarithromycin
			Erythromycin
	Nitrofurans	bacterial infection	Nitrofurantoin
	Nitroimidazole	bacterial, protozoal, amoebic infections	Metronidazole
			Tinidazole
	Penicillins	bacterial infection	Amoxicillin
			Amoxicillin clavulanate
			Ampicillin
			Penicillin V
	Sulfonamides	bacterial infection	Sulfamethoxazole
	Tetracyclines	bacterial infection	Doxycycline
			Minocycline
			Tetracycline
	Misc. Antibiotics	bacterial infection	Clindamycin
			Mupirocin
			Trimethoprim
	Misc. Antifungals	fungal infection	Amphotericin B (oral)
			Griseofulvin
			Nystatin
			Terbinafine
	Misc. Antiparasitics	parasitic infection	Albendazole
			Nitazoxanide
			Permethrin
	Misc. Antivirals	viral infection	Acyclovir
			Valacyclovir
Hormonal agents	Estrogens	menopausal conditions, irregular menses, etc.	Conjugated estrogens
			Estrone
			Estradiol
			Estriol
			Ethinyl estradiol
			Estropipate
			Estrogen esters
	Progesterone	menopausal conditions, irregular menses, etc.	Progesterone
			Progestins
	Testosterone	androgen replacement therapy	Testosterone
	Thyroid hormones	hypothyroidism	USP Thyroid
			Levothyroxine
			Liothyronine
			Liotrix

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Compiled by K. Paddock, ND 04/07/2015

MNDA
MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

Naturopathic Formulary Workgroup
Maryland Board of Physicians
4201 Patterson Avenue
Baltimore, MD 21215

Dear Fellow Workgroup Members,

At the last formulary work group meeting, the topic again came up of applying FDA guidelines regarding health claims for supplements to the doctor-patient relationship as a means for the Board of Physicians to have a standard against which to judge the actions of naturopathic doctors in practice. Our association does not believe that the use of these guidelines will have the intended effect and has concerns that there may be unintended consequences, and so opposes a motion that the work group recommend their use as a standard of care. Instead, we would propose that the topic be take on by the Naturopathic Medicine Advisory Committee, and would suggest several references for the Board to consult in establishing customary practice.

In discussion with Dr. Singh both during and following the meeting, I have come to understand that the Board's concerns largely center on the fact that customary practice has not yet been established for naturopathic doctors. Dr. Singh gave the example of off-label uses for prescription drugs, stating that when a disciplinary panel is reviewing a case of harm due to a medication being used for an off-label use, the panel judges the physician's actions based on clinical evidence and customary practice. Because dietary supplements, herbs, and vitamins do not have FDA-approved uses, a disciplinary panel would turn to clinical evidence and customary practice in determining whether an ND recommending such a substance would have provided substandard care. He stated that, due to the short history of naturopathic practice in Maryland as well as the limited number of naturopathic doctors who could potentially serve as expert witnesses, the Board had concerns about its ability to properly establish customary practice standards for naturopathic doctors.

Let me underscore the fact that our association is not opposing the use of FDA standards in order to prevent the establishment of standards or to prevent proper disciplinary actions from being taken. One of our primary arguments in favor of licensure was that it would permit for greater public protection, and allowed for recourse in cases where harm had been done. Our goal in offering this feedback is to provide for patient protection via a route that has more meaningful, timely, and accurate impact. However, we must oppose this proposal.

The legislature mandated that this work group be convened to address the topic of including prescription drugs in a naturopathic formulary; this had proven to be a major sticking point in the legislative process, and so all convened stakeholders, including the Board of Physicians and MedChi, determined that it should be studied in more detail by a work group, and, if the work group recommended their inclusion, that such a law be discussed separately by the MGA. It was not their intent that the committee discuss the use of dietary supplements or standards of care; these are important topics, but were not intended to be discussed in this venue. This work group

has an important charge, and should work to meet the expectations of the legislators who requested its creation. We should therefore keep our scope limited to the issue at hand, which is the creation of a naturopathic formulary, and the inclusion of drugs, medicines and devices on that formulary, as well as the issue of routes of administration.

However, in considering the matter of customary practice, the work group should remember that the FDA's guidelines regarding health claims for supplements are not intended to be applied to the doctor-patient relationship as a standard of care. The FDA does not regulate the practice of medicine in any state, but instead provides for the safety of food and drugs on a national level. FDA guidelines for health claims related to foods or dietary supplements are intended to prevent false or misleading claims in advertizing, and to promote population-level health and safety. In permitting health claims, the FDA reviews only studies conducted on healthy or at risk populations, they do not review studies of nutrients used in diseases populations. Because of this, they are an inadequate reference for clinical practice, which is by necessity the treatment of diseased individuals. The FDA guidelines were not intended to guide the practice of medicine by individual healthcare providers, acting on published evidence, to effectively treat individual patients to the best of their ability. These are very different situations and the same standard cannot be applied to both. It is also important to note that no other professions are currently held to these guidelines as a standard of care.

Additionally, instead of providing clarity for disciplining naturopathic doctors in cases of negligence or unethical care, the use of FDA standards will prove to muddy the waters. The adoption of such a standard will be interpreted by some to be an effective ban on the use of dietary supplements in clinical practice, which would be at direct odds with the statute's allowance for the use of "all dietary supplements" by naturopathic doctors. This apparent conflict will result in confusion and may yield complex enforcement problems.

It should also be noted that should the work group recommend the adoption of these guidelines, they will not allow for timely enforcement of standards. In order for this recommendation to have the force of law, it will first have to be drafted into law, then passed by the MGA, then be promulgated. Even assuming that such a process is achieved, which it may not be, the earliest possible implementation of such guidelines is well beyond the March 1st deadline by which the Board of Physicians must have issued licenses to naturopathic doctors.

It is our opinion that these concerns should be communicated to the Naturopathic Medicine Advisory Committee to be considered as part of the code of ethics. The Advisory Committee has recently completed a set of draft regulations, which provide grounds for disciplinary action to be taken against NDs, including all of the same grounds upon which physicians can be disciplined. The Advisory Committee will soon be creating a Code of Ethics, which will outline the ethical practice of naturopathic medicine in Maryland, including the ethical guidelines which govern the doctor-patient relationship.

In creating these guidelines, it is my understanding that the Advisory Committee will be consulting similar documents in other states. One such document is the code of ethics created by

MARYLAND NATUROPATHIC DOCTORS ASSOCIATION

for naturopathic doctors in Hawaii, which I have attached to this letter. Based on this document and others, the Naturopathic Medicine Advisory Committee will be able to create a set of standards of practice that will allow for much more timely and effective enforcement.

Additionally, I would recommend that the Board of Physicians consult evidence-based clinical reference guides for the use of dietary supplements when establishing customary practice within the disciplinary process. Such guides include but are not limited to: the Physician's Desk Reference for Herbal Medicines; the Physician's Desk Reference for Nonprescription Drugs, Dietary Supplements, and Herbs; and the Natural Medicines website (formerly Natural Standard). These reference guides, which are produced, reviewed, and edited by a combination of naturopathic doctors, physicians, pharmacists, and other experts in the fields of pharmacology, public health, herbalism and nutrition, are reliable third-party documents which the Board can utilize to determine customary use of natural therapies. The FDA's set of approved health claims are broad and are designed to prevent misleading advertizing; these documents are designed for clinical practice and will provide far more effective guides for the Board.

My association again wishes to express its opposition to the motion that these FDA standards be applied to the doctor patient relationship. Such an action would be an inappropriate transfer of standards, would create confusion, and would not provide for timely enforcement. Rather, the Board should communicate its concerns to the Naturopathic Medicine Advisory Committee for them to be addressed in the Code of Ethics, and should consult the above mentioned reference guides in establishing customary practice.

Sincerely,

K Paddock, ND

Kristaps Paddock, N.D.
President, MNDA

cc:
Wynee Hawk, R.N., J.D., Chief, Legislation and Policy Maryland Board of Physicians
Yemisi Koya, Director, Communications Education and Policy
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The attachment (regarding Hawaii) to the preceding letter is not included.

Appendix 3

Society for Science-Based Medicine

Report to the Maryland Board of Physicians Naturopathic Advisory Committee: Recommendations for Naturopathic Regulation

October 2014

About the Society for Science-Based Medicine

The Society is a community of like-minded individuals, both in and out of health care, who believe that people should not suffer, die and lose hope, time and money due to pseudo-medicine. We support a single, science-based standard of care for all health care and believe that effective, reliable care can only be delivered within a consistent framework of scientific knowledge and standards.

Our mission is to educate consumers, professionals, and policymakers about science-based medicine. We support sound consumer health care laws and oppose legislation that undermines science-based medicine.

The Society has members all across the U.S., including Maryland, and in other countries. Formed in 2013, the Society is a 501(c)(3) tax-exempt charitable organization. All of our work is done by volunteers.

The Society maintains a website providing resources and information free to the public, including a beta version of a wiki that will eventually include a vast library of information about pseudo-scientific practices that are detrimental to the health, safety and welfare of the public. Additional information about the topics addressed in this Report can be accessed there. www.sfsbm.org.

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Introduction

The Maryland Legislature passed a naturopathic doctor licensing act in 2014 in order to "*protect the health, safety, and welfare of the public, and specifically protect individuals who are the direct recipients of services regulated [by the law]*." As public protection is the constitutional basis of the state's authority to regulate health care practitioners, via the state's police power, all other legislative goals are by necessity subservient to this goal.[1] The law is also intended to maintain standards in the delivery of naturopathic services, ensure naturopathic care by qualified naturopathic doctors is available and provide a means for identifying qualified naturopathic doctors.

The act defines "naturopathic medicine" as

"The prevention, diagnosis, and treatment of human health conditions, injury, and disease using only patient education and naturopathic therapies and therapeutic substances recognized by the Council of [sic]Naturopathic Medical Education."

However, the Council on Naturopathic Medical Education, the accrediting agency for four-year naturopathic schools, does not officially "recognize" any particular "therapies and therapeutic substances," and the meaning of this language is unclear. [2]

The Legislature specifically rejected the broader scope of practice and self-regulation naturopaths lobbied for in favor of a more limited scope of practice, regulation by the State Board of Physicians, notice to patients of the limitations of naturopathic practice, and a required collaboration/consultation agreement with an MD or DO physician. The Legislature did agree to give naturopaths a voice in their regulation by specifying that two members of a five-member Naturopathic Medicine Advisory Committee, appointed by the Board, would be naturopaths. Other members include two MD or DO physicians and a consumer member.

The Committee is to "develop and recommend to the Board regulations to carry out" the licensing act and can "provide any service and perform any function necessary" to do so. Specific tasks include evaluating the content of clinical, practical or residency requirements for licensure, as well as developing procedures for issuing licenses by reciprocity, examination standards, a code of ethics and continuing education.

In its role as a consumer protection organization and advocate for science-based medicine, the Society has researched naturopathic education, training and practice. The Society feels it can be of service to the Committee in fulfilling its role by presenting the results of this research as well as recommending specific regulations that will assist the Committee in fulfilling its statutory duties.

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[1] *Hawker* v. *N.Y.*, 170 U.S. 189, 18 S.Ct. 573, (1898)

[2] Council on Naturopathic Medical Education, http://www.cnme.org/.

This Report is divided into three sections:

1. **Section I** provides background information on naturopathic education, training and practice.

2. **Section II** presents the results of the Society's survey of Maryland naturopaths. Appendix A contains additional materials relevant to the survey. Appendix B is a list of conditions and diseases Maryland naturopaths claim they treat. Appendix C is a list of diagnostic methods used by Maryland naturopaths.

3. **Section III** addresses specific subjects of regulation and provides the Society's recommendations for regulations which we feel should be adopted as Committee recommendations to the Board of Physicians. Appendix D contains further information relevant to the Society's recommendations.

An exhaustive discussion of naturopathic education, training and practices is beyond the scope of this brief. However, the Society submits that the information contained herein is an honest representation of naturopathy as practiced in Maryland and will be of invaluable assistance in the Committee's work.

Section I
Background: Naturopathic Education, Training and Practice

A. Naturopathic Education and Training

Little is known outside of naturopathic circles about naturopathic education and training. While the American Association of Naturopathic Physicians (AANP) claims that naturopaths are "primary care" physicians who "treat all medical conditions and can provide both individual and family health care," their actual ability to do so safely and effectively remains unproven. In fact, as discussed further below, the medical literature casts doubt on the AANP's assertion. [3]

The U.S. Department of Education, which permits the Council on Naturopathic Medical Education (CNME) to accredit naturopathic schools, has not itself investigated, nor does it make any determination of, the appropriate naturopathic scope of practice. More specifically, the Department does not determine the scientific validity of what is taught in naturopathic schools nor does it determine whether any particular diagnosis or treatment students learn is evidence-based, or even scientifically plausible. The Department's main concerns in granting accrediting authority are the ability of the accrediting agency to ensure financial stability, adequate staffing, honesty in determining credit hours, due process-type protections for students and transparency.[4]

Likewise, while the law requires that a candidate for licensure pass Parts I and II of a licensing exam administered by the North American Board of Naturopathic Examiners (currently, the "NPLEX" exam), no authority independent of naturopaths has ever investigated this exam to determine if it adequately assesses whether a naturopath can safely and effectively diagnose and treat patients.

Probably the most troubling deficiency in naturopathic preparation for practice is the extremely limited clinical training naturopaths undergo in comparison to that of MDs or DOs. This difference is illustrated by a chart from the American Association of Family Physicians. [5]

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[3] Atwood KC, Naturopathy, pseudoscience, and medicine: myths and fallacies versus truth. *Medscape Gen Med.* 2004; 6(33). http://www.medscape.com/viewarticle/471156#vp_1

[4] U.S. Department of Education, Accreditation in the United States, Subpart B, http://www2.ed.gov/admins/finaid/accred/accreditation_pg13.html.

[5] AAFP, Education and Training: Family Physicians versus Naturopaths, http://www.aafp.org/dam/AAFP/documents/advocacy/workforce/gme/ES-FPvsNaturopaths-110810.pdf.

The below tables offer a side-by-side comparison of the education and training involved in becoming a family physician versus the requirements to become a naturopath.

Degrees Required and Time to Completion

	Undergraduate Degree	Entrance Exam	School	Residency	Residency Completion Time
Family Physician (MD or DO)	Standard 4-year BA/BS	Medical College Admissions Test (MCAT)	4 years	REQUIRED	3 years
Naturopath (ND or NMD)	Standard 4-year BA/BS	None Required	4 years	OPTIONAL	1 year

Medical/Professional School and Residency/Post-Graduate Hours for Completion

	Lecture Hours (Pre-Clinical Years)	Study Hours (Pre-Clinical Years)	Combined** Hours (Clinical Years)	Residency Hours	TOTAL HOURS
Family Physician	2,700	3,000	6,000	9,000 – 10,000	20,700 – 21,700
Naturopath***	1,500	1,665	2,600	535 – 1,035	5,505 – 6,485
DIFFERENCE	1,200	1,335	3,400	8,465 – 8,965	15,195 – 15,215

*Council on Naturopathic Medical Education CNME standards were used for this comparison.
**Clinical and lecture hours
***Naturopath "Lecture Hours" and "Combined Hours" are averaged across publicly-available curricula advertised on the web sites of the four CNME-accredited institutions of naturopathic study (Bastyr University, National College of Natural Medicine, Southwest College of Naturopathic Medicine, and the University of Bridgeport).

Even though naturopaths will not be allowed to practice as primary care physicians, the practicing naturopath will often see the undifferentiated patient in his or her office and may be the first contact that patient has with the health care system. Thus, the naturopath will be required to evaluate the patient, perform or order appropriate diagnostic testing, and reach an accurate diagnosis before either treating the patient or referring him or her to another health care professional. With their limited clinical experience, patients can be at risk of misdiagnosis and inappropriate treatment. In addition, it is not known how, or whether, naturopaths keep abreast of the medical literature regarding patient evaluation, proper diagnosis or when to refer.

The Society feels this lack of information about naturopathic education and training will hamper the Committee in its ability to perform its statutory duties in two ways. First, as noted above, the Committee is charged with the responsibility of recommending procedures for issuing licenses to those who apply for license by reciprocity, developing the content of clinical and practical requirements for licensure, and developing and recommending examination standards and continuing education requirements.

Second, the Committee is charged, more generally, with developing and recommending regulations to carry out the licensing law. Yet, the entire scope of naturopathic practice is defined by one important limitation imposed by the Legislature: any diagnostic method or treatment employed by a naturopath must be *"consistent with naturopathic education and training and competence demonstrated by passing the [NPLEX]."*

It will be extremely difficult for the Committee to appropriately advise the Board on naturopathic regulation without fully understanding exactly what the content of that education and training is or what level of competence the NPLEX in fact demonstrates. Both

the U. S. Medical Licensing Examination [6] and the National Board of Osteopathic Medical Examiners [7] offer a plethora of information to the public about the medical and osteopathic licensing exams. In contrast, there is virtually no publicly available information about the NPLEX on the website of the North American Board of Naturopathic Examiners. [8]

To remedy this, the Society recommends that the Committee investigate naturopathic education and training so it can adequately determine the scope and content of the regulations it will recommend to the Board. The Society respectfully suggests that, while the naturopathic members of the Committee can provide some of this information, they should not be the sole source nor should conclusory assertions, as opposed to actual factual information, be accepted as the final word.

The Society suggests, at a minimum, that the Committee review the curricula, syllabi of courses, and textbooks used (including which portions of those texts are actually taught if not the entire textbook), as well as the content of the NPLEX exams. Most importantly, the Committee should determine the exact content of clinical training: the number of patients naturopathic students see and the conditions presented by the patients, what diagnostic methods and therapies they use, how the students are evaluated, patient outcomes, and the like. MD or DO Committee members will be aware of, and have access to further information regarding, the education and training of MDs and DOs and can use this as a point of comparison. This groundwork will be invaluable to both the Committee and the the Board of Physicians as without it neither the Committee nor the Board can adequately fulfill their statutory duty to protect the public health, safety and welfare via regulation.

B. Naturopathic practice

Naturopaths claim that they find and treat the underlying ""cause" of disease, while medical doctors treat only the "symptoms" of disease. As well, they diagnose patients with diseases and conditions which will be unfamiliar to physicians. [9] Typical of these is candidiasis, which is diagnosed based on vague symptoms and without any clinical symptoms or laboratory evidence of candidemia. [10] Naturopaths also diagnose subclinical food "sensitivities." "Adrenal fatigue" is another common diagnosis, again based on vague symptoms like fatigue. Other treatments include severely restrictive diets, such as those which require the elimination of all products containing gluten in the absence of any objective evidence of celiac disease or gluten intolerance. [11] Prescription of dietary supplements and herbs, often sold to the

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[6] USMLE, http://www.usmle.org.
[7] NBOME, http://www.nbome.org.
[8] NABNE, https://www.nabne.org.
[9] Caufield T, et al., Supported by Science?: What Canadian Naturopaths Advertise to the Public. *Allergy Asthma Clin Immunol.* 2011 Sep 15; 7:14.
[10] Elder CR, Integrating Naturopathy: Can We Move Forward? *Perm J*, 2013 Fall; 17(4): 80-83.
[11] Atwood, KC. Naturopathy: A Critical Appraisal. *Medscape Gen Med*. 2003; 5(4). http://www.medscape.com/viewarticle/465994_2

patient by the naturopath, is a mainstay of naturopathic practice despite the dearth of evidence that they are safe or effective for any disease or condition. [12]

Naturopaths are traditionally anti-vaccination, although this ideology is sometimes obfuscated by terms like parental "informed choices" and promotion of "vaccination safety." [13] This opposition is well documented in the medical literature.

- Children were significantly less likely to receive each of the four recommended vaccinations if they saw a naturopathic physician. Children aged 1–17 years were significantly more likely to be diagnosed with a vaccine preventable disease if they received naturopathic care.[14]
- A survey of Massachusetts naturopaths and homeopaths found that most did not recommend vaccination.[15]
- A survey of children's records from an Ontario naturopathic clinic identified 8.9% of children had not been vaccinated. [16]
- Consultation with a naturopath was associated with anti-vaccination attitudes among mothers of pediatric patients.[17]
- Consultation with a naturopath was found to have an independent inverse association with annual flu shots among women in contact with young children. [18]

This ideology appears to originate with the naturopathic schools themselves, which should be taken into account in determining the educational and clinical requirements for practice in Maryland.[19]

- Surveys of students attending the CNME-accredited Canadian College of Naturopathic Medicine found that only 12.8% of the respondents would advise parents that their children receive all recommended vaccinations and that anti-vaccination attitudes *increased* in the last two years of school.[20]

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[12] American College of Medical Toxicology, Choosing Wisely: Five Things Physicians and Patients Should Question, http://www.acmt.net/Choosing_Wisely.html.

[13] Gavura S, Naturopathy vs. Science: Vaccination Edition, Science-Based Medicine, http://www.sciencebasedmedicine.org/naturopathy-vs-science-vaccination-edition/

[14] Downey L, et al, Pediatric Vaccination and Vaccine-Preventable Disease Acquisition: Associations with Care by Complementary and Alternative Medicine Providers. *Matern Child Health J,* 2010 Nov; 14(6): 922–930.

[15] Lee AC, et al., Homeopathy and naturopathy: Practice characteristics and pediatric care. *Arch Pediatr Adolesc Med,* 2000 Jan; 154(1): 75-80.

[16] Wilson K, et al., Characteristics of Pediatric Patients Attending a Naturopathic College Clinic in Canada. *Pediatrics,* 2005 Mar; 115(3): e338-e340.

[17] Benin J, et al., Qualitative analysis of mothers' decision-making about vaccines for infants: the importance of trust. *Pediatrics,* 2006 May; 117(5): 1532-41.

[18] Chambers CT, et al., Consultation with health care professionals and influenza immunization among women in contact with young children. *Canadian J Pub Health,* 2010 Jan/Feb; 101(1):15-19.

[19] Busse J, et al., Attitudes towards vaccination among chiropractic and naturopathic students. *Vaccine,* 2008; 26: 6237-43.

[20] Wilson K, et al., A survey of attitudes towards paediatric vaccinations amongst Canadian naturopathic students. *Vaccine* 2004; 22(3-4): 329-34.

- A survey of the CNME-accredited National College of Natural Medicine students found that only 26% planned on regularly advising vaccinations for their patients and 96% would recommend a schedule different from the standard CDC-ACIP schedule.[21]

In addition to failure to recommend immunization, what little data there is in the medical literature suggests that utilizing a naturopath is associated with worse care: less cancer screening, mammography and *Chlamydia* screening[22] and use of unproven treatments in management of cervical atypia.[23] Other articles suggest sub-standard care as well.[24] [25] [26]

Positive studies of naturopathic care often cited by naturopaths are of limited value. First, in each instance, the naturopaths were providing only adjunctive care to patients that had been diagnosed by, and were being managed by, physicians. Nothing in Maryland's licensing law requires that naturopaths limit themselves in this manner. Second, because naturopathy does not generally follow evidence-based standardized protocols, there is no assurance that this care is typical of practicing naturopaths.

Specific naturopathic diagnostic methods and treatments described below. In Section II, **you will see at least one example of each employed by an MDNA-member naturopath.**

Homeopathy

Naturopaths are required to study homeopathy in naturopathic school. Homeopathy is a 200 year-old, pre-scientific set of beliefs about medicine known to be at odds with basic laws of chemistry, physics, and biology. It is based mainly on two tenets: *like cures like*, which holds that the correct remedy for a patient is a substance that, when given to a healthy individual, produces "symptoms" similar to those of the patient; and *potentization*, which holds that serial dilutions and succussions (shakings) render a remedy increasingly potent, even well past the point at which any of the original substance exists in the preparation.[27]

Despite its implausibility, hundreds of clinical trials of homeopathy have been conducted. In 2013, the Australian government conducted an exhaustive review of the evidence and concluded "the available evidence is not compelling and fails to demonstrate that

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[21] Ali, et al., Vaccination attitudes and education in naturopathic medicine students. *J Alter Comp Med* 2014 May: A115.
[22] Downey L; et al., Preventive screening of women who use complementary medicine and alternative medicine providers. *J Women's Health* 2009; 18(8): 1133-43.
[23] Leaver CA, et al., Naturopathic management of females with cervical atypia: a Delphi process to explore current practice. *Integr Med Insights* 2013; 8: 9-17.
[24] Gavura S, Naturopathy vs. Science: Prenatal Vitamins, *Science-Based Medicine*, http://www.sciencebasedmedicine.org/naturopathy-vs-science-prenatal-vitamins/.
[25] Gavura S, Naturopathy vs. Science: Allergy Edition, *Science-Based Medicine*, http://www.sciencebasedmedicine.org/naturopathy-vs-science-allergy-edition/.
[26] Hall H, Misguided naturopath claims to have cured cervical dysplasia, *Science-Based Medicine*, http://www.sciencebasedmedicine.org/misguided-naturopath-claims-to-have-cured-cervical-dysplasia/.
[27] "Homeopathy," *The Skeptic's Dictionary*, http://skepdic.com/homeo.html.

homeopathy is an effective treatment for any of the reported clinical conditions in humans."[28] This is accord with earlier reviews of the evidence.[29] [30]

Biotherapeutic drainage

A mélange of homeopathic remedies designed to eliminate "toxins" from the body.[31] According to one naturopathic source, a biotherapeutic product line, called UNDA numbers, includes different homeopathic formulae containing a combination of certain plants and/or minerals. Plant sources are alleged to have a specific effect on particular organs or tissues. Mineral sources supposedly "catalyze the detoxification process within cells."[32] "Biotherapeutic drainage" is wholly implausible and, not surprisingly, there is no evidence that it is effective for anything.

"Detoxification"

Many naturopaths maintain that patient health is adversely affected by ubiquitous, often unidentified, "toxins" and that these "toxins" can be removed from the body through a process called "detoxification," which can take various forms. There does not seem to be a standardized method for determining what is, or is not, a "toxin." Nor is there a standard protocol for determining the purported location of the "toxins" in the patient's body, when any particular "toxin" reaches a level that requires removal, or a validated method for determining removal has been successful. Diagnosis is apparently based on the patient's exhibiting vague symptoms like fatigue or gastrointestinal upset. Methods of alleged "detoxification" include colonic hydrotherapy, which is specifically excluded from naturopathic practice by the licensing act, taking dietary supplements, which naturopaths are allowed to prescribe and which they often sell to patients, and special diets. [33]

Cranial-sacral/Craniosacral therapy

This "therapy" is based on the anatomically impossible concept that the therapist can detect a "craniosacral rhythm" in the cranium, sacrum, cerebrospinal fluid and membranes enveloping the craniosacral system. Therapists claim that maintaining proper "rhythm" is essential to good health and that they can measure this "rhythm" with their hands. The therapist purports to manipulate the cranium and sacrum to restore proper functioning, which

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[28] National Health and Medical Research Council (NHMRC) (Australia), Effectiveness of Homeopathy for Clinical Conditions: Evaluation of the Evidence (2013), http://www.nhmrc.gov.au/_files_nhmrc/file/your_health/complementary_medicines/nhmrc_homeopathy_overview_report_october_2013_140407.pdf.

[29] House of Commons (United Kingdom), Evidence Check 2: Fourth Report of Session (2009-2010) http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf.

[30] Ernst E, Homeopathy: what does the "best" evidence tell us? *Med J Aust*, 2010 Apr; 192(8):458-60.

[31] Gorski D, "Naturopathy and Science," *Science-Based Medicine*, http://www.sciencebasedmedicine.org/naturopathy-and-science/.

[32] Bottom Line Publications, "Biotherapeutic drainage for your digestive woes." http://www.bottomlinepublications.com/content/article/health-a-healing/biotherapeutic-drainage-helps-your-drainage-problems.

[33] "Detoxification," *The Skeptic's Dictionary*, http://www.skepdic.com/detox.html.

is purported to relieve pain and address other ailments. While the treatments can be relaxing, there is no evidence that craniosacral therapy has any effect beyond placebo.[34]

Bio-identical hormones

"Bio-identical hormone" is a marketing, not a medical, term. The FDA has evaluated claims that bio-identical hormones are safer and more effective than pharmaceutical hormone replacement therapies and claims that they can prevent or cure certain diseases. It also evaluated claims that bio-identical hormones can be individualized based on saliva testing. The FDA found no evidence to support these claims.[35] *The Medical Letter on Drugs and Therapeutics* warns that patients should be discouraged from taking them.[36]

Alkaline Diets

Some alternative practitioners claim that when the body is too acidic the risk of disease is increased. They therefore advocate a diet purported to alter the body's pH to make it more alkaline. In fact, because the body's natural mechanisms strive to maintain its pH in a normal range, if the pH shifts outside this range and becomes too acidic or too alkaline, the body automatically corrects itself to bring things back to normal. Thus, it is almost impossible to maintain a high alkaline pH for very long. There are no human studies supporting the notion that a high alkaline pH will prevent or cure any disease.[37]

Electrodermal screening

This unvalidated diagnostic method involves the use of a galvanometer to measure the electrical resistance on the skin's surface. The galvanometer is usually hooked up to software programs that purportedly diagnose conditions such as allergies and recommend treatments, such as dietary supplements.[38]

MELISA testing

There is evidence that this test can detect sensitivity to certain metals. However, naturopaths may be employing it beyond its validated purposes and the Committee should further investigate this.[39]

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[34] "Craniosacral Therapy," *The Skeptic's Dictionary,* http://www.skepdic.com/craniosacral.html.
[35] FDA, Bio-Identicals: Sorting Myth from Facts. http://www.fda.gov/forconsumers/consumerupdates/ucm049311.htm.
[36] *The Medical Letter on Drugs and Therapeutics*, "Bioidentical Hormones," Issue 1339, Vol. 52, pages 43-44, May 31, 2010.
[37] Aetna InteliHealth, Alkaline Diets and Cancer: Fact or Fiction? https://www.intelihealth.com/article/alkaline-diets-and-cancer-fact-or-fiction.
[38] American Cancer Society, Electrodermal Screening," http://www.cancer.org/treatment/treatmentsandsideeffects/complementaryandalternativemedicine/manualhealingandphysicaltouch/electrodermal-screening.
[39] American Academy of Allergy, Asthma & Immunology, "Lymphocyte Transformation Testing for Contact Dermatitis to Metal," http://www.aaaai.org/ask-the-expert/lymphocyte-transformation-testing.aspx.

Society for Science-Based Medicine

Autonomic Response Testing (ART)

An unvalidated and implausible diagnostic method positing that when a substance is placed over an area of the patient's body that contains this identical substance, a stress signal is elicited, which makes a strong indicator muscle go weak. ART purports to diagnose allergies to foods and other substances.[40] It is apparently a mechanized version of an equally implausible and invalidated diagnostic method called "applied kinesiology."[41]

Far-infrared saunas

These devices use light to produce heat instead and warm the body[42] and can have side effects if used improperly.[43] Naturopaths claim they are useful for "detoxification" and weight loss. As with any sauna, weight loss is due to water loss and is temporary.

Chelation

Chelation therapy is a proven treatment for heavy metal poisoning and it is rarely necessary for any legitimate medical purpose. However, it is often used by alternative practitioners who diagnose chronic metal poisoning based on a poorly documented environmental exposure, vague clinical findings, and inappropriate diagnostic testing. (See, "DMSA Challenge Protocol," below.) The results are incorrectly presented to the patient as evidence of metal "toxicity," leading to expensive chelation treatments. In 2009, the American College of Medical Toxicologists issued a statement condemning this practice and saying that it should be abandoned.[44]

Dietary supplements are also marketed for the purpose of chelation. The FDA has sent warning letters to several marketers telling them to stop advertising these supplements as treatment for serious diseases. The FDA warned consumers that all of the approved chelation agents require a prescription and can't be purchased without one. The FDA also found that some of the chelation supplements sold without prescriptions actually contain dangerous prescription drugs.[45]

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[40] Gorski D, Your Friday Dose of Woo-2, Respectful Insolence, http://scienceblogs.com/insolence/2010/03/26/your-friday-dose-of-woo-2/.

[41] "Applied kinesiology," Wikipedia, http://en.wikipedia.org/wiki/Applied_kinesiology.

[42] Mayo Clinic, "What is an infrared sauna?" http://www.mayoclinic.org/healthy-living/consumer-health/expert-answers/infrared-sauna/faq-20057954.

[43] Health Physics Society, "Ask the Experts," http://hps.org/publicinformation/ate/q10677.html.

[44] American College of Medical Toxicology, "Medical Toxicologists Determine Chelation Therapy Rarely Necessary" (Mar 2012). http://www.acmt.net/cgi/page.cgi/zine_service.html?aid=4509&zine=show.

[45] American Cancer Society, "Chelation Therapy," http://www.cancer.org/treatment/treatmentsandsideeffects/complementaryandalternativemedicine/pharmacologicalandbiologicaltreatment/chelation-therapy.

DMSA Challenge Protocol

"Urine mobilization test," "challenge test," and "provoked urine test" are all terms used to describe the administration of a chelating agent to a person prior to collection of urine to test for metals. The American College of Medical Toxicology has issued a position statement that "post-challenge urinary metal testing has not been scientifically validated, has no demonstrated benefit, and may be harmful when applied in the assessment and treatment of patients in whom there is concern for metal poisoning."[46] Other professional and government organizations recommend against the use of provoked urine testing as well. Current evidence does not support the use of DMPS, DMSA (dimercaptosuccinic acid), or other chelation challenge tests for the diagnosis of metal toxicity. Since there are no established reference ranges for provoked urine samples in healthy subjects, no reliable evidence to support a diagnostic value for the tests, and potential harm, these tests should not be utilized.[47]

Salivary Hormone Testing

According to the FDA, "some compounding pharmacies and other promoters of 'bioidentical hormone replacement therapy' claim that estrogen levels in a person's saliva can be tested by practitioners to estimate the amount of hormone a person needs. This is used to "customize" the hormone therapy for individual patients. There is no scientific basis for using saliva testing to adjust hormone levels."[48]

Blood Nutrition Analysis

There are several different names and methods for this unvalidated lab analysis. All claim to reveal deficiencies not apparent in standard lab analysis of blood and are used as a rationale for prescribing dietary supplements. [49]

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[46] American College of Medical Toxicology, "Position Statement on Post-Chelator Challenge Urinary Metal Testing (2009). http://www.acmt.net/cgi/page.cgi?aid=2999&_id=462&zine=show.

[47] Ruha AM, Recommendations for provoked challenge urine testing. *J Med Toxicol.* 2013 Dec; 9(4):318-25.

[48] FDA, Compounded Menopausal Hormone Therapy Questions and Answers, http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm183088.htm.

[49] See, e.g., Life Extension: Foundation for a Longer Life, http://www.lef.org/Vitamins-Supplements/Blood-Tests/Nutrient-Testing; Science-Based Nutrition, http://www.sciencebasednutrition.com; NBA Research Group, http://nbaresearchgroup.com

Section II
Survey of Maryland Naturopathic Doctors

A. Introduction

During the month of September, 2014, the Society conducted an informal survey of Maryland naturopaths. The survey reviewed the website of each member of the Maryland Naturopathic Doctors Association who listed a website on the MDNA's "Find a Doctor" page, as well as the MNDA itself. We found that *all* members surveyed, save one practicing under physician supervision, offered diagnoses and treatments on their websites that are not supported by adequate evidence of safety and effectiveness and should not be considered an acceptable part of standard patient care. The MNDA offers continuing education courses that endorse such practices. As noted earlier, these findings are in accord with similar reports in the literature. [50] [51] [52] A list of these naturopaths and a sample of the claims made appears below.

All of the surveyed MNDA members graduated from an accredited naturopathic school and are presumably eligible for licensing in Maryland. (One practices in Delaware, where naturopaths are not licensed, and would be eligible if she established a residence in Maryland.)

As noted, the licensing law will permit naturopaths to treat any patient will any condition or disease. The Society found that Maryland naturopaths claim they treat a vast array of diseases and conditions that appear to be beyond their limited education and training. In medicine, many of these diseases and conditions require specialty training before the physician is considered competent to manage them. Yet the individual naturopath will claim he or she treats conditions that would subsume several medical specialties. Some of these diseases are not recognized in medicine at all. Other medical conditions are never mentioned. The diseases and conditions which MDNA members claim they treat are listed in Appendix B.

Naturopaths will also be permitted to

> *(1) Order and perform physical and laboratory examinations for diagnostic purposes, including phlebotomy, clinical laboratory tests, orificial examinations, electrocardiograms with overread by a cardiologist, and physiological function tests;*
>
> *(2) Order diagnostic imaging studies and interpret the reports of diagnostic imaging studies.*

Appendix C contains a list of diagnostic methods utilized by MDNA-member naturopaths, according to their websites. Some of these are standard lab tests, but others are unvalidated diagnostic methods and standard tests which appear to be employed in a non-standard manner.

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[50] Caufiled, op. cit.
[51] Elder, op. cit.
[52] Atwood, op. cit.

B. Excerpts from Maryland naturopath websites

Maryland Naturopathic Doctors Association

Continuing Education
http://www.marylandnd.org/continuing-education/

"The Top Five Homeopathic Remedies in the Treatment of Depression featuring Drs. Amy Rothenberg and Paul Herscu
Date: July 22, 2014: Drs. Herscu and Rothenberg are 1986 graduates of the National College of Naturopathic Medicine, and each have nearly 3 decades of clinical and classroom experience. They are the founders of the New England School of Homeopathy, and have developed the Cycles and Segments style of homeopathy."

"Eric Yarnell, ND 'Naturopathic Treatment of Chronic Kidney Disease' For 2 CEUs Oct. 6, 2014"[53]

Practicing naturopaths

Donna Acree ND
www.doctordonna.net

Recommendations for depression: raw vegetable juicing, gluten-free diet, various dietary supplements, herbs, detoxification, drinking only fluoride-free water, using fluoride-free toothpaste, reducing or eliminating sugar.[54]

A copy of Acree's "Nutritional Assessment Questionnaire" is included in Appendix A.

Nazirahk Amen, ND
http://wisdompath.net/

"Acupuncture and Chinese herbs can treat just about any and everything. Except it doesn't treat cancer, only patients with cancer."

Angela Duncan Diop, ND
www.naturedrs-detox-info.com/

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[53] Yarnell's website: http://www.dryarnell.com/. A brief review of the website indicates he employs treatments that do not have a sufficient evidentiary basis (see, e.g, http://www.dryarnell.com/kidney-stones-and-naturopathic-medicine-2/#more-500), and apparently does not understand the concept of evidence-based medicine (see, http://www.dryarnell.com/artemisinin-and-prostate-cancer/).

[54] From an interview of Acree in the *Frederick [MD] News Post*, posted on her website, http://www.fredericknewspost.com/news/health/holistic-approach-for-depression-and-anxiety/article_da2012c8-7f7f-5647-855d-8da826ee9714.html.

"The basic idea of a detox is to reduce the amount of toxins in your body so that your body can function at its best."

Claims detoxification will benefit "most people;" benefits include improving organ function, immune function, sleep, and digestion, and increased energy, natural weight loss, better stress management, and a "sexier you." Offers numerous detoxification regimens.

Paul Faust, ND
http://chesapeakenatrual health.com

Sells herbal and other dietary supplements to patients, including herbal remedies for children.

Autumn Frandsen, ND
Erin Kenney, ND
Michelle Ridell, ND
www.velisetotalhealth.com

Allergy Elimination Program: *"With a combination of Electrodermal screening, blood testing for food allergies and environmental allergens, and MELISA testing for metals, the patient's allergic response can be identified while a unique blend of antigenic serums are prepared to desensitize the patients."*

FAR Infrared sauna: *"A powerful detoxification and weight loss tool. It penetrates deeper into the tissues than a stream sauna and 20 minutes in it will detoxify as well as I hour of exercise."*

Kim D. Furtado, ND
www.DrKimFurtado.com

Under "Naturopathic Services," the following are offered:

"Detoxification and heavy metals chelation therapy: targeted use of substances and herbs to remove environmental toxins associated with various chronic diseases and symptoms."

"Salivary Hormone Testing: specialized testing panels to assess hormonal imbalances, stress response, and chronic disease risks."

A copy of the "DMSA Challenge Protocol" available on her website is included in Appendix A.

Amber Golshani, ND
http://drambergolshani.com

Please see Appendix A for an example of her "Instructions for Homeopathic Intake Form" downloaded from her website.

Offers "Fatigue-Proof Body Blend," an herbal concoction described as *"natural energy boosters and adaptogenic herbs . . . designed to work with your body to build real, sustainable and balanced energy."*

Veronica Haydeuk, ND
http://secondnaturehealth.com

Claims that *"when the body is more acidic than alkaline it can lead to a progression of chronic diseases, decreased immunity and in general poor health."* Advises that one should *"consume 20% of your diet with acidic foods, 80% with alkalizing foods."*

Describes symptoms of, and diagnostic methods for, "heavy metals toxicity," which is addressed with "detoxification." Alleged sources of heavy metals include dental fillings, aluminum from antacids, and non-organic produce and meat.

Advises use of, among other things, for PMS: eliminating refined sugars, coffee and alcohol, using glandular products "like ovary and anterior pituitary," and "uterine tonic to balance the hormones."

Stacy Kargman, ND
www.marylandnaturalhealthcenter.com

"Many medical conditions can be treated effectively with foods and nutritional supplements as they can by any other means, but with fewer complications and side effects."

"Homeopathic medicine" is "a powerful system of medicine" that "uses highly diluted substances to cure illness" and is "very safe for children, who respond particularly well."

"Many plant substances are powerful medicines, having advantages over pharmaceutical drugs."

Duffy J. MacKay, ND
Keri Marshall, ND
www.makainaturopathic.com

Clinical services include:

Constitutional hydrotherapy: *"strengthens the immune system and assists the body in detoxification."*

Biotherapeutic drainage: *"a unique form of homeopathy that decreases inflammation and promotes detoxification on a cellular level to stimulate the body's self-healing response."*

Janene E. Martin, ND
http://sunlightnaturalhealth.com

Describes homeopathy *as "an effective and scientific system of healing which assists the natural tendency of the body to heal itself. It recognizes that all symptoms of ill health are expressions of disharmony within the whole person and that it is the patient who needs treatment, not the disease. . . . the homeopathic remedy acts as a stimulus to the curative powers of the body. . . If you develop a runny cold, rash or some form of discharge, this is*

probably the remedy cleansing the body. . . they are an important part of the healing process."

Employs "blood nutrition analysis," which purports to "adequately assess your own physiology."

Kristaps Paddock, ND
www.drpaddock.com

"Homeopathy is a system of natural medicine [that] is used to treat a range of illnesses, from simple coughs to chronic conditions. It is known for . . . being able to alleviate symptoms where other treatments have been ineffective."

Kevin Passero, ND
www.greenhealingwellness.com

"Natural treatment of hypothyroidism" includes *"herbal therapy, vitamin/nutrient therapy, homeopathy and prescriptive thyroid hormones including natural glandular extracts and compounded thyroid hormone."* Criticizes standard medical diagnosis and treatment of thyroid disease.

Prescribes "bio-identical hormones" and claims that they do not have the same risks as prescription-only HRT and that their use can *"reduce risk related to certain conditions including bone loss and even certain forms of cancer."*

Stephany Porter, ND
www.bodhiclinic.com

Claims a specialty in *"cancer, sugar imbalances, women's health and gastroenterology."* Treatments include homeopathy, botanicals and detoxification.

Emily Telfair, ND
http://dremilytelfair.com

Advertises "Fall Detox . . . adapted from Thorne's MediClear Detox Plan." According to the Thorne MediClear Detox website, *"The MediClear Plus program is designed to do two things: first, to decrease your exposure to toxins and allergens, and second, to help your body cleanse." It is a "formula that blends a combination of rice and pea protein with a full complement of vitamins, minerals, amino acids, botanicals, probiotics, and other nutrients for the enhancement of detoxification."*[55]

"Detox add-on kits" are also offered on Telfair's website, which are "additional supplements to further enhance your detox experience." These include

"Belly Boost: To help aide digestion for those with sensitive stomachs.
"Liver Love: To help clear toxins while protecting the liver.

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[55] https://thorne.com/practitioners/resources/articles/mediclear-plus.

Detox Reviver: To help reduce fatigue & headache while eliminating caffeine, sugar and alcohol."

Section III

Recommendations for Regulations

Sections I and II demonstrate that this Committee must recommend, and the Maryland Board of Physicians must enact, stringent regulations to ensure that the public is not subjected to unvalidated diagnostic methods, treatments that do not have sufficient evidence of safety and effectiveness or practitioners whose education and training do not allow them to safely practice. Many regulations are already set forth in the licensing law, but the Committee has the authority to recommend others. The Society further recommends that Maryland regulations governing physicians be used as a guide. In particular, Sec. 10.32.01.12, Code of Maryland Regulations, governing advertising, should be adopted in full.

A. Naturopathic Education and Training

While the Legislature set graduation from a school accredited by the CNME and passing the NPLEX as a *minimum requirement*, the fact that a naturopath has fulfilled these requirements is of limited significance in determining whether patients will be protected from financial or physical harm due to a lack of appropriate education and training.

Importantly, there is nothing in the licensing law to indicate that graduating from school and passing the NPLEX was intended to grant *carte blanche* to naturopaths, prevent further inquiry into the content of that education and training, or set more specific requirements. Indeed, legislative purposes mentioned in the act include maintaining standards in the delivery of naturopathic services to the public and providing a means of identifying qualified naturopathic doctors. The Legislature clearly granted the Board, and by logical extension, the Committee, the authority to look beyond this minimal requirement in regulating naturopaths and to establish (or, in the Committee's case, recommend) regulations that go beyond those requirements.

Although it will be better able to formulate specific regulations after further study of their education and training, the Society believes that sufficient information is already available to support the following:

1. A two-year probationary period for all naturopaths who will begin practice in Maryland directly from naturopathic school. Continuing education beyond that normally required, testing and more direct supervision from a collaborating physician (a subject addressed below) should be required during this period.
2. Consideration of additional testing beyond NPLEX on specific subjects such as evidence-based diagnostic methods and treatments.

B. Continuing Education

It is unfortunately obvious from information already presented that naturopaths require additional education and training in order to practice effectively and that current offerings from the MNDA are insufficient for the task. Fortunately, the Committee is specifically empowered to recommend regulations regarding continuing education.

1. No fewer than **30 hours of continuing education should be required annually**, or 60 hours biennially, as is required in California.[56] All continuing education courses should be conducted by the Board of Physicians, or, if provided by an outside source, approved by the Board. They should meet the same standards as those required by the Board for physicians.

2. **CE subjects** should include public health and vaccination, evidence-based medicine, appropriate diagnostic testing, pharmacognosy, and evidence-based courses on homeopathy, "detoxification," and ethics, including informed consent.

C. Practice

As is the case with naturopathic education, there is no indication that the Maryland Legislature intended to grant *carte blanche* to naturopaths to continue with their current practices. Indeed, doing so would defeat the very purpose of this legislation, which is to protect the public health, safety and welfare. Significantly, the Legislature granted the Board of Physicians the authority to regulate naturopaths and amended the original licensing bill to reject self-regulation. The licensing statute itself explicitly rejects naturopathic standards as the sole arbiter of the appropriateness of patient care. A naturopath is subject to discipline if he or she

"Engages in an act or omission that does not meet generally accepted standards of practice of naturopathic medicine ***or of the safe care of patients, whether or not actual injury to a patient is established.***"

1. It is imperative that the Committee recommend regulations that will **prevent the use of discredited diagnostic methods, and diagnoses and treatments**, such as chronic candidiasis, adrenal fatigue and "detoxification" unless and until naturopaths can come forth with convincing evidence of their validity. Some of these prohibited methods suggest themselves in the excerpts from Maryland naturopathic websites.

2. Homeopathy is specifically permitted by the licensing law. However, a patient's right to informed consent, as defined by Maryland law and discussed below, requires that all patients be informed of the lack of evidence of effectiveness for all homeopathic remedies. Thus, a regulation stating that **"Naturopaths should not prescribe, dispense or administer homeopathic remedies without informing the patient that there is no reliable evidence that homeopathy is effective for any disease or condition"** should be adopted. If naturopaths wish to revise the regulation to permit the use of homeopathic remedies in certain situations, they should be required to present substantial competent evidence that it is safe and effective for the intended purpose.

3. The Declaration of Helsinki requires that "Medical research involving human subjects **must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information** . . ." No human diagnostic method or treatment should fall below this standard. At the very

[56] California Bus. & Prof. Code, Sec. 3635(a).

least, the Committee should recommend a regulation stating that all naturopathic diagnoses and treatments "conform to generally accepted scientific principles."

D. **Collaboration and consultation agreement**

The licensing act requires that all naturopaths have a "collaboration and consultation agreement" with a licensed physician. Fortunately, Missouri recently passed a law which can serve as a template for this requirement. The law, Senate Bill 716 (not yet codified) will allow medical school graduates who have not completed a residency to practice in underserved areas. They will be able to call themselves "doctor" but will be licensed as "assistant physicians" with significant limitations on their practice. (Missouri does not license naturopaths.) To be eligible for assistant physician licensing, a medical school graduate (including graduates of osteopathic medical schools) must successfully complete the first two parts of the U.S. Medical Licensing Exam no more than 3 years after graduation. They must clearly identify themselves as assistant physicians, including an ID badge, and may use the title "doctor."

All must have an "assistant physician *collaborative practice arrangement*" with a fully licensed physician, who can oversee no more than 3 assistant physicians. These arrangements must be written agreements, jointly agreed-upon protocols or standing orders. The assistant physician must practice in the same physical location as the physician for 30 days. After that, they must be within "geographic proximity" of one another. The assistant physician must submit at least 10% of his charts to the collaborating physician every 14 days for review. The collaborating physician "is responsible at all times for the oversight of the activities and accepts responsibility for primary services rendered by the assistant physician." However, as long as the licensed physicians follow the procedures set forth in the law, they won't be held vicariously liable.

While not entirely applicable to Maryland's situation, we believe the Committee should recommend similar provisions for naturopath/physician collaboration and consultation, including chart review, geographic proximity, identification requirements, and written agreements, jointly agreed-upon protocols or standing orders. We suggest the Committee contact the Missouri Board of Registration for the Healing Arts for further information, as the Board is charged with developing regulations to implement the assistant physician licensing law.

E. Informed consent.

In Maryland,

"[I]nformed consent is predicated on the notion that a patient has a right to exercise control over her own body. Because a patient, however, generally does not possess the expertise necessary to understand the consequences of submitting to a particular medical treatment, she, necessarily, relies on the physician for such information. Accordingly, the doctrine of informed consent imposes on a physician **a duty to disclose material information that 'a physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure,' including 'the nature of the ailment, the nature of the proposed treatment, the probability of**

success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences associated with such treatment.'"

Shannon v. Fusco, 438 Md. 24, 89 A.3d 1156 (2014) (citations omitted, emphasis added).

Of course, legally and ethically, naturopaths will be required to employ informed consent even if there is no regulation requiring that they do so. However, given the apparently widespread use of methods without a sufficient basis in evidence, the Society believes a specific regulation setting forth the elements of informed consent required in Maryland is appropriate. In addition, the consent should be in writing and applied to each and every diagnostic method and treatment for every patient. Blanket consents signed before the patient is examined should not be allowed.

F. Vaccination

One of the most disturbing aspects of naturopathic care is the anti-vaccination ideology of naturopathy. *Vaccination is excluded from the naturopathic scope of practice in Maryland.* To insure that patients receive evidence-based advice regarding immunization, the Society recommends a regulation stating that **naturopaths must tell patients that vaccination is outside their scope of practice and must refer any inquiries regarding vaccination to the patient's primary care physician. Nor should they be allowed to give advice contrary to other evidence-based public health practices**, like fluoridation of public water supplies and supplemental fluoride, as in toothpaste.

G. Disclosure

The licensing law requires that naturopathic patients sign a consent form stating that the naturopath's practice of naturopathic medicine is limited to the scope of practice identified in the law. The Society believes that additional disclosures are required to ensure that patients fully understand the limitations of naturopathic practice, including the following:

1. Maryland does **not license naturopaths as primary care providers** and the naturopath is not responsible for the overall medical care of any patients. Naturopathic care is intended only **as an adjunct to, and not a substitute for, medical care from a physician** or allied health practitioner practicing under the supervision of a physician. Patients are **urged to have a primary care MD or DO** physician and to have all specialty care provided by a properly credentialed MD or DO specialist.

2. Naturopaths are **not permitted to practice** chiropractic, acupuncture or psychology without a maintaining a separate license as such.

3. Information about the **collaboration/consultation agreement** between the naturopath and an MD/DO physician, including his or her contact information and the **right of the patient to have any naturopathic advice reviewed by the consulting physician or the patient's primary care or specialty physician.** Patients should be advised to **keep their physicians informed** of all naturopathic diagnoses and treatments.

4. The **U.S. Food and Drug Administration has not evaluated or approved any dietary supplements or herbal and homeopathic remedies**, for safety or effectiveness.

5. Naturopaths are regulated by the Maryland Board of Physicians and instructions on **how to file a complaint** against a naturopath.

6. The **right to informed consent** as to each and every diagnostic procedure and treatment employed and that blanket consents are not appropriate.

7. Naturopaths are **not licensed to prescribe drugs or to advise patients regarding prescription drugs** beyond possible dietary supplement/herb – prescription drug interactions. All questions regarding prescription medications should be directed to the prescribing physicians or to the patient's primary care physician.

8. Naturopaths are not authorized to advise patients to **alter or amend advice from the patient's physician or to advise patients regarding health matters that are outside the scope of naturopathic medical practice**, including immunization. All questions regarding such matters should be referred to the patient's physician.

9. Patients should be advised of their **right to copies of all naturopathic medical records** and to request that copies be sent to their physicians, subject to the payment of reasonable copying costs.

10. Patients should be told of their right to purchase any product from sources other than the naturopath prescribing them. They should also be given information on the USP Dietary Supplement Verification Program [57] so that patients can identify dietary supplements meeting the USP's requirements when shopping.

H. Medical Records

The licensing law requires naturopaths to "keep written medical records justifying the course of treatment of a patient." In Colorado, where a naturopathic registration (not licensing) act was passed last year, regulations spell out what those medical records must include. The regulations also cover retention of records after retirement and destruction of records. A copy of the regulation is attached as a part of Appendix D. The Society recommends that a similar regulation be enacted in Maryland covering these subjects, adjusted, if necessary, to this state's requirements for physician retention and destruction of records.

I. Malpractice Insurance

Colorado's naturopathic registration act requires naturopaths to **maintain liability insurance** in an amount not less than one million dollars. [58] It also states that each naturopath is liable for his or her acts or omissions in the performance of naturopathic medicine. The Society believes

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[57] U.S. Pharmacopeial Convention, "USP Verified Dietary Supplements," http://www.usp.org/usp-verification-services/usp-verified-dietary-supplements.
[58] Sec.12-37.3-114, C.R.S. (2013)

such insurance is absolutely necessary to ensure that the burden of any adverse consequences of naturopathic practice does not fall on the patient or the State of Maryland.

J. Reciprocity

Reciprocity should not be granted based simply on the fact that a naturopath has a license from another state. Unlike physician scope of practice, **naturopathic scope of practice and licensing requirements vary greatly from state to state**. Unless each licensing state's requirements are independently reviewed for concordance with Maryland's licensing law and regulations, it would be unwise to assume that another state's licensing law is the same as, or even similar to, Maryland's. It would also be unwise to license naturopaths who do not meet Maryland's standards for licensing.

Although actual figures are hard to come by, it appears that many naturopaths are not practicing or are underemployed (e.g., working in health food stores) due to the **oversupply of naturopaths in relation to demand**. There are about 4,750 licensees in the U.S. While some practice in Canada, that number exceeds the number of graduates from naturopathic schools, apparently by a large factor. Although the figure cannot be confirmed, the naturopathic schools are graduating 500 naturopaths per year. Naturopathic members of the Committee will be able to provide more accurate figures.

Independent surveys show that the demand for naturopathic services is extremely limited. In Washington State, two studies demonstrated less than 2% of insured patients made a health insurance claim for naturopathic services even though coverage of their services is mandated by state law. [59] [60] Maryland does not want to encourage an influx of un- or underemployed naturopaths licensed in other states by enacting low standards for reciprocity.

K. Ethics

The American Association of Naturopathic Physicians has adopted a Code of Ethics but it consists of a little over two pages and provides only bare bones guidance.[61]

While not ignoring the AANP Code, the Society urges the Committee to review the American Medical Association's Code of Medical Ethics[62] as a template for naturopathic regulation. Many of the subjects the Committee will address, such as the sale of health care products to patients, are covered there. We believe it can serve as an excellent model upon which to

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[59] Bellas A, et al., Frequency, predictors, and expenditures for pediatric insurance claims for complementary and alternative medical professionals in Washington State. *Arch Pediatr Adolesc Med*, 2005 Apr; 159(4):367-72.

[60] Lafferty WE, et al., Insurance coverage and subsequent utilization of complementary and alternative medicine providers. *Am J Manag Care*, 2006 Jul; 12(7):397-404.

61 American Association of Naturopathic Physician, Code of Ethics, http://www.naturopathic.org/files/For_Members/Position_Papers/AANP%20Code%20of%20Ethics%20Updated%202012.pdf.

[62] American Medical Association, Code of Medical Ethics, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page

base its recommended regulations and prevent the Committee's having to "reinvent the wheel."

Summary

Current naturopathic practices in Maryland reveal the need for **adequate regulation to ensure the health, safety and welfare of Maryland citizens** who chose to see a licensed naturopath. This should include the **prohibition of those practices** for which there is lack of sufficient evidence of safety or effectiveness to warrant their use, including diagnostic methods that have not been scientifically validated and do not have any diagnostic value. As well, naturopaths should **not be allowed to practice in areas for which they are not adequately educated or trained or are outside their scope of practice**. Effective collaboration and consultation agreements with physicians, continuing education requirements, stringent ethical rules, disclosure to patients, informed consent in accordance with Maryland law, and professional liability insurance will all serve to ensure the goals of the licensing act.

Appendix 4

MedChi
The Maryland State Medical Society

Your Advocate.
Your Resource.
Your Profession.

April 4, 2015

Devinder Singh, M.D.
Chair, Maryland Board of Physicians
4201 Patterson Ave.
Baltimore, MD 21215

RE: Naturopathic Formulary Workgroup

Dear Dr. Singh:

I am writing on behalf of MedChi with regard to the Naturopathic Formulary Workgroup, which is currently undertaking those tasks identified in Chapter 399 of 2014, Health Occupations-State Board of Physicians-Naturopathic Doctors. Specifically, I want to raise two matters for your consideration at this time. I recognize the Workgroup's schedule is such that it will continue to meet through the summer of 2015, and MedChi will likely provide further comments during that period.

First, as to the contents of any formulary which may be developed, MedChi does not support the inclusion of any 'legend' or prescription drugs. As a threshold matter, the advocates for the licensure of naturopathic medicine have advanced time and again the argument that naturopathy involves the use of "natural substances" and using the natural healing power of the body, at times even suggesting that an over-reliance on prescription drugs is a weakness of modern medicine. Why then, would a naturopathic doctor want to utilize prescription drugs? It seems anathema to the very foundation of naturopathy, which was advanced as an "alternative" to these standard notions of modern health care. On a more practical level, Chapter 339 specifically prohibited a naturopathic doctor from prescribing, dispensing or administering any prescription drug. Any discussion of a formulary that includes prescription drugs is tantamount to changing the naturopath scope of practice before the first license has even been issued.

Second, other substances which are included on the formularies of other states which have licensed naturopathy, and which presumably are under discussion here, are not regulated in the same manner as prescription drugs are by the Food and Drug Administration (FDA). While the FDA has rigorous standards and trials that must be successfully completed for prescription drugs, the natural supplements and dietary supplements now in the marketplace are not subject to such scrutiny. The FDA does, however, have enforcement authority over manufacturers of certain products who make false or misleading claims about these products. As the Formulary Workgroup considers products for inclusion on any formulary, consideration should be given as to ensuring that similar enforcement authority exists at the State level for providers who make false or misleading claims or advertisements about such products.

1211 Cathedral Street • Baltimore, MD 21201-5516 • 410.539.0872 • Fax: 410.547.0915 • 1.800.492.1056 • www.medchi.org

MedChi appreciates the opportunity to provide these comments to the Formulary Workgroup. We will continue to monitor the progress of the Workgroup and look forward to providing additional comments in the months ahead.

Sincerely

Gene M Ransom III

Gene M. Ransom III
Chief Executive Officer

cc: The Honorable Van Mitchell

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23 April 2015

Maryland Board of Physicians
Naturopathic Doctors Formulary Workgroup

Re: Naturopathic Formulary

To the Workgroup Members:

I recently learned that a Naturopathic Doctors Formulary Workgroup was established to make recommendations regarding a naturopathic formulary and the routes of administration that naturopathic doctors can use. I am writing the committee because I have very important first-hand knowledge regarding the pervasive misinformation provided to policymakers regarding the licensing of naturopathic doctors, the expansion of their scopes of practice, and the claims made about naturopathic education. I believe it is my ethical duty to inform policymakers and the public about the shortcomings of naturopathic education and the dangers of naturopathic practice.

My name is Britt Marie Deegan Hermes. In 2011, I graduated from Bastyr University (an accredited naturopathic school) with a doctorate in naturopathic medicine. I passed the Naturopathic Physicians Licensing Examination (NPLEX) and completed a competitive one-year naturopathic residency in family medicine and pediatrics at an out-patient clinic in Seattle. After residency, I practiced in Arizona until 2014.

In Arizona, I learned that many of my licensed naturopathic colleagues practice using illegal and illegitimate therapies. I began critically looking at naturopaths in other states and back at my naturopathic education at Bastyr. I discovered that naturopathic leaders and organizations systematically deceive students, patients, and legislators about what naturopathic medicine is all about.

Let me be clear: Naturopathic education is rich in pseudoscience and fake medicine, and it is devoid of legitimate medical training. Naturopaths are not trained in the rigors of medical science, and this leads to a severe lack of competency and a huge risk of patient harm.

I left naturopathy because I could not tolerate being a part of a self-proclaimed medical profession that is so embedded in deceit. I decided to enroll in a Master's program at Christian-Albrechts University in northern Germany to get a graduate education based in real medical science. Here, my tuition is covered, and once I graduate, I plan to return to my native California to pursue a career in molecular medicine and biomedical ethics. (I am still an American citizen and maintain a permanent residence in California.)

In order to provide this Workgroup with the truth about naturopathic medicine, I am sharing my naturopathic training, education and clinical experiences as they relate to the issues before you.

KEY POINT #1: Naturopaths graduating from Bastyr University receive 561 hours in "primary care" training, but which is not real primary care medicine.

Naturopathic clinical training takes place in a naturopathic teaching clinic, which is an outpatient clinic that caters to a small subset of patients. No clinical training takes place in a hospital setting, like it does for medical doctors, physician assistants, or nurse practitioners.

Clinical training at naturopathic teaching clinics encompasses the diagnosis and treatment of fake medical conditions, such as "adrenal fatigue" and "systemic yeast overgrowth." Many patients are not actually sick, but the clinical training of naturopaths teaches us how to diagnose these patients with such fake diseases, which require long-term and expensive naturopathic treatments.

Treatments include supplement and diet based "detox" programs, energy medicine, homeopathy,[1] hydrotherapy like colon irrigation, botanical medicines, intravenous injections of vitamins, and very little conventional medicine.

Naturopaths often show lawmakers education comparison charts to claim they are qualified to practice medicine based on the number of training hours they receive in such clinics, and in particular courses such as pharmacology and basic medical sciences.

Based on how I, and my colleagues, earned our naturopathic degrees from Bastyr University, I can attest that these charts mislead lawmakers with false information. Naturopathic graduates tend to exaggerate or miscalculate their training hours. I calculated my clinical training hours spent in patient care based on my transcript and my student clinician handbook.

I calculated 561 direct patient care hours spent at Bastyr's teaching clinic. This clinical training is the closest type of training to real primary care medicine but is nowhere near the type of training that medical doctors, nurse practitioners, or physician assistants receive.

Of the hours that Bastyr provided to me and my classmates in purported primary care training, one quarter of this time was spent in case preview and review. The remaining time (561 hours) contained dubious diagnostics and experimental treatments that were

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[1] Homeopathy is an archaic medical belief that infinitely dilute substances can treat illnesses. There is no scientific evidence to support its medical efficacy and has been debunked by the global medical community as magic, quackery, and fraud. For more information, visit: https://www.sciencebasedmedicine.org/reference/homeopathy/

so embedded within a pseudo-medical practice that the student clinician becomes confused into thinking that disease can be effectively treated with esoteric treatments.[2]

My clinical training included a very small amount of pharmacological experience. I spent far more time learning how to write a prescription for homeopathy and herbs than how to prescribe appropriate pharmaceutical medications.

I think it is apparent that the 561 hours of what I calculated to be "direct patient contact" in clinical training are nothing of the sort that would instill confidence in anyone that naturopathic education can produce competent primary care physicians. While I realize that Maryland naturopaths are not authorized to practice primary care per se, they are permitted to diagnose and treat any patient who walks in the door with any disease or condition – in other words, they will be diagnosing and treating the same patient base as primary care physician.

Lawmakers are often told that naturopathic students receive at least 1,200 clinical training hours in primary care medicine. These reported hours are inflated with training in counseling, therapy applying water to the body, herbal medicine, "detoxification" programs,[3] homeopathy, energy medicine, healing touch, visceral manipulation, and acupuncture. Such esoteric practices are not relevant for the practice of real medicine and have almost zero scientifically documented efficacy.

KEY POINT #2: The naturopathic licensing exam (NPLEX) is not a reliable measure of medical competency.

The NPLEX is the naturopathic licensing exams administered by the North American Board of Naturopathic Examiners (NABNE). It is written entirely by naturopaths and not made publicly available like the USMLE or COMPLEX-USA for MDs and DOs.

Since the development of the NPLEX more than 25 years ago, the NPLEX has not been made available for external audit or review by non-naturopathic medical providers. The NPLEX continues to be kept secret by NABNE, making it impossible for legislators and health organizations to assess the quality of the licensing examinations and to assess claims that the exams are as rigorous and comprehensive as the USMLE or COMPLEX-USA. An external review of medical licensing examinations, such as the USMLE, is understood by medical regulatory bodies as a necessary practice. This audit ensures the

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[2] Hermes, B. (2015) Naturopathic clinical training inside and out. Science-Based Medicine. https://www.sciencebased medicine.org/nd-confession-part-1-clinical-training-inside-and-out/

[3] Allen, J. et al. (2011) Detoxification in naturopathic medicine:a survey. *Journal of Complementary and Alternative Medicine* 17(12), 1175-80. http://www.ncbi.nlm.nih.gov/pubmed/22103982

exam is standardized, the test material is relevant, and those passing the examinations are qualified to practice medicine.[4]

A lack of transparency has caused a huge number of unqualified naturopaths to be legally permitted to practice in several states. Some states have their own licensing exams, which has caused confusion and has opened the door for outright misconduct by state licensing boards. For example, in 2000, the Arizona Auditor General found that the state's Naturopathic Medical Physicians board had inflated exam scores so all applicants passed.[5]

Without external review by non-naturopathic medical experts, there is no way to ensure that naturopathic examinations are comprehensive or sufficiently assess the standard medical knowledge of naturopaths.

KEY POINT #3: Naturopathic graduates are not required to complete residency training in order to practice medicine.

Upon graduation from naturopathic school, naturopaths are considered clinically competent by their profession to practice medicine. By any measure according to medical standards, this belief is false.

In order to graduate, naturopathic students are required to see a variety of health conditions but the majority of students never had the opportunity to see an actual patient suffering from many conditions seen at a real primary care clinic. Some diseases were very common in the Bastyr teaching clinic. These included irritable bowel syndrome, anxiety, food "allergies", fibromyalgia, chronic fatigue, "adrenal fatigue," "heavy metal toxicity," chronic back pain, and esophageal reflux. Patients with diseases that are commonly seen in hospitals and medical clinics were extremely rare. If students were unable to have direct contact with a mandatory health condition required for competency, students could orally present to fellow students on their clinic shift about the disease/condition to earn competency.

Students were required to achieve physical exam benchmarks, such as a cardiovascular exam, a respiratory exam, a prostate exam, or a neurological exam. Students were only required to complete one exam in each system and could perform the exam on another student if a patient was not available or the student never had the opportunity to perform the exam on a patient.

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[4] Melnick, D.E. (2009) Licensing Examinations in North America: Is external audit valuable? *Medical Teacher* 31(3), 212-4. http://informahealthcare.com/doi/abs/10.1080/01421590902741163

[5] Arizona Auditor General Report on the Naturopathic Physicians Board of Medical Examiners. (2000) http://www.azauditor.gov/reports-publications/state-agencies/naturopathic-physicians-board-medical-examiners/report/arizona

Naturopathic graduates performing just one or two examinations on a patient (or classmate) during their schooling are deemed competent by naturopathic boards to practice medicine in licensed states. This is a gross lack of training.

By comparison, students in real medical school begin seeing patients alongside medical residents and licensed medical doctors in their third and fourth years of school. This clinical training is completed in a hospital setting where the students are exposed to hundreds, if not thousands, of patients over the course of two years. Due to the sheer volume of patients, and how medical school programs are structured, medical students are not required to track patient conditions in order to graduate because there are too many to count!

A key difference between medical school and naturopathic school is that medical school graduates are not considered competent to practice medicine after graduation. Despite seeing a huge number of patients and training for thousands of hours in a hospital, experts agree that medical student clinical rotations do not provide the graduate with enough expertise to practice medicine.

The medical residency provides the true medial education and experience necessary to competently practice medicine. Medical residents are required to keep track of procedures that are required by the Accreditation Council for Graduate Medical Education (ACGME) for residency completion; for example: central line placement, paracentesis, thoracentesis, lumbar puncture, etc. Medical doctors need to provide this information throughout their career whenever applying for hospital privileges that involve procedures at a hospital. Naturopaths do not have exposure to any of the medical procedures listed above, and do not complete any clinical training in a hospital.

KEY POINT #4: Naturopaths do not use medical standards of care.

Unlike medical professionals, naturopaths do not have standards of care based on medical science. Instead, there is a community standard that is based on naturopathic licensing laws in licensing states. In the state of Arizona, for example, a naturopathic community standard is based on what is taught in naturopathic schools and any practice used by two or more naturopaths.[6] This means that any two naturopaths in Arizona using hydrogen peroxide intravenously to treat cancer is considered a standard and acceptable practice by naturopathic regulatory agencies. As a result, state licensing boards do not hold naturopaths to the same rigorous medical standards as licensed medical professionals. In fact, practices that are disallowed by medical licensing boards, which could result in severe sanctioning, are paradoxically allowed in a naturopathic practice.

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[6] American Naturopathic Clinical Research Institute. http://naturopathicstandards.org/goals-purpose-mission-statement/

Another example of a naturopathic community standard comes from Bastyr University for the treatment of angina, which includes a variety of dubious treatments: nutrient therapy with selenium, CoQ10, magnesium, and niacin; limiting fat intake, removing sucrose, alcohol and caffeine from the diet; botanical medicine doses of ginger, ginkgo biloba, aconite, and bromelain; recommendations to address a type A personality; a detoxification diet; colon hydrotherapy; castor oil packs; food allergy elimination; juice fasts; hormone replacement therapy; lifestyle changes; and monitoring of uric acid levels. Bastyr has a closed database of medical conditions and how they are treated with such esoteric therapies, usually without regard for medical standards of care.

According to any medical doctor, none of these treatments are indicated for angina. In fact, mistreating angina can lead to life-threatening complications. Naturopathic treatments are essentially like picking dubious therapies out of a hat, rather than relying on widely accepted medical science. This is how naturopathic students are taught to practice medicine.

KEY POINT #5: Naturopathic programs and professional organizations do not support public health recommendations, like vaccinations.

Naturopathic position papers published by the American Association for Naturopathic Physicians (AANP) do not make firm clinical or public health recommendations that are rooted in science.

The AANP position paper on vaccinations does not mention any vaccine schedule specifically nor does the paper recommend an adherence to any standard of care regarding immunizations. The paper instead leaves room open for exemptions and custom inoculation schedules "within the range of options provided by state law." Since many states have major loopholes in public health law regarding vaccine exemptions, this statement basically means vaccinate as you like or even not at all. The position paper also grossly overstates the risks associated with vaccines.[7]

Many naturopaths recommend that their patients to not receive vaccinations at all or receive them on a delayed schedule.[8] In fact, students start naturopathic programs with a very low opinions of childhood vaccines, and as they advance in the programs, their views on vaccines become even less favorable.[9]

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[7] AANP Position Paper on Vaccinations. http://www.naturopathicdiaries.com/wp-content/uploads/2015/02/Immunizations.pdf

[8] Downey L., et al. (2010) Pediatric Vaccination and Vaccine-Preventable Disease Acquisition: Associations with Care by Complementary and Alternative Medicine Providers. *Maternal and child health journal.* 14(6):922-30. http://link.springer.com/article/10.1007%2Fs10995-009-0519-5

[9] Wilson, K., et al. (2004) A survey of attitudes towards paediatric vaccinations amongst Canadian naturopathic students. *Vaccine* 22(3-4), 329-34. http://www.sciencedirect.com/science/article/pii/S0264410X03006042

Naturopathic teaching clinics and naturopaths in private practice go so far as to offer homeopathic vaccinations (nosodes) instead of actual inoculations.[10] As a homeopathic preparation, nosodes have no efficacy whatsoever. Bastyr's teaching clinic sells an MMR nosode.[11] This type of weak public health care policy and practice contribute to infectious disease outbreaks like the pertussis outbreak in California in 2010 and the 2015 Measles outbreak.[12,13]

It is also worth mentioning that my pediatrics classes at Bastyr University (NM 7314 & 7315) listed the following books on the course syllabus:

- Paul Herscu, ND. *The Homeopathic Treatment of Children.*
- Anne McIntyre (herbalist). *Herbal Treatment of Children: Western and Ayurvedic Perspectives.*
- Mary Bove, ND. *Encyclopedia of Natural Healing for Children* (2nd edition).
- Aviva Romm (midwife). *Vaccinations: A Thoughtful Parent's Guide: How to make safe, sensible decisions about the risks, benefits and alternatives.*
- Jared Skowron, ND. *Naturopathic Pediatrics.*
- Robert Sears, MD. *The Vaccine Book.* (You may recognize this author as the California pediatrician who popularized the alternative childhood immunization schedule associated with disease outbreaks.)

The education at Bastyr is heavily loaded with pseudoscience and alternative practices that are either disproven or not tested by science because they are extremely implausible. At its root, the education of naturopaths is rooted in implausible and dangerous medical practices. This characterization is true for all clinical courses I took at Bastyr University.

KEY POINT #6: Naturopaths receive poor training in pharmacology and medical procedures

Naturopaths graduating from accredited naturopathic schools claim they have adequate training in pharmacology and medical procedures which should grant them a scope of practice equivalent to primary care doctors. This claim is false.

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[10] Crislip, M. Homeopathic Vaccines. *Science-Based Medicine.* https://www.sciencebasedmedicine.org/homeopathic-vaccines/

[11] Screenshot of Bastyr Center for Natural Health's website dispensary search (http://www.bastyrcenter.org/dispensary/search): http://www.naturopathicdiaries.com/wp-content/uploads/2015/04/bastyr-clinic-mmr-nosode.png

[12] Atwell, J.E., et al. (2013) Nonmedical Vaccine Exemptions and Pertussis in California, 2010. *Pediatrics* 132(4), 624-30. http://pediatrics.aappublications.org/content/early/2013/09/24/peds.2013-0878.full.pdf

[13] Saada, A., et al. (2015) Parents' Choices and Rationales for Alternative Vaccination Schedules A Qualitative Study. *Clinical Pediatrics* 54(3), 236-43. http://cpj.sagepub.com/content/54/3/236.abstract

I outlined my required training in pharmacology and medical procedures. It is important to note that this training for each topic occurred in just one course and was taught in a lecture or lab format; material was not reiterated in other classes or in clinical training: BC 6305 Pharmacology for ND Students: "pharmacology for the ND student population"

- **55 lecture hours** in one course
- No additional pharmacology training provided in other courses
- Minimal, if any, additional pharmacology training provided in clinical training hours

NM 7417 Medical Procedures: Lecture course that covered common primary care procedures such as epi-pen injection, intravenous therapy safety issues, nebulizer use, how to use an oxygen tank and CPR/ first aid. This course also covered esoteric and non-conventional medical practices such as provoked urine heavy metal testing,[14] sinus irrigation, naso- sympatico, eustachian tube massage, and ear lavage.

- **33 hours lecture hours**
- No required clinical training
- No clinical competency exam required for graduation or licensing
- This class meets the "16 hours of IV training required" to be licensed as a naturopathic doctor in the state of Washington.

KEY POINT #7: Naturopaths receive less pharmacology training than PAs and NPs

Naturopaths commonly claim that their clinical education and training exceeds that of both Physician Assistants and Nurse Practitioners. This claim is false.

To illustrate this misrepresentation, I compiled training hours for naturopathic doctors at accredited naturopathic programs and compared this training to that of Physician Assistants and Nurse Practitioners. Please refer to the following table:

[14] American College of Medical Toxicology statement on provoked heavy metal urine testing. http://www.acmt.net/cgi/page.cgi?aid=2999&_id=462

ND v NP v PA Education Comparison Chart:

	Educational Institution	Loc.	Pharmacology Hours	Homeopathy Hours	Botanical Hours	Manipulation Hours
Naturopathic	Bastyr University	WA	27.5*	88	132	203.5
	National College of Natural Medicine	OR	72	144	96	216
	University of Bridgeport	CT	72	144	144	315
Nurse Practitioner	Long Island University	NY	105	0	0	0
	Vanderbilt University	TN	115	0	0	0
	Ohio State University	OH	101	0	0	0
Physician Assistant	Salus University	PA	90	0	0	0
	Lincoln Memorial University	TN	90	0	0	0
	University of Utah	UT	120	0	0	0

Sources:

http://www.bastyr.edu/sites/default/files/images/pdfs/course-catalog/2013-14-catalog/Catalog-2013-14.pdf

http://www.ncnm.edu/images/academic/curriculum/2013-14_ND_4yr_winter.pdf

http://www.bridgeport.edu/academics/graduate/naturopathic-medicine-nd/curriculum-and-program-requirements/

http://www.liu.edu/~/media/Files/Brooklyn/Academics/Schools/Nursing/SON_StudentHandbook_2012-13.ashx

http://www.nursing.vanderbilt.edu/current/handbook.pdf

https://nursing.osu.edu/assets/attachments/Masters_programs/MS_student_handbook.pdf

http://www.salus.edu/physicianAssistant/paStudentHandbookClassof2015Highlighted.pdf

http://www.lmunet.edu/dcom/pdfs/pa-student-handbook.pdf

http://medicine.utah.edu/physician-assistant-program/program/curriculum.php

*In 2012-2013 Bastyr University changed their naturopathic curriculum. The former program contained 55 hours of pharmacology training as reported by a Bastyr alumnus who graduated in 2011: http://www.sciencebasedmedicine.org/nd-confession-part-1-clinical-training-inside-and-out/

Physician Assistants receive far more pharmacology training and apply this knowledge in a very active setting working alongside a Physician (Medical Doctors or Doctors of Osteopathic Medicine). For example, Salus University in Pennsylvania, Lincoln Memorial University in Tennessee, and University of Utah provide their students with 90, 90, and 120 hours in pharmacology, respectively.

Even with this training, though, Physician Assistants must always practice under the supervision of a Physician (MD or DO). Because naturopaths receive less training in pharmacology than Physician Assistants, naturopaths are not capable of practicing independently.

When compared to the pharmacology training for Nurse Practitioners, naturopathic programs still fall short. From Nurse Practitioner programs at Long Island University, Vanderbilt University, and Ohio State University, graduates will have received 105, 115, and 101 hours, respectively in pharmacology. Like Physician Assistants, Nurse Practitioners are trained in hospitals and medical clinics.

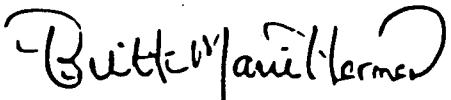
Conclusion

Based on my knowledge of naturopathic education, clinical training and my experience in practice, I do not believe naturopaths should be allowed to dispense, order or administer any "natural medicines" beyond those already allowed by Maryland law nor go beyond routes of administration allowed by the current law. They certainly should not be able to prescribe, dispense, order or administer legend drugs or employ IV administration. I also advise the Workgroup to be very skeptical of claims made by naturopaths regarding their education and practice because there is serious risk of harming the public.

The legislature asked the Workgroup to study these issues and make recommendations. That does not preclude an honest evaluation by the Workgroup that no formulary be established and that no further routes of administration be allowed. To come to any other conclusion would be to resign the Workgroup's responsibility to the legislature and to the citizens of Maryland.

Please feel free to contact me for more information. I can be reached through my advocacy website: http://www.naturopathicdiaries.com.

Sincerely,



Britt Marie Deegan Hermes, ND (ret.)

Further resources on naturopathic medicine:

Dr. Kimball Atwood, IV, MD. 2003. Naturopathy: A critical appraisal.
http://www.medscape.com/viewarticle/465994

Dr. Robert Carroll, PhD. 2015. The Skeptic's Dictionary: Naturopathy.
http://skepdic.com/natpathy.htmlhttp://www.medscape.com/viewarticle/465994

Dr. David Gorski, MD, PhD. 2011. Naturopathy and Science.
https://www.sciencebasedmedicine.org/naturopathy-and-science/

Britt Hermes, ND. 2015. Naturopathic clinical training inside and out.
https://www.sciencebased medicine.org/nd-confession-part-1-clinical-training-inside-and-out/

Britt Hermes, ND. 2015. Naturopathic Diaries: Confessions of a former naturopath. http://www.naturopathicdiaries.com

Dr. Stephen Barrett, MD. 2013. A Close Look at Naturopathy. http://www.quackwatch.com/01QuackeryRelatedTopics/Naturopathy/naturopathy.html

American Cancer Society. 2013. Naturopathic Medicine. http://www.cancer.org/treatment/treatmentsandsideeffects/complementaryandalternativemedicine/mindbodyandspirit/naturopathic-medicine

Society for Science-Based Medicine

www.sfsbm.org

April 24, 2015

Maryland Board of Physicians
Naturopathic Doctors Formulary Workgroup

Dear Workgroup Members:

The Society for Science-Based Medicine's *Report to the Maryland Board of Physicians Naturopathic Advisory Committee: Recommendations for Naturopathic Regulation* was provided to you earlier in your deliberations. However, the Society was recently made aware that naturopaths are citing the absence of malpractice claims as evidence that they can safely prescribe.

We wish to bring to your attention research relevant to this claim. This research concluded that, in fact, there is no relationship between the incidence of malpractice claims against healthcare providers and whether the care provided was negligent. Thus, malpractice claims are not a reliable determinant of the quality or safety of care. The Workgroup should therefore not rely on malpractice data in determining whether naturopaths can safely prescribe.

Brennan TA, Sox CM, Burstin HR. Relationship between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation. *NEJM* 1996; 335: 1963-1967.

Studdert DM, et al. Relationship between Quality of Care and Negligence Litigation in Nursing Homes. *NEJM* 2011; 364:1243-1250.

Studdert DM, et al. Negligent Care and Malpractice Claiming Behavior in Utah and Colorado. *Med. Care* 2000; 38:1250-1260.

Should you need any further information regarding this matter, please do not hesitate to contact the Society.

Sincerely,

Jann J. Bellamy

Jann J. Bellamy
Board Secretary
jbellamy@sfsbm.org.com

MARYLAND

Yemisi Koya -DHMH- <yemisi.koya@maryland.gov>

Naturopath Formulary Group

1 message

Gregory S Pokrywka MD FACP FNLA NCMP <gpokmd@verizon.net> Sat, Apr 25, 2015 at 4:58 PM
To: sandi.vanhorn@maryland.gov, yemisi.koya@maryland.gov, wynee.hawk@maryland.gov, Devinder Singh MD <dsingh.md@gmail.com>

I am writing to offer my whole hearted support of Mr Ranson's letter. For the reasons he mentions , and others well documented in the Society for Science Based Medicine's report on Maryland Naturopaths, as well as in continuing articles on the Sciencebasedmedicne.org website, Naturopaths are clearly not properly trained to prescribe prescription drugs.

Gregory S Pokrywka MD FACP FNLA NCMP

Prevention of Cardiovascular Disease and Women's Menopausal Health

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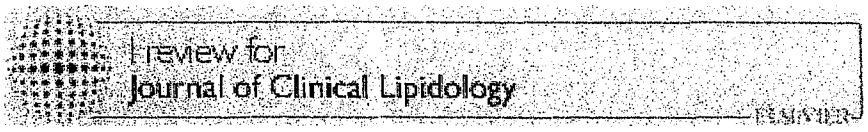

Executive Director, WatersEdge Kayak Club, http://www.meetup.com/watersedgekayak/

Founder, President Emeritus, Board Member of the Mid-Atlantic Turtle and Tortoise Society, Inc. http://www.matts-turtles.org/

Appendix 5

STATE OF MARYLAND
DHMH Board of Physicians
Maryland Department of Health and Mental Hygiene
Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

July 1, 2015

The Honorable Joan Carter Conway, Chair
Senate Education, Health and
Environmental Affairs Committee
2 West Miller Senate Building
11 Bladen Street
Annapolis, MD 21401-1991

The Honorable Peter A. Hammen, Chair
House Health and
Government Operations Committee
241 House Office Building
6 Bladen Street
Annapolis, MD 21401-1991

RE: CH 153 and 399 of the Acts of 2014 (HB 402),
State Board of Physicians and Allied Health Advisory Committees –
Naturopathic Doctors Formulary Workgroup Report

Dear Chair Carter Conway and Chair Hammen:

Thank you for the opportunity for the Maryland Board of Physicians (the "Board") to comment on the report of the Naturopathic Doctors Formulary Workgroup (the "Workgroup"), which was convened to study the development of a naturopathic formulary to regulate pharmaceuticals in Maryland.

At its meeting on June 10, 2015, the Board discussed the report and voted to support the Workgroup's recommendations. However, the Board does have a comment about the report and some concerns about the practice of naturopathic medicine in Maryland.

Report

The Board agrees with the Workgroup's recommendations that controlled substances and legend drugs be excluded from a naturopathic formulary in Maryland. The Workgroup voted to recommend that an exception be made for epinephrine (such as EpiPen for anaphylaxis) and oxygen so that these basic emergency agents would be included in the formulary. While the Board also supports this recommendation, it believes that the report does not provide sufficient clarity. The Board wants to emphasize that epinephrine and oxygen should be utilized *only* in emergency situations and *not* for chronic conditions.

Practice of Naturopathic Medicine

There is a Naturopathic Medicine Advisory Committee (the "NMAC") that is separate from the Workgroup. The NMAC is promulgating regulations for the licensure of naturopathic doctors ("NDs") and the practice of naturopathic medicine. Though the Board eventually will review these regulations drafted by the NMAC, the Board wishes to express the following concerns:

Supervision of NDs

The statute requires that applicants seeking licensure as an ND submit a written attestation that they have a collaboration and consultation agreement with a licensed physician. The attestation must state that the applicant – "as needed" – will refer patients to and consult with physicians and other health care providers licensed or certified under the Health Occupations Article. As it stands now, it will be left to the ND to decide if and when referral or consultation is needed, which could impact patient safety. The Board is aware that the NMAC is drafting language (for the attestation) to define circumstances that would require consultation or patient referral. The Board applauds additional levels of oversight; however, it is of the opinion that, should NDs be granted additional prescriptive authority in the future, higher levels of supervision would be needed.

Naturopathic Medicine Practice Standards

1. The Board is concerned that the standard of care for the practice of naturopathic medicine has not been established. For cases involving standard of care issues, the Board relies upon the opinions of experts or peer reviewers when it considers disciplinary action. The Board believes that there will be few NDs to participate as reviewers once licensure begins in March 2016. And, as the report indicates, a topic of particular interest to the Workgroup members was the initial training and continuing education of naturopathic doctors. It's unclear to the Board how NDs serving as reviewers will measure standards for quality care in a profession that will be newly licensed in Maryland. By relying on these experts under the regulatory scheme, the Board may find itself bound by a decision with which is does not agree in regard to public protection.
2. It's unclear how the Board will resolve complaints about NDs accused of making false statements about herbals and dietary supplements, which are not regulated by the U.S. Food and Drug Administration. The benefits or effects of such products are open to interpretation. Again, there could be an impact to patient safety.

Self-regulation of NDs

In light of the fact that allopathic standards are different from naturopathic education, the Board believes that there should be a separate board to license and regulate NDs. The Board's consideration of case resolution and disciplinary action is based on allopathic standards. As NDs establish a history and develop customary practice standards in Maryland, in the future, NDs may be better served by a board consisting of their peers.

Again, on behalf of the Board, I thank you for the opportunity to comment. The Board urges consideration of the enclosed comments as your committees review the Workgroup's report.

Sincerely,

Christine A. Farrelly

Christine A. Farrelly, Executive Director
Maryland Board of Physicians

Appendix 6

Motions Approved by the Naturopathic Doctors Formulary Workgroup

Meeting Date	Motion
February 23, 2015	That the workgroup met its objective to review the formularies of other states.
	To recommend the establishment of a naturopathic doctors formulary in Maryland.
March 9, 2015	That a formulary include a qualifying statement that it be categorized as complementary and not alternative. The term "integrative" was suggested.
	That the formulary including medicines, drugs, or devices shall not be applied for cosmetic purposes or indications for patients.
	To accept the definition of legend drugs (as drafted by Mr. Jones).
	To exclude controlled substances (categories I-V) from the formulary with an amendment to set aside testosterone for later discussion.
April 6, 2015	That a formulary should include no legend drugs with limited exceptions to be discussed by class.
	That all Over-The-Counter (non-legend) medications be included in the formulary.
	To exclude anti-depressants from a formulary.
	To grant an exception for the basic emergency agents epinephrine (including EpiPen) and oxygen.
	For a recommendation of a continuing formulary council.
April 20, 2015	That the formulary council will have the ability to recommend future changes and devices.
	That the formulary council include two NDs, two MDs – allopathy or osteopathy, one pharmacist, one public health representative, and one consumer representative. And, that the council meet at least annually or at the discretion of the council. And, that recommendations of the council are to be brought before the Board, and the Board would retain the discretion to accept or reject council recommendations.
May 4, 2015	To include in the formulary Over-The-Counter devices and two prescription barrier contraceptives: diaphragms and cervical caps.
	That devices be added by the formulary council.
	To reconcile the routes for ordering and dispensing with administering, but to exclude "intramuscular" as a route for administration. [That §14–5F–14 (a)(4) be amended to add oral, nasal, auricular, ocular, rectal, and vaginal routes of administration; §14–5F–14 (a)(4) already includes transdermal.]