

**Department of Legislative Services**  
Maryland General Assembly  
2016 Session

**FISCAL AND POLICY NOTE**  
**Third Reader - Revised**

Senate Bill 806

(Senator Pugh)

Education, Health, and Environmental Affairs

Health and Government Operations

---

**State Board of Physicians - Naturopathic Doctors - Establishment of  
Naturopathic Doctors Formulary Council and Naturopathic Formulary**

---

This bill establishes a Naturopathic Doctors Formulary Council within the State Board of Physicians (MBP). Among other duties, the council has to develop and make recommendations to MBP regarding a formulary for licensed naturopathic doctors. MBP is required to adopt a formulary based on the council's recommendations. The bill also specifies prescription, dispensing, and administration requirements for formulary drugs and devices.

---

**Fiscal Summary**

**State Effect:** The bill's requirements can likely be absorbed with existing budgeted resources. Revenues are not affected.

**Local Effect:** None.

**Small Business Effect:** Meaningful. Naturopathic doctors may not prescribe, dispense, or administer drugs or devices not listed on the formulary. The bill also expands authorized routes of administration for naturopathic doctors.

---

**Analysis**

**Bill Summary:** The bill alters the definition of "naturopathic medicine" to include prescribing, dispensing, or administering nonprescription and prescription drugs and devices listed in the formulary. "Device" means a device used in the diagnosis, treatment, or prevention of disease; it does not include any surgical or dental instrument, any physical therapy equipment, any X-ray apparatus, or any component or accessory thereof.

“Nonprescription drug” means a drug that may be sold without a prescription and is lawfully labeled for consumer use.

The council consists of the Deputy Secretary of Public Health Services (or designee), two naturopathic doctors licensed in Maryland, two licensed physicians or osteopathic physicians, a pharmacist, and a consumer member. The bill specifies term limits and authorizes members to receive standard reimbursement for travel expenses. MBP must staff the council.

The council must develop and recommend a formulary to MBP for use by licensed naturopathic doctors. The council must annually review the formulary adopted by MBP to determine if any changes are necessary for compliance with current prescribing standards or the practice of naturopathic medicine. Recommendations relating to the formulary must be made by the council to MBP. MBP may modify or reject any of the council’s recommendations.

The formulary must include (1) nonprescription drugs and devices; (2) prescription oxygen and auto-injectable epinephrine; and (3) prescription diaphragms and cervical caps for contraception. The formulary may not include other prescription drugs and devices or controlled substances.

A licensed naturopathic doctor may dispense, order, or administer drugs listed in the formulary using various routes of administration, as specified. A licensee may also administer auto-injectable epinephrine. However, a licensee may *not* prescribe, dispense, or administer any prescription or nonprescription drug or device listed in the formulary *for cosmetic purposes*. Moreover, the bill expands the existing prohibition against a licensee prescribing, dispensing, or administering any prescription drug to encompass devices and clarifies that the prohibition does not apply to prescription drugs or devices required to be included in the formulary.

**Current Law:** Pursuant to Chapters 153 and 399 of 2014, an individual must be licensed by MBP in order to practice naturopathic medicine in the State.

“Naturopathic medicine” means the prevention, diagnosis, and treatment of human health conditions, injury, and disease using only patient education, naturopathic therapies, and therapeutic substances recognized by the Council of Naturopathic Medical Education. Naturopathic medicine includes counseling and the practice of the mechanical and material sciences of healing.

A licensed naturopathic doctor may:

- order and perform physical and laboratory examinations for diagnostic purposes;
- order and interpret the reports of diagnostic imaging studies;
- dispense or order natural medicines, dietary supplements, and nonprescription drugs that use various routes of administration;
- administer natural medicines of mineral, animal, or botanical origin;
- administer or perform hydrotherapy, naturopathic physical medicine, electromagnetic energy, and therapeutic exercise;
- provide health education and counseling; and
- perform naturopathic musculoskeletal mobilization.

A licensee may not prescribe, dispense, or administer any prescription drug; perform surgical procedures; practice or claim to practice as a medical doctor, physician, osteopath, dentist, podiatrist, or other specified health care professional; use general or spinal anesthetics; administer ionizing radioactive substances for therapeutic purposes; perform chiropractic adjustments or manipulations unless the licensee is also a licensed chiropractor; or perform acupuncture unless the licensee is also a licensed acupuncturist.

**Background:** MBP advises that it began licensing naturopathic doctors on March 1, 2016; as of March 21, 2016, six licenses have been issued and an additional eight applications are pending.

In addition to establishing licensing requirements, Chapters 153 and 399 of 2014 required MBP to convene a workgroup to study the development of a naturopathic formulary in the State. The Naturopathic Doctors Formulary Workgroup was required to make recommendations regarding (1) the establishment of a naturopathic formulary, including the types of drugs, medicines, and devices to be included and the method by which they will be included and (2) the routes of administration that may be used.

The workgroup issued its final report in July 2015. After reviewing the formularies of other states, the workgroup recommended the establishment of a naturopathic formulary in Maryland.

Specifically, the workgroup recommended:

- excluding controlled substances and legend drugs from the formulary, with the exception of epinephrine and oxygen;
- including over-the-counter medications and devices and prescription diaphragms and cervical caps in the formulary;

- expanding the routes of administration;
- prohibiting the use of drugs or devices on the formulary for cosmetic purposes; and
- establishing a formulary council to meet at least once a year to review and recommend changes to the formulary.

**State Fiscal Effect:** MBP advises that it must hire a part-time (50%) assistant Attorney General, a part-time (50%) office secretary, a part-time (50%) administrator, and a full-time health policy analyst in order to staff the council. The board advises that these positions are needed to research other formulary councils, interpret laws and regulations, prepare and update the formulary, make recommendations to the council, coordinate council meetings, and provide other administrative support, as appropriate. MBP additionally estimates that the council must meet once per month.

The Department of Legislative Services (DLS) disagrees. Although the council may need to meet more frequently in the first few months after formation in order to develop and finalize the formulary, the council likely must only review the formulary annually thereafter. The Naturopathic Doctors Formulary Workgroup recommended that the council meet at least once per year. Thus, this analysis assumes that the council meets – at most – monthly for six months in fiscal 2017; beginning in fiscal 2018, the council must only meet once per year to review the formulary and make recommendations for needed changes. This estimate reflects the bill’s October 1, 2016 effective date and assumes a slight delay between council formation and the first meeting.

Additionally, the Naturopathic Doctors Formulary Workgroup reviewed the laws and regulations relating to naturopathic medicine in 21 states and jurisdictions, including other states’ formularies for naturopathic doctors. Based on this review, the workgroup recommended creating a formulary with a narrow scope and specified the required parameters. Given the workgroup’s comprehensive report and the specific requirements for the formulary, DLS advises that the council’s staffing needs will likely be limited to administrative tasks rather than significant research requirements. MBP can likely absorb these administrative responsibilities with existing budgeted resources. Standard travel expense reimbursement for council members can also likely be absorbed with existing budgeted resources. To the extent the board cannot absorb these responsibilities in the short term, special fund expenditures increase minimally in fiscal 2017.

---

## **Additional Information**

**Prior Introductions:** None.

**Cross File:** None.

**Information Source(s):** Department of Health and Mental Hygiene, Department of Legislative Services

**Fiscal Note History:** First Reader - February 18, 2016  
mel/jc Revised - Senate Third Reader/Updated Information - March 24, 2016

---

Analysis by: Sasika Subramaniam

Direct Inquiries to:  
(410) 946-5510  
(301) 970-5510