

SENATE BILL 806

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6lr3075

By: **Senator Pugh**

Introduced and read first time: February 5, 2016

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 4, 2016

CHAPTER _____

1 AN ACT concerning

2 **State Board of Physicians – Naturopathic Doctors – Establishment of**
3 **Naturopathic Doctors Formulary Council and Naturopathic Formulary**

4 FOR the purpose of establishing a Naturopathic Doctors Formulary Council within the
5 State Board of Physicians; providing for the membership, terms, compensation,
6 chair, and staff the Council; requiring the Council to develop and recommend to the
7 Board a certain formulary, provide certain reviews of the formulary adopted by the
8 Board, and make certain recommendations to the Board; requiring the Board to
9 adopt a certain formulary; authorizing the Board to modify or reject any
10 recommendation of the Council regarding the formulary; requiring a certain
11 formulary to include certain nonprescription drugs and devices and certain
12 prescription drugs and contraceptives; prohibiting a certain formulary from
13 including certain prescription drugs and devices and controlled substances;
14 providing that a license authorizes a licensed naturopathic doctor to dispense, order,
15 or administer certain natural medicines and nonprescription drugs listed in a certain
16 formulary; altering the routes of administration for certain natural medicines and
17 nonprescription drugs that a license authorizes a licensee to use; authorizing a
18 licensee to administer auto-injectable epinephrine; excluding prescription drugs and
19 devices included in the formulary from the prohibition against a licensed
20 naturopathic doctor prescribing, dispensing, or administering prescription drugs and
21 devices; providing that a license does not authorize a licensed naturopathic doctor to
22 prescribe, dispense, or administer certain drugs or devices for cosmetic purposes;
23 defining certain terms; and generally relating to the establishment of the
24 Naturopathic Doctors Formulary Council and naturopathic formulary.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 BY repealing and reenacting, with amendments,
2 Article – Health Occupations
3 Section 14–5F–01 and 14–5F–14
4 Annotated Code of Maryland
5 (2014 Replacement Volume and 2015 Supplement)

6 BY adding to
7 Article – Health Occupations
8 Section 14–5F–04.1
9 Annotated Code of Maryland
10 (2014 Replacement Volume and 2015 Supplement)

11 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
12 That the Laws of Maryland read as follows:

13 **Article – Health Occupations**

14 14–5F–01.

15 (a) In this subtitle the following words have the meanings indicated.

16 (b) “Approved naturopathic medical program” means a naturopathic medical
17 education program:

18 (1) In the United States that:

19 (i) Provides the degree of Doctor of Naturopathy or Doctor of
20 Naturopathic Medicine;

21 (ii) Offers a 4–year graduate–level, full–time didactic and
22 supervised clinical training;

23 (iii) Is accredited, or has achieved candidacy status for accreditation,
24 by the Council on Naturopathic Medical Education or an equivalent federally and
25 Board–recognized accrediting body for naturopathic medical programs; and

26 (iv) Is part of an institution of higher education that is either
27 accredited, or is a candidate for accreditation, by a regional or national institutional
28 accrediting agency recognized by the United States Secretary of Education; or

29 (2) In a diploma–granting, degree–equivalent college or university in
30 Canada that:

31 (i) Offers graduate–level, full–time didactic and supervised clinical
32 training;

1 (ii) Is accredited, or has achieved candidacy status for accreditation,
2 by the Council on Naturopathic Medical Education or an equivalent federally and
3 Board-recognized accrediting body for naturopathic medical programs; and

4 (iii) Has provincial approval for participation in government-funded
5 student aid programs.

6 **(C) “AUTO-INJECTABLE EPINEPHRINE” MEANS A PORTABLE, DISPOSABLE**
7 **DRUG DELIVERY DEVICE THAT CONTAINS A PREMEASURED SINGLE DOSE OF**
8 **EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.**

9 ~~(D)~~ **(D)** “Board” means the State Board of Physicians.

10 ~~(E)~~ **(E)** “Committee” means the Naturopathic Medicine Advisory Committee.

11 ~~(F)~~ **(F)** “COUNCIL” MEANS THE NATUROPATHIC DOCTORS FORMULARY
12 COUNCIL.

13 ~~(G)~~ **(G)** (1) “DEVICE” MEANS A DEVICE USED IN THE DIAGNOSIS,
14 TREATMENT, OR PREVENTION OF DISEASE.

15 (2) “DEVICE” DOES NOT INCLUDE:

16 (I) ANY SURGICAL OR DENTAL INSTRUMENT;

17 (II) ANY PHYSICAL THERAPY EQUIPMENT;

18 (III) ANY X-RAY APPARATUS; OR

19 (IV) ANY COMPONENT PART OR ACCESSORY OF ANY OF THE
20 ITEMS LISTED IN ITEMS (I) THROUGH (III) OF THIS PARAGRAPH.

21 ~~(H)~~ **(H)** “FORMULARY” MEANS A LIST OF DRUGS AND DEVICES
22 DEVELOPED AND ADOPTED IN ACCORDANCE WITH § 14-5F-04.1 OF THIS SUBTITLE.

23 ~~(I)~~ **(I)** “Licensed naturopathic doctor” means a naturopathic doctor who is
24 licensed to practice naturopathic medicine.

25 ~~(J)~~ **(J)** “Naturopathic doctor” means an individual who practices naturopathic
26 medicine.

27 ~~(K)~~ **(K)** (1) “Naturopathic medicine” means the prevention, diagnosis, and
28 treatment of human health conditions, injury, and disease using only patient education and
29 naturopathic therapies and therapeutic substances recognized by the Council of
30 Naturopathic Medical Education.

1 (2) “Naturopathic medicine” includes:

2 (i) Counseling;

3 (ii) The practice of the mechanical sciences of healing, including
4 mechanotherapy, articular manipulation, corrective and orthopedic gymnastics,
5 hydrotherapy, electrotherapy, and phototherapy; [and]

6 (iii) The practice of the material sciences of healing, including
7 nutrition, phytotherapy, treatment by natural substances, and external applications; AND

8 (IV) **PRESCRIBING, DISPENSING, OR ADMINISTERING**
9 **NONPRESCRIPTION AND PRESCRIPTION DRUGS AND DEVICES LISTED IN THE**
10 **FORMULARY.**

11 [(h)]~~(H)~~ **(L)** “Naturopathic musculoskeletal mobilization” means the treatment by
12 manual and other mechanical means of all body tissues exclusive of high-velocity thrusts
13 at or beyond the end range of normal joint motion.

14 ~~(H)~~ **(M)** “NONPRESCRIPTION DRUG” MEANS A DRUG THAT:

15 (1) **MAY BE SOLD WITHOUT A PRESCRIPTION; AND**

16 (2) **IS LABELED FOR USE BY A CONSUMER IN ACCORDANCE WITH**
17 **STATE AND FEDERAL LAW.**

18 [(i)]~~(M)~~ **(N)** “Prescription drug” means any drug defined in § 503(b) of the federal
19 Food, Drug, and Cosmetic Act if the drug’s label is required to bear the statement “Rx only”.

20 **14-5F-04.1.**

21 (A) (1) **THERE IS A NATUROPATHIC DOCTORS FORMULARY COUNCIL**
22 **WITHIN THE BOARD.**

23 (2) **THE COUNCIL CONSISTS OF THE FOLLOWING MEMBERS:**

24 (I) **THE DEPUTY SECRETARY OF PUBLIC HEALTH SERVICES,**
25 **OR THE DEPUTY SECRETARY’S DESIGNEE; AND**

26 (II) **THE FOLLOWING MEMBERS, APPOINTED BY THE BOARD:**

27 1. **TWO INDIVIDUALS WHO:**

28 A. **PRACTICE NATUROPATHIC MEDICINE IN THE STATE;**

1 **B. ARE CERTIFIED BY THE NORTH AMERICAN BOARD OF**
2 **NATUROPATHIC EXAMINERS;**

3 **C. HAVE A MINIMUM OF 2 YEARS EXPERIENCE; AND**

4 **D. ARE LICENSED NATUROPATHIC DOCTORS;**

5 **2. TWO LICENSED PHYSICIANS OR DOCTORS OF**
6 **OSTEOPATHY WHO PRACTICE IN THE STATE;**

7 **3. ONE PHARMACIST WHO HAS A BACKGROUND IN**
8 **PHARMOCOGNOSY AND WHO PRACTICES IN THE STATE; AND**

9 **4. ONE CONSUMER.**

10 **(3) (I) THE TERM OF AN APPOINTED MEMBER IS 4 YEARS.**

11 **(II) AT THE END OF A TERM, AN APPOINTED MEMBER**
12 **CONTINUES TO SERVE UNTIL A SUCCESSOR IS APPOINTED.**

13 **(4) A MEMBER OF THE COUNCIL:**

14 **(I) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE**
15 **COUNCIL; BUT**

16 **(II) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER**
17 **THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE**
18 **BUDGET.**

19 **(5) THE BOARD SHALL DESIGNATE THE CHAIR OF THE COUNCIL.**

20 **(6) THE BOARD SHALL PROVIDE STAFF FOR THE COUNCIL.**

21 **(B) THE COUNCIL SHALL:**

22 **(1) DEVELOP AND RECOMMEND TO THE BOARD A FORMULARY FOR**
23 **USE BY LICENSED NATUROPATHIC DOCTORS;**

24 **(2) ANNUALLY REVIEW THE FORMULARY ADOPTED BY THE BOARD**
25 **UNDER SUBSECTION (C) OF THIS SECTION TO DETERMINE IF ANY CHANGES ARE**
26 **NECESSARY FOR COMPLIANCE WITH CURRENT PRESCRIBING STANDARDS OR THE**
27 **PRACTICE OF NATUROPATHIC MEDICINE;**

1 **(3) OTHERWISE REVIEW THE FORMULARY AT THE DIRECTION OF THE**
2 **BOARD; AND**

3 **(4) MAKE RECOMMENDATIONS TO THE BOARD BASED ON THE**
4 **REVIEWS CONDUCTED UNDER ITEMS (2) AND (3) OF THIS SUBSECTION.**

5 **(C) (1) THE BOARD SHALL ADOPT A FORMULARY BASED ON THE**
6 **RECOMMENDATIONS OF THE COUNCIL MADE UNDER SUBSECTION (B) OF THIS**
7 **SECTION.**

8 **(2) THE BOARD MAY MODIFY OR REJECT ANY RECOMMENDATION OF**
9 **THE COUNCIL REGARDING THE FORMULARY.**

10 **(D) (1) THE FORMULARY ADOPTED BY THE BOARD SHALL INCLUDE:**

11 **(I) NONPRESCRIPTION DRUGS AND DEVICES;**

12 **(II) PRESCRIPTION OXYGEN AND AUTO-INJECTABLE**
13 **EPINEPHRINE, ~~INCLUDING A PORTABLE, DISPOSABLE DRUG DELIVERY DEVICE~~**
14 **~~THAT CONTAINS A PREMEASURED SINGLE DOSE OF EPINEPHRINE THAT IS USED TO~~**
15 **~~TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION; AND~~**

16 **(III) PRESCRIPTION DIAPHRAGMS AND CERVICAL CAPS FOR**
17 **CONTRACEPTION.**

18 **(2) THE FORMULARY MAY NOT INCLUDE:**

19 **(I) EXCEPT AS PROVIDED IN PARAGRAPH (1)(II) AND (III) OF**
20 **THIS SUBSECTION, PRESCRIPTION DRUGS OR DEVICES; OR**

21 **(II) CONTROLLED SUBSTANCES.**

22 14-5F-14.

23 (a) A license authorizes a licensee, consistent with naturopathic education and
24 training and competence demonstrated by passing the naturopathic physician licensing
25 examination, to:

26 (1) Order and perform physical and laboratory examinations for diagnostic
27 purposes, including phlebotomy, clinical laboratory tests, orificial examinations,
28 electrocardiograms with over read by a cardiologist, and physiological function tests;

29 (2) Order diagnostic imaging studies and interpret the reports of diagnostic
30 imaging studies;

1 (3) Dispense or order natural medicines of mineral, animal, or botanical
2 origin, including food, extracts of food, nutraceuticals, vitamins, amino acids, minerals,
3 enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, and
4 all dietary supplements and nonprescription drugs [as defined by the federal Food, Drug,
5 and Cosmetic Act] **LISTED IN THE FORMULARY** that use various routes of administration,
6 including oral, nasal, auricular, ocular, rectal, vaginal, transdermal, and intramuscular;

7 (4) Administer natural medicines of mineral, animal, or botanical origin,
8 including food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes,
9 botanicals and their extracts, botanical medicines, homeopathic medicines, and all dietary
10 supplements and nonprescription drugs [as defined by the federal Food, Drug, and
11 Cosmetic Act] **LISTED IN THE FORMULARY** using [transdermal] **VARIOUS** routes of
12 administration, **INCLUDING ORAL, NASAL, AURICULAR, OCULAR, RECTAL, VAGINAL,**
13 **AND TRANSDERMAL, AND INTRAMUSCULAR;**

14 **(5) ADMINISTER AUTO-INJECTABLE EPINEPHRINE;**

15 ~~(5)~~ **(6)** Administer or perform hot or cold hydrotherapy, naturopathic
16 physical medicine, electromagnetic energy, and therapeutic exercise for the purpose of
17 providing basic therapeutic care services, except that if a referral to another licensed
18 provider is appropriate for ongoing rehabilitation or habilitation services, the naturopathic
19 doctor shall make the referral;

20 ~~(6)~~ **(7)** Provide health education and health counseling; and

21 ~~(7)~~ **(8)** Perform naturopathic musculoskeletal mobilization.

22 (b) A license does not authorize a licensee to:

23 (1) [Prescribe] **EXCEPT FOR A PRESCRIPTION DRUG OR DEVICE**
24 **INCLUDED IN THE FORMULARY UNDER § 14-5F-04.1(D)(1)(II) OR (III) OF THIS**
25 **SUBTITLE, PRESCRIBE, dispense, or administer any prescription drug OR DEVICE;**

26 (2) Perform surgical procedures;

27 (3) Practice or claim to practice as a medical doctor or physician, an
28 osteopath, a dentist, a podiatrist, an optometrist, a psychologist, a nurse practitioner, a
29 physician assistant, a chiropractor, a physical therapist, an acupuncturist, or any other
30 health care professional unless licensed under this article;

31 (4) Use general or spinal anesthetics;

32 (5) Administer ionizing radioactive substances for therapeutic purposes;

1 (6) Perform chiropractic adjustments or manipulations that include
2 high-velocity thrusts at or beyond the end range of normal joint motion unless the licensee
3 is also a licensed chiropractor; [or]

4 (7) Perform acupuncture unless the licensee is also a licensed
5 acupuncturist; **OR**

6 **(8) PRESCRIBE, DISPENSE, OR ADMINISTER ANY PRESCRIPTION OR**
7 **NONPRESCRIPTION DRUG OR DEVICE LISTED IN THE FORMULARY FOR COSMETIC**
8 **PURPOSES.**

9 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
10 October 1, 2016.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.