STATE OF NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER GOVERNOR

MANDY COHEN, MD, MPH SECRETARY

January 15, 2019

SENT VIA ELECTRONIC MAIL

The Honorable Josh Dobson, Co-Chair Joint Legislative Oversight Committee on Health and Human Services North Carolina General Assembly Room 301N, Legislative Office Building Raleigh, NC 27603-5925

The Honorable Donny Lambeth, Co-Chair Joint Legislative Oversight Committee on Health and Human Services North Carolina General Assembly Room 303, Legislative Office Building Raleigh, NC 27603-5925

The Honorable Joyce Krawiec, Co-Chair Joint Legislative Oversight Committee on Health and Human Services North Carolina General Assembly Room 308, Legislative Office Building Raleigh, NC 27603-5925

Dear Chairmen:

Session Law 2018-24, Section 1.(a), requires the Secretary of the Department of Health and Human Services ("Department") to convene a workgroup to study the delivery of naturopathic medicine in North Carolina. In addition, Section 1.(c) requires the workgroup to report its finding to the Joint Legislative Oversight Committee on Health and Human Services on or before January 15, 2019. Pursuant to the provisions of law, the Department is pleased to submit the attached report.

Should you have any questions, please contact Walker Wilson, Assistant Secretary for Policy, at 919-855-4800.

Sincerely, Mark T. Burlow

Mandy Cohen, MD., MPH

LT McCrimmon Matt Gross cc: Marjorie Donaldson Joyce Jones Theresa Matula Denise Thomas Susan Perry-Manning Deborah Landry Mark Collins

Dave Richard Katherine Restrepo Erin Matteson

Rod Davis Steve Owen Mark Benton

Jessica Meed

Kody Kinsley Lisa Wilks Zack Wortman

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Recommendations for Appropriate Oversight and Regulation of the Practice of Naturopathic Medicine in North Carolina

Session Law 2018-24, House Bill 277



Report to

Joint Legislative Oversight Committee on Health and Human Services

and

The Fiscal Research Division

by North Carolina Department of Health and Human Services

January 15, 2019

Response to Legislative Request

This report is in response to the General Assembly's provision included in House Bill 277, S.L. 2018-24, which reads:

SECTION 1.(a) Naturopathic medicine is a distinct health care profession that affects the public health, safety, and welfare of the State's residents. Certification of professionals practicing naturopathic medicine will aid in protecting citizens from deception, fraud, and damage to their health status. On or before September 15, 2018, the Secretary of the Department of Health and Human Services, or the Secretary's designee, shall convene a work group to study the delivery of naturopathic medicine in North Carolina. The work group shall be comprised of the following individuals: two naturopathic doctors, selected by the North Carolina Association of Naturopathic Physicians; one medical doctor, who has knowledge of the practice of naturopathic medicine, selected by the North Carolina Medical Society; the chairperson of the North Carolina Medical Board, or the chairperson's designee; and the Secretary of the Department of Health and Human Services, or the Secretary's designee.

SECTION 1.(b) The work group shall develop recommendations necessary to provide appropriate oversight and regulation of naturopathic medicine in the State of North Carolina. The work group's recommendations shall include at least the following:

- (1) Identification of an approved program of study of naturopathic medicine that provides graduate-level, full-time didactic and supervised clinical training in naturopathic medicine and is accredited by the Council on Naturopathic Medical Education or an equivalent federally recognized accrediting body for the naturopathic medical profession. The program must be offered by an institution of higher education and lead to a degree as a Doctor of Naturopathic Medicine, or equivalent.
- (2) A scope of practice for naturopathic doctors, including the extent of their responsibilities as licensed health care professionals; the extent of their ability to diagnose and treat individuals in accordance with the method, thought, and practice of naturopathic medicine and use of diagnostic techniques and therapies; and their prescriptive authority.
- (3) Whether the practice of naturopathic medicine should constitute the practice of medicine or surgery as defined in Chapter 90 of the General Statutes.

SECTION 1.(c) The work group shall report findings and recommendations to the Joint Legislative Oversight Committee on Health and Human Services on or before January 15, 2019. The report shall include findings and recommendations on the topics outlined in this section and other issues necessary to provide for the appropriate oversight and regulation of the practice of naturopathic medicine in North Carolina. Additionally, the report shall also include recommendations on appropriate fees for application, examination, certification, renewals, and late renewals, as appropriate, to cover the costs associated with oversight.

Executive Summary

The work group developed and agreed to the following recommendations. First, the work group recommends that Naturopathic Doctors with a Doctor of Naturopathy (ND) or Doctor of Naturopathic Medicine (NMD) degree through formal study, should be licensed either under their own board or as the first practice area of a combined board of allied/complimentary

practices. Second, Naturopathic Doctors should meet the minimum requirements of education enumerated herein, including training in accredited programs and passing post-graduate board examinations. Third, licensees should be qualified to independently perform a defined scope of practice, which should not be construed as the practice of medicine. Finally, it is the work group's recommendation that only persons licensed as Naturopathic Doctors in North Carolina may use the titles "Naturopathic Doctor," "Doctor of Naturopathic Medicine," "Doctor of Naturopathy," "Naturopathic Medicine," "Naturopath," "Licensed Naturopathic Doctor," or the abbreviations "N.D.", "ND," or any other titles, words, letters, abbreviations, or insignia indicating or implying that the individual is a licensed Naturopathic doctor unless the individual has been licensed as a Naturopathic Doctor. The work group believes that these recommendations for appropriate oversight and regulation of the practice of naturopathic medicine will ultimately promote public health and safety for the people of North Carolina.

Background

Naturopathic medicine is a distinct healthcare profession that encompasses modern, traditional, scientific, and empirical methods of diagnosis, treatment, and prevention. Naturopathic Doctors combine their specialty knowledge of natural therapies with the rigors of modern science, focusing on prevention and treatment of acute and chronic disease through optimal diet, healthy lifestyle, and the utilization of natural therapies. There are six fundamental principles of naturopathic medicine: 1) the healing power of nature; 2) identify and treat the causes; 3) first do no harm; 4) doctor as teacher; 5) treat the whole person; and 6) prevention. Naturopathic medicine is a specialty. Naturopathic Doctors provide optimal care and improve health outcomes when Naturopathic medicine is included in as a healthcare option and integrated into the healthcare system.

Regulation of the practice of Naturopathic medicine varies from state to state in the United States and from province to province in Canada.

States and jurisdictions that license	Alaska, Arizona, California, Connecticut, Hawaii,	
Naturopathic Doctors	Kansas, Maine, Maryland, Massachusetts,	
	Montana, New Hampshire, North Dakota,	
	Oregon, Rhode Island, Utah, Vermont,	
	Washington State, Washington DC, Puerto Rico,	
	and the Virgin Islands	
States that register Naturopathic Doctors	Colorado, Minnesota, and Pennsylvania	
as an alternative to licensure but		
essentially equivalent		
States that prohibit the practice of	South Carolina and Tennessee	
Naturopathic medicine		

Public safety is the most important aspect of licensure of Naturopathic Doctors and regulation of Naturopathic medicine. For health and safety purposes, it is imperative that the public be able to distinguish between Naturopathic Doctors and laypersons who complete an online or non-clinical training program. Licensed Naturopathic Doctors have attended Council on Naturopathic

Medical Education (CNME) accredited four-year Naturopathic medical schools and earned a Doctor of Naturopathy (ND) or Doctor of Naturopathic Medicine (NMD) doctoral-level professional degree. Laypersons may have earned a diploma, distance-learning diploma, or distance-learning degree in "naturopathy" from a non-accredited institution and have no requirement for formal, supervised clinical Naturopathic medical training. Additionally, in states without regulation of Naturopathic medicine and licensure or registration of Naturopathic Doctors, there is no title protection for Naturopathic Doctors. Therefore, in those states, a Naturopathic Doctor, who earned a doctoral degree (ND or NMD) from a CNME-accredited naturopathic medical school and a layperson not licensed to practice Naturopathic medicine with an online diploma from a non-accredited institution can both use "ND" or "NMD" as initials after their name. In states with licensure or registration of Naturopathic Doctors and regulation of Naturopathic medicine, there is title protection for the use of "NMD" or "ND" after a person's name. The national standard is that these titles are restricted to Naturopathic Doctors who have earned an NMD or ND degree from a CNME-accredited Naturopathic medical school.

Public Health and Safety

In states where Naturopathic Doctors are licensed, the practice of Naturopathic Medicine is regulated and individuals without formal CNME accredited training cannot claim to be a Naturopathic Doctor. In these states, the events of harm from those attempting to practice without proper credentials are rare. In response to inquiries conducted by the NCANP, regulatory authorities in Maine, Oregon, and Arizona have responded that there are no known incidences or complaints of individuals making such claims in those states.

Naturopathic Medicine is an unregulated healthcare profession in North Carolina, and as such, the state is attracting large numbers of individuals without clinical, hands-on training claiming to be Naturopathic Doctors. Because these individuals lack formal, supervised training, they jeopardize patients' health and safety and have already negatively impacted public health in the state. North Carolinians who seek natural and integrative medicine are being subjected to fraud, abuse, harm and even death because there is no regulation of Naturopathic Medicine in North Carolina. There have been two known deaths in the state resulting from treatment by individuals claiming to be Naturopathic Doctors but possessing no formal Naturopathic medical education and training.

In 1999, an 8-year-old type 1 diabetic girl was harmed by an individual who held himself out to be a Naturopathic Doctor but was unqualified and not trained in Naturopathic medicine. He told the child's mother that the young girl was not diabetic, but rather had a viral infection and her "system could be cleansed" to make her well. The mother was instructed to stop giving her daughter insulin, and the 8-year-old tragically died at Mission Hospital in Buncombe County several days later in a diabetic coma. Fortunately, the individual was prosecuted and given a 12-to 15-month prison sentence; however, he later returned to practice in Henderson County until his death. The tragic and senseless death of this young girl is a clear example of the importance of regulation of a health care profession.

Licensure of Naturopathic Doctors by North Carolina law would have deterred this individual from practicing Naturopathic medicine with no formal training. The child's parents would have been able to see that he was not licensed by any regulatory authority and making a false claim to having clinical, professionally recognized training in Naturopathic medicine; and an oversight regulatory authority could have intervened and kept the individual from "practicing medicine," then likely this tragedy would have been prevented.

The second known death was in 2012 of a 43-year-old mother of two children who died from treatment for breast cancer by an herb store owner who practiced as a Naturopathic Doctor but had no formal, accredited training from a CNME recognized program. The individual convinced the patient to forgo conventional cancer treatment and to use his herbs and "miracle water" instead. Because he claimed to be a "Doctor," the woman trusted his advice. As there is no regulatory authority overseeing the practice of Naturopathic Medicine in North Carolina, there was no oversight of the claims being made by the herb store owner and the woman's family had no recourse rights through a regulatory Board.

The North Carolina Association of Naturopathic Physicians estimates there are 85 to 100 individuals without formal, accredited Naturopathic medical training practicing in North Carolina as "naturopathic providers." These individuals often claim to be "licensed" by the State of North Carolina through an entity identified as the "North Carolina Board of Naturopathic Examiners." In addition, many of these individuals carry "licenses" provided by the "American Naturopathic Medical Association," a private credentialing company located in Nevada. Neither the "North Carolina Board of Naturopathic Examiners" nor the "American Naturopathic Medical Association" has been granted regulatory authority by any state or the federal government.

Today there are approximately 40 Naturopathic Doctors practicing in North Carolina who are graduates of 4-year, in-residence, full-time, nationally and regionally accredited Naturopathic medical schools recognized by the US Department of Education. These doctors have passed rigorous post-doctoral board examinations administered by the North American Board of Naturopathic Examiners (NABNE) and all but one of those providers hold valid Naturopathic medical licenses from one of the 23 states and/or jurisdictions that currently regulate the practice of Naturopathic Medicine. However, without a regulatory authority in North Carolina and without a license to practice Naturopathic Medicine in this state, these doctors cannot practice to the full extent of their education and training. Without licensure Naturopathic Doctors are prevented from ordering blood labs, PAP smears, x-rays, ultrasounds, and many other diagnostic tests which are important for a full assessment of the patient's health. These tests are often critical to make a proper diagnosis for their presenting condition. Additionally, without licensure there is often barriers to work within the medical community as an integrated team for the optimal benefit of all patients.

The lack of regulation and licensure of Naturopathic Medicine in North Carolina allows untrained individuals to potentially harm the public and simultaneously prevents Naturopathic Doctors with formal medical training from fully utilizing their training which can improve the public health of North Carolina. It is the position of the work group that the passage of licensure

legislation will benefit the citizens of North Carolina by allowing them to enjoy the full benefit of healthcare options provided by qualified Naturopathic Doctors while also being protected from risk of the harm inflicted by individuals not qualified to provide such care. There was agreement among work group members that licensure based upon national standards of education and board examination and regulated by a duly sanctioned board is indeed an effective deterrent.

Work Group Members

The work group was comprised of five members:

Dr. Arthur Apolinario, MD, MPH,	Appointed by and represented the North Carolina
FAAFP	Medical Society and currently serves on the NCMS
	Board of Directors
Shawn Parker, JD, MPA	Designee of NCMB President Timothy Lietz, MD
	and current NCMB Board Member
Dr. Amy Hawkins, ND	Appointed by and represented the North Carolina
	Association of Naturopathic Physicians and currently
	serves as its current President
Dr. Susan Delaney, ND,	Appointed by and represented the North Carolina
	Association of Naturopathic Physicians and currently
	serves as its Legislative Chair
Walker Wilson, MPH	Designated by Secretary Mandy Cohen, MD to serve
	on behalf of DHHS and as the work group
	Chairperson

The work group convened September 4, 2018 and held two additional meetings on October 16, 2018 and November 27, 2018, and one conference call on December 18, 2018.

Recommendations for Approved Program of Study and Requirements for Licensure

The current lack of regulation of naturopathy in North Carolina may be creating consumer confusion and risk to public health in the state of North Carolina. The work group believes the public needs to be able to distinguish between the education and training of a provider who has obtained a doctoral degree from an accredited Naturopathic medical program and someone who has not. Without being able to make such distinctions, individuals may seek healthcare from a layperson not licensed to be a Naturopathic Doctor.

Therefore, the work group recommends a qualification for licensure include completion of an approved program of study that meets all the following conditions:

1. A program that provides graduate-level, full-time didactic and supervised clinical training in naturopathic medicine that is accredited, or has achieved candidacy status for accreditation, by the Council on Naturopathic Medical Education (CNME) or an equivalent federally recognized accrediting body for the Naturopathic medical profession. If the program existed prior to the existence of the CNME, the program must have (i) provided graduate-level, full-time didactic and supervised clinical training in naturopathic

medicine for a duration of not less than 132 weeks and required completion within a period of not less than 35 months, (ii) be recognized as a reputable program by, and in good standing with, CNME, and (iii) if the program is still in existence, be currently accredited, or have achieved candidacy status for accreditation, by the CNME or an equivalent federally recognized accrediting body for the naturopathic medical profession.

- 2. A program that is offered by an institution of higher education that is accredited by a regional or national institutional accrediting body recognized by the Secretary of the United States Department of Education.
- 3. If the program is offered in the United States, a program that awards the degree of Doctor of Naturopathy or Doctor of Naturopathic Medicine. If the program is offered in Canada, a program that awards the degree or diploma of Doctor of Naturopathy or Doctor of Naturopathic Medicine and is offered by an institution of higher education that has provincial approval for participation in government-funded student aid programs.

Additionally, the work group recommends the following requirements to be licensed as a Naturopathic Doctor in North Carolina:

- 1. Good moral and ethical character.
- 2. Graduate of an approved program of Naturopathic medicine as defined above.
- 3. Meet one, or both, of the following two conditions:
 - a. Has successfully passed the Naturopathic Physicians Licensing Examination (NPLEX), a competency-based national naturopathic licensing examination administered by the North American Board of Naturopathic Examiners or an equivalent successor agency.
 - b. Has successfully passed a competency-based state or Canadian province naturopathic licensing examination administered prior to the existence of NPLEX.
- 4. Provide a satisfactory criminal background report as provided by the State Bureau of Investigations. If the applicant has been a resident of this State for less than five years, the applicant shall provide a satisfactory criminal background report from both the State and National Repositories of Criminal Histories.
- 5. Completion and submission to the regulatory board of a board-approved written attestation that states the applicant for licensure has a collaboration and consultation agreement with a physician licensed by NCMB. The work group's recommendation is not to be construed as a requirement for supervision of Naturopathic Doctors by any other healthcare professional.

Recommendations for Scope of Practice

Public health and safety are the most important considerations of the scope of practice in any jurisdiction. Like all healthcare providers, having an appropriate scope of practice that accurately reflects the extent and degree of training allows for the delivery of safe and effective care.

The work group recommends a Naturopathic Doctor be a licensed healthcare provider having the same responsibilities as other licensed or registered healthcare providers regarding public health laws, reportable diseases and conditions, communicable disease control and prevention, and the recording of vital statistics. In diagnosing and treating an individual, the work group

recommends that a Naturopathic Doctor may employ the following therapies, modalities, procedures, or remedies consistent with Naturopathic education and training:

1. Dispense, administer, order, and advise the use of natural remedies derived from or substantially similar in molecular structure or function to natural sources for preventive and therapeutic purposes, including food, extracts of food, nutraceuticals, vitamins, minerals, amino acids, enzymes, botanicals and their extracts, homeopathic remedies prepared according to the Homeopathic Pharmacopoeia of the United States, and all dietary supplements and nonprescription drugs as defined by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq.

The work group further recommends creation of a Naturopathic Doctors Formulary Council within the regulatory board that is tasked with ongoing development and recommendation to the regulatory board a formulary for use by Naturopathic Doctors. The Council should be comprised of two licensed Naturopathic Doctors, two licensed physicians one pharmacist, and one consumer. The work group's intention with this recommendation is to ensure that Naturopathic Doctors are not restricted if a natural remedy or a remedy derived from or substantially similar in molecular structure or function to natural sources becomes a prescription drug. These substances are currently allowed within the scope of practice and should be protected within the future scope of practice for Naturopathic Doctors.

- 2. Order and perform physical examinations and physiological function tests.
- 3. Order, perform, and interpret laboratory tests, including performing waived tests as defined by the United States Food and Drug Administration Clinical Laboratory Improvement Amendments of 1998 (CLIA), including obtaining specimens to assess and treat disease.
- 4. Order diagnostic imaging, including X-ray, MRI, CT scan, ultrasound, mammogram, and bone densitometry. Scope excludes electrocardiograms, echocardiograms, electroencephalograms, and nuclear imaging.
- 5. Perform hot or cold hydrotherapy, naturopathic physical medicine, electromagnetic therapy, and therapeutic exercise.
- 6. Perform health education and health counseling, including dietary and lifestyle counseling.
- 7. Utilize routes of administration for substances, including oral, nasal, auricular, ocular, rectal, vaginal, and transdermal.
- 8. Perform care incidental to superficial lacerations and abrasions, including the application of topical and local anesthetics and antimicrobials.

The work group also recommends that a Naturopathic Doctor may not perform any of the following functions unless otherwise licensed by this State to do so:

- 1. Prescribe, dispense, or administer any prescription drug or controlled substance, except as authorized by this Article.
- 2. Use general or spinal anesthetics.
- 3. Perform surgical procedures.
- 4. Administer ionizing radioactive substances for therapeutic purposes.
- 5. Child delivery.

6. Diagnose and treat cancer. Prohibition does not apply to adjunctive/complementary care of patients who have previously been or are currently diagnosed with cancer.

Recommendations as to whether the Practice of Naturopathic Medicine Constitutes the Practice of Medicine or Surgery per Chapter 90 of the General Statues

The work group reviewed and discussed the statutory definition of medicine and believe the modalities, procedures, and remedies employed by a licensed Naturopathic Doctor in his or her performance within the scope of practice described above could be construed to be the practice of medicine or surgery as defined in Article 1 of Chapter 90. As such, the work group recommends including the licensed practice of Naturopathic medicine within the statutory exceptions to the practice of medicine or surgery found in North Carolina General Statute 90-18(c).

Recommendations on Licensure and Regulatory Oversight

The work group strongly recommends regulation of Naturopathic Medicine and licensure of Naturopathic Doctors in North Carolina. The work group acknowledges that licensure legislation has been introduced in every legislative session for over 18 years without enactment and wishes to communicate consensus that licensure is in the best interest of public health in North Carolina.

The work group reviewed and discussed three options for regulatory oversight of Naturopathic medicine in North Carolina and recommends Option 1 below.

Option 1: Regulatory oversight provided by an independent North Carolina Naturopathic Medicine Licensing Board.

In this model of regulatory oversight, an independent Naturopathic licensing board would be created which would be self-governing and self-sustaining. This regulatory structure is used for most of the healthcare professions in North Carolina. Currently, this regulatory structure is used in 12 jurisdictions: Arizona, California, Connecticut, Hawaii, Massachusetts, New Hampshire, Oregon, Rhode Island, Utah, Washington, Puerto Rico, and the US Virgin Islands.

Due to the large number of existing licensing boards in North Carolina, the work group acknowledges that creation of a new professional licensing board possibly would not be a favorable option to some members of the North Carolina General Assembly. However, the work group recognizes the need for passage of licensure legislation and recommends an independent licensing board, the well-established successful model in 12 jurisdictions and the model for other healthcare professions in North Carolina. The work group also acknowledges that the small numbers of Naturopathic Doctors that would be eligible for licensure in North Carolina may generate concerns regarding the sustainability of an independent board. It is the work group's opinion that the fees outlined in the section covering fees will allow an independent board to be self-sustaining. The group's opinion recognizes that licensure will attract new Naturopathic Doctors to the state and the number of licensees will grow. Note: For these reasons, the work group recommends an independent Naturopathic licensing board and views this structure as the most direct route to regulation and licensure of Naturopathic Doctors in North Carolina.

Option 2: Regulatory oversight provided by a North Carolina Board of Healing Arts.

In this model of regulatory oversight, North Carolina State Board of Healing Arts would be created which would be self-governing and self-sustaining. This Board would initially provide regulatory oversight and licensure for Naturopathic medicine and Naturopathic Doctors. However, in the future, the Board of Healing Arts could provide a regulatory home for other licensed allied/complementary healthcare professions in North Carolina. Currently, this regulatory structure is used in Kansas, Maine, Montana, and North Dakota. The work group recognizes the benefits of autonomy, appropriate professional oversight, and shared resources with an independent Board of Healing Arts and recommends this regulatory structure as a secondary option.

The work group acknowledges that this regulatory structure may be more amenable to overall legislative goals of reducing the number of professional licensing boards in North Carolina. The work group also recommends that each allied healthcare profession regulated by the Board of Healing Arts have its own Advisory Committee, which reports to the Board on matters pertaining to that allied healthcare profession.

Option 3: Regulatory oversight provided by the North Carolina Medical Board (NCMB) assisted by a North Carolina Naturopathic Doctors Licensure Advisory Committee serving within and reporting to the North Carolina Medical Board.

In this model of regulatory oversight, the Advisory Committee would conduct the business of regulating providers and issuing licenses to Naturopathic Doctors who meet the criteria for licensure in North Carolina. The Advisory Committee would report to the NCMB and no action taken by the Committee would be effective unless approved by the NCMB. Currently, this structure of regulation is used in 4 jurisdictions: Maryland, Minnesota, Pennsylvania, and the District of Columbia.

This option provides the primary benefit of regulation under an already established Board. The work group does not recommend this option if Naturopathic medicine is limited to the scope of practice outlined in this report, and collaborative agreements are formed with physicians licensed by the NCMB. Given this, it is not necessary for the regulatory oversight of Naturopathic Doctors to be under the North Carolina Medical Board, and oversight by its own board, or a Healing Arts Board would still be adequate to provide for the safety of our citizens and the maintenance of professionalism within the group.

Recommendations on Fees to Cover Cost Associated with Oversight

As a basis for determining fees to cover cost associated with oversight, the work group reviewed current fees under all healthcare professional licensing boards in North Carolina. It is the work group's recommendation that fees should be comparable to other licensing boards and recommends the following reasonable fees for licensure of Naturopathic Doctors.

1.	Application and examination	\$200.00
2.	License	\$300.00
3.	License renewal	\$350.00
4.	Late renewal	\$200.00
5.	Reinstatement	\$1,000.00

- 6. Reasonable charges for duplication services and material.7. Criminal history record check fee equal to the amount imposed by the Department of Justice to conduct the criminal history record check requested by the Board.