

From: Dr.Richard Malik <doctor@maliknd.com>
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To: PHC Testimony
Subject: Richard Malik, ND Testimony Documents
Attachments: CT ND Scope Testimony, Malik, Richard.pdf; VT Report on Prescriptive Authority for Naturopathic Physicians.pdf; ADMINISTRATIVE RULES FOR NATUROPATHIC PHYSICIANS.pdf

Dear Sir or Madame:

I will be testifying to the Public Health Committee on the modernization and expansion of the scope for naturopathic doctors in Connecticut.

I submit these documents for my testimony to the Public Health Committee on March 14, 2014

Richard Malik, ND

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Friday, March 14, 2014

Testimony to the Connecticut Public Health Committee

Richard Malik, ND

I am Richard Malik, a naturopathic physician with a full-time practice in Salisbury Connecticut which is in the northwest corner of the state and a part-time practice in Manchester Center, Vermont. I started my Connecticut practice in 2006 and my Vermont practice in 2010.

This scope of practice for naturopathic physicians in Vermont is broader than our scope of practice in Connecticut.

Currently, all Vermont naturopathic physicians can prescribe from a limited formulary that includes many classes of legend drugs.

Antibiotics that all Vermont naturopaths can prescribe include like:

- amoxicillin (commonly used for upper respiratory tract infections) and other penicillins,
- tetracyclines including doxycycline (commonly used for Lyme Disease),
- macrolides including Azithromycin (commonly used for pneumonia), and
- Bactrim (commonly used for urinary tract infections).

The current Vermont scope of practice also includes:

- drugs for treating gastrointestinal parasitic infections including metronidazole
- hydrochlorothiazide for treating elevated blood pressure
- statin medications for treating elevated cholesterol
- thyroid hormones for treating hypothyroidism
- antiviral agents for treating shingles
- short-acting and long-acting agents for treating asthma
- prednisone for treating acute allergic reactions
- oral contraceptive pills

I regularly prescribe these medications for patients in my Vermont practice.

Vermont naturopathic physicians have been able to prescribe prescription medications since 1996 and, due to our safety record, the formulary has been expanded in 1998, 2008, 2011, and again in 2014.

The most recent expansion of the formulary is a sea change in the approach Vermont uses to regulate naturopathic physicians. It will take effect later this year. Instead of listing medications Vermont naturopaths can prescribe, the Vermont Office of Professional Regulation and Dr. Harry Chen, the Director of the Vermont Department of Public Health, have decided that naturopaths should be regulated like other healthcare providers and be able to prescribe from the complete formulary of prescription medications to the extent a physician's training and experience allows. In order to

qualify for this vastly expanded prescriptive authority, Vermont naturopaths must do two things:

- pass a pharmacology examination that is accepted by the Office of Professional Regulation and
- their prescriptions are to be supervised for at least one year by an objective, independent supervising Vermont licensed physician with at least 5 years experience with full prescriptive authority (see Administrative Rules for Naturopathic Physicians).

The impetus behind this change in Vermont did NOT come from Vermont naturopathic doctors, but from Dr. Chen, the Director of the Vermont Department of Public Health and the Office of Professional Regulation who submitted a report on the training and safety of naturopathic physicians to Vermont legislative committees. Legislation was proposed and passed both houses of the Vermont legislature and was signed into law by Peter Shumlin, the Governor of Vermont on July 1, 2013.



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Christopher D. Winters, Director

To: Senate and House Committees on Government Operations

From: Christopher D. Winters, Director, Office of Professional Regulation 

Date: February 5, 2013

Re: Prescriptive Authority for Naturopathic Physicians

Last year, Act 116, Section 64 required the Director of the Office of Professional Regulation to prepare a report on the education and clinical training of Naturopathic Physicians as follows:

By January 31, 2013 and prior to the adoption of the rules required by Sec. 60, 26 V.S.A. § 4125(d) of this act, regarding the regulation of a special license endorsement which shall authorize a naturopathic physician to prescribe, dispense, and administer prescription medicines, the director of the office of professional regulation, in consultation with the commissioner of health, pharmacologists, and clinical pharmacists, shall review and prepare a report on the education and clinical training of naturopathic physicians in order to determine whether naturopathic physicians receive sufficient academic training in pharmacology and clinical training in using all prescription drugs to safely:

- (A) prescribe and administer without limitation all prescription drugs;
 - (B) prescribe all controlled substances on schedules II through IV;
 - (C) prescribe all prescription drugs for both FDA-approved label indications and for off-label uses; and
 - (D) administer all prescription drugs by all routes of administration, including oral, topical, transdermal, transmucosal, intravenous, and intramuscular.
- (2) Representatives of the University of Vermont College of Medicine and naturopathic physician medical colleges shall have an opportunity to review and comment on the draft report.
- (3) The report shall recommend any limitations or conditions on the authority of naturopathic physicians to prescribe and administer prescription drugs that are found to be necessary to ensure consistency with the scope of the naturopathic physicians' education and clinical training.

There are many excellent naturopathic physicians for whom these safeguards may be unnecessary. However, in the interest of moving forward in a manner that should satisfy the concerns of all interested parties, this report includes a conservative approach to Naturopathic Physician prescribing that errs on the side of public protection.

Report on the Education and Clinical Training of Naturopathic Physicians (Act 116)

Background

In Vermont, the naturopathic profession has grown and evolved in recent years. Vermont law now requires a health insurance plan to provide coverage for medically necessary health care services covered by the plan when provided by a naturopathic physician licensed in Vermont for treatment within a naturopathic physician's scope of practice. *See 8 V.S.A. §4088d(a)*. Moreover, Vermont law now recognizes naturopathic physicians who practice primary care to be primary care physicians. *Id.*

As the naturopathic profession has evolved, the ability to prescribe primary care pharmaceuticals has become essential to the practice of naturopathic medicine in order to allow naturopathic physicians to meet patient demand, provide the most effective health care for their patients, and fulfill their role in Vermont as primary care physicians. Although naturopathic physicians try to minimize the use of pharmaceuticals by utilizing natural medicines to support the innate self-healing ability of the patient, there will be cases where it is in the best interests of the patient in a primary care setting to prescribe a pharmaceutical when doing so falls within a the scope of a naturopathic physician's education and clinical training.

As a result, in 2012, the Vermont Legislature passed Act No. 116, which revised the law relating to the prescribing authority of naturopathic physicians. The law creates a special license endorsement which shall authorize a naturopathic physician to prescribe, dispense, and administer prescription medicines. The special license endorsement will be available to those who successfully pass a naturopathic pharmacology examination, which shall be established and made available by July 1, 2013.

Prior to the establishment of the naturopathic pharmacology examination, and no later than January 1, 2013, Section 64 of Act 116 compels the Director of the Office of Professional Regulation to prepare a report on the adequacy of naturopathic education and clinical training in order to determine whether naturopathic physicians receive sufficient academic training in pharmacology and clinical training to safely prescribe prescription drugs by all routes of administration, including controlled substances on schedules II through IV, for both FDA-approved label indications and for off-label use prescription drugs. The report is required to recommend any limitations or conditions on the authority of a naturopathic physician to prescribe that are necessary to ensure consistency with the scope of their education and clinical training. This paper is the Director's report pursuant to Section 64.

Section 60 of Act 116 further requires that the Director, in consultation and consistent with the recommendations of the Commissioner of Health, adopt rules regulating the special license endorsement that are consistent with the findings in the report. The rules shall require a

naturopathic physician to pass a naturopathic pharmacology examination in order to obtain this special license endorsement.

Finally, it is important to note at the outset that this new law authorizes a naturopathic physician to prescribe, dispense, and administer prescription medicines *within a naturopathic physician's scope of practice*. Accordingly, this law does not open the floodgates and authorize an individual naturopathic physician to prescribe all pharmaceuticals. To the contrary, it has long been the law in Vermont that it is unprofessional conduct for a naturopathic physician to perform treatments or provide services "which are beyond the scope of the licensee's education, training, capabilities, experience or scope of practice." 3 V.S.A. §129a(a)(13). Accordingly, granting naturopathic physicians the authority to prescribe starts with the most fundamental limitation or condition on that authority which is that the prescription must be consistent with the scope of their education and clinical training. To ensure consistency with the scope of their education and clinical training, this report recommends further limitations and conditions on the authority of a naturopathic physician to prescribe.

Education and Training

The Council on Naturopathic Medical Education ("CNME") was founded in 1978 and is the accepted programmatic accrediting agency for naturopathic medical education by the four-year naturopathic colleges and programs in the United States and Canada and is recognized by U.S. Department of Education. CNME requires and advocates high standards in naturopathic education, and its grant of accreditation to a program indicates prospective students and the public may have confidence in the educational quality of the program.

In all regulated U.S. and Canadian jurisdictions, including Vermont, naturopathic physicians ("NDs") are required to graduate from a college which is accredited by the CNME. In these accredited programs, NDs are broadly trained in the pre-clinical sciences and the clinical disciplines, with an emphasis on health promotion, disease prevention, and treatment based on the stimulation or support of natural processes. NDs are educated in all of the same basic sciences and clinical diagnostic methods at the same level as medical and osteopathic doctors, followed by two years of clinical training and systems based medicine. *Kreutzer MJ, et al. Health Professions Education and Integrative Health Care. Commissioned for the IOM Summit on Integrative Medicine and the Health of the Public. February, 2009.* Their clinical education is designed to prepare them to be primary care providers. *JAMA. 1998; 280(9):795-802.* In addition to a standard medical curriculum, naturopathic physicians also study holistic approaches to therapy with a strong emphasis on disease prevention and optimizing wellness.

CNME does not set specific standards for naturopathic pharmacology education. Similarly, the Commission on Osteopathic College Accreditation, recognized by the U.S. Department of Education to accredit colleges of osteopathic medicine, does not have specific guidelines for osteopathic pharmacology education. Likewise, for allopathic medicine education, the Liaison Committee on Medical Education does not have specific guidelines for allopathic pharmacology education. In all three professions, schools set the pharmacology curriculum.

Table 1: Comparison of Basic Science Education for Different Physician Types

	Allopathic MD	Osteopathic DO	Naturopathic ND
Anatomy	380	362	350
Physiology	125	126	250
Biochemistry	109	103	125
Pharmacology	114	108	100
Pathology	166	152	125
Microbiology/ Immunology	185	125	175

Jenson, C.B., Common Paths in Medical Education. Alternative & Complementary Therapies, Aug. 1997.

A recent comparison of the basic science education of naturopathic medical students at Bastyr University and allopathic medical students at the University of Washington showed a nearly identical credit load with 5 credit hours in pharmacology at Bastyr and 8 credit hours at UW. *Association of Accredited Naturopathic Colleges, <http://www.aanmc.org/education/comparing-nd-md-curricula.php>.*

For a detailed review of specific pharmacology programs at several naturopathic medicine schools, please see Appendix A attached hereto.

Above and beyond the basic academic and clinical training of naturopathic physicians, training and experience varies between individual naturopathic physicians due to specialization in different areas of medicine. Specialty organizations include the Oncology Association of Naturopathic Physicians, the American Association of Naturopathic Midwives, the Naturopathic Association of Environmental Medicine, the Institute of Naturopathic Generative Medicine, and the Pediatric Association of Naturopathic Physicians.

Finally, in addition to graduating from a college which is accredited by the CNME, many naturopathic physicians complete 1 or 2 year residency program at a school clinic. Some naturopathic physicians have completed residencies in conventional programs accredited by recognized professional organizations such as the American Academy of Cardiology.

Licensing

Naturopathic physicians take a rigorous professional board examination termed the Naturopathic Physicians Licensing Exam (NPLEX). This exam is nationally recognized as the standard for licensing NDs. Since its creation in 1986, NPLEX has followed the standards for examination development and scoring set by the National Board of Medical Examiners, the National Board of Osteopathic Medical Examiners, and the American Educational Research Association.

NPLEX has undertaken psychometric evaluation of all aspects of its examination, trained

more than 100 naturopathic physicians and basic science faculty (PhDs) in item writing techniques, used the expertise of physician level reviewers to ensure relevance and quality, used trained raters and standard criterion-referenced methods to set the passing scores on all examinations, and conducted studies to assess the test's validity.

The pharmacology portion of the NPLEX assesses knowledge of prescription drugs to ensure that entry level NDs can safely treat patients who have been prescribed drugs by other practitioners. Passage of the NPLEX Part II - Core Clinical Science Examination requires that the entry-level ND know:

1. the pharmacology of commonly prescribed drugs;
2. the primary actions, adverse effects, indications, contraindications, and potential interactions with botanical medicines, nutritional supplements, and other drugs;
3. the natural therapeutic interventions that have effects similar to commonly prescribed pharmaceuticals; and
4. how to monitor and assess for therapeutic drug levels and toxicity.

Safety Record

The safety records of NDs in states with licensure are typically better than those of MDs and DOs in these states. In 2006, the California Bureau of Naturopathic Medicine contacted the licensing agencies in states that allow NDs to prescribe. None of the states reported any patient harm or disciplinary action due to ND prescribing, nor were there any civil actions against NDs for prescribing.

The Bureau also contacted the NCMIC Insurance Company, which insures NDs in all licensing states, as well as all the naturopathic medical schools. In a letter dated June 7, 2006, NCMIC stated: "In the five years that NCMIC has been insuring Naturopathic Physicians and the colleges, we have never opened a claim against a Naturopathic Physician involving prescription medications."

Additionally, the Bureau contacted Jury Verdicts Northwest (JVN) to see if there were any civil actions filed against licensed NDs. JVN covers both Oregon and Washington, the two states with the greatest number of NDs and the longest histories of licensure (since 1919 and 1927, respectively). JVN found no cases against NDs for prescription negligence, and added that, "for that matter our database contained no cases against naturopaths at all."

The safety record of naturopathic physicians regarding pharmacologic substances is well demonstrated in the northwest where NDs have broad prescriptive authority. Jury Verdicts Northwest, a legal database which records court cases in Washington and Oregon, the area of the country with the largest number of naturopathic physicians, shows no judgments for malpractice

against N.D.s since the database was started in 1983 through 2010.

In Vermont, there has been only one complaint to OPR regarding a prescription by an ND.

Recommendations

Naturopathic physicians complete a four year post-graduate education that includes clinical pharmacology training to prepare them for prescribing medications commonly used in general and primary care practice. Didactic training in the uses of pharmaceuticals varies from college to college and ranges from sufficient to wanting. The Naturopathic Board Examination (NPLEX) tests for pharmacological knowledge but focuses on drug interactions and side effects and *not on dosing and safe, effective prescribing*. Some naturopathic programs have clinical training in prescribing medications through all routes of administration *and some do not*.

Due to the variations in both classroom and clinical training related to prescribing medications at the various naturopathic colleges, I am making the following three recommendations that will address the naturopath who has received the most limited training in pharmaceutical medications:

1. A Pharmacology Examination

In order to ensure a consistent and adequate knowledge base in prescribing medications safely and effectively, the naturopathic pharmacology examination, the passage of which will be required for the special prescriptive license endorsement, shall be the examinations given in the Medical Pharmacology course taught within the Department of Pharmacology through Continuing Medical Education at UVM's College of Medicine, *or a substantially equivalent course* approved by the Director, after consultation with the Commissioner of Health. The UVM College of Medicine course is a four-week, intensive pharmacology course taught every June that synthesizes medical school pharmacology. Because the course is offered by Continuing Education at UVM, it is open to non-matriculated students. It is typically populated by medical students from throughout North America who wish to gain pharmacology course credits or who wish to prepare for their board exams. There are several segmented exams during the course. In order to obtain the special license endorsement, an otherwise qualified naturopathic physician will be required to pass all of the Medical Pharmacology course exams at UVM, or the examination(s) given in a substantially equivalent course approved by the Director, after consultation with the Commissioner of Health. I will propose administrative rules that will establish the UVM Medical Pharmacology course exams as pre-approved for those seeking the special license endorsement and also a process for an applicant/petitioner to seek approval for a substantially equivalent examination associated with another school, college or university pharmacology course.

2. A Period of Prescription Review for New Practitioners

I will propose a rule requiring a prescription review process for a period of not less than 1 year by another physician (MD, DO, ND) in good standing who has been prescribing for five years or

more in Vermont. The rule will establish adequate supervision standards and requirements.

3. Prescribing Scope of Practice

The current Vermont Naturopathic Formulary includes FDA approved indications, routes and dose regimens as well as, "off-label" indications, routes and dose regimens that may be prescribed for patients and conditions the naturopathic physician is competent to treat based on that physician's training and experience. I will propose rules requiring that this continue to be followed.

While there will be those naturopaths who have received adequate training who will also be required to meet the more stringent requirements, I believe that a conservative approach will best protect the public.

APPENDIX A

PHARMACOLOGY EDUCATION AT NATUROPATHIC MEDICINE PROGRAMS

1. Boucher Institute of Naturopathic Medicine (BINM), Vancouver, BC, Canada

At BINM, students are given didactic introduction on the principles behind administration via enteral routes (oral, sublingual, rectal) and parenteral routes (IV, IM, subcutaneous), as well as by inhalation, intranasal, topical, and transdermal administration. Students also receive introductory education on the indications for administration of anesthetic medications including topical, infiltration, nerve block, IV regional, spinal, and epidural.

Emergency intravenous administration is covered in the Emergency Medicine course. A separate certification must be taken outside of the BINM program in order to be certified to administer intravenous therapies.

Students receive practical training on the all routes of administration of natural medicines with the exception of intravenous during their clinic training. The pharmacology of some controlled substances is covered in the program including opiates, amphetamines, benzodiazepines, etc. Further training in prescription of pharmaceutical substances must be taken following graduation in order for ND's to receive prescriptive rights in British Columbia. Therefore, students do not actually prescribe or administer pharmaceuticals during their clinical training. Instead, students learn about pharmaceutical prescribing in a mentored environment under the direct supervision of licensed naturopathic physicians. Clinical supervisors with prescriptive rights write prescriptions for patients in the teaching clinic as part of a full naturopathic assessment, work-up and plan which involves the students. Students are expected to research the medications that their patients are taking in order to understand potential nutrient deficiencies, side effects, contraindications and interaction with other pharmaceuticals. Students are also expected to understand interactions between pharmaceuticals as well as between a pharmaceutical and a botanical/nutraceutical product.

2. Canadian College of Naturopathic Medicine (CCNM), Toronto, Ontario, Canada

At CCNM, the ND four-year program of study consists of over 3000 hours of classroom training and more than 1200 hours of clinical experience. Naturopathic students at CCNM receive in-depth training and education in pharmacology, diagnosis and herb-drug and dietary-drug interactions.

Learning outcomes throughout CCNM's extensive four year curricula are taught to naturopathic students to enable them to competently prescribe pharmacologic agents used in primary care practice. In addition to being provided with a scientific foundation as well as specific training in pharmacology, students are educated in the prescribing competencies recently developed by the National Prescribing Service, a not-for profit organization funded by the Australian Government Department of Health and Ageing. These include obtaining full

knowledge of a patient's condition by understanding their clinical needs, conducting differential diagnoses, understanding and collaborating on treatment options and conducting follow-up treatment.

In addition to taking a 70-hour course devoted to pharmacology, students are also taught about food/drug interactions in clinical nutrition courses as well as the effective and safe therapeutic use of botanicals in botanical medicine courses. Students are also required to take the courses in specialty areas of medicine which incorporate prescribing competencies: Primary Care, Emergency Medicine, Clinical Nutrition, Botanical Medicine, In-Office Procedures I, Pediatrics, Maternal and Newborn Care and Men's and Women's Health. The Primary Care course integrates previously learned competencies into the third year program by increasing students' knowledge of first-line pharmacotherapy, current guidelines and best practices. This course also investigates how to critically evaluate therapeutic options through evidence-based risk-benefit assessment, modifiable disease factors and harm reduction in clinical practice.

Finally, during their fourth year of study, students practice the clinical skills they have learned under the direction of a licensed ND, while completing a twelve-month clinical internship at the Robert Schad Naturopathic Clinic and at five satellite clinics in Community Health Centers in Toronto. All students undergo a thorough assessment of their clinical skills throughout their internship. In addition, intramuscular routes of administration are taught in the In-Office Procedures course in the third year. To support this learning, in the fourth year as a clinical intern, students are expected to have 5 shifts as a Duty Intern – where they are assigned to be in the lab. It is there and in clinic that they practice their skills in IM. The In-Office Procedures I course accounts for approximately 67.5 hours. Duty Intern hours in clinic are a minimum of 30 hours.

The ability to provide intravenous treatment in Ontario is only allowable after one registers as an ND and passes the parenteral exam. IV therapy is available, however, at the school's teaching clinic, so students get first-hand observation of IV therapies as performed by licensed naturopathic doctors.

3. National College of Naturopathic Medicine (NCNM), Portland, OR

The pharmacology course is taught by an MD/ ND and utilizes a format whereby the basic principles of pharmacology are taught. These principles include the main clinical indications, main mechanisms of action, and the chief side effects for prototypical drugs of the major contemporary drug categories. The main emphasis of lecture material is on the clinical applications of these drugs. The relative advantages and disadvantages of the drugs presented in class are discussed.

Students are taught the major drug classes commonly in use today. Prototypical medications from these drug classes are discussed at each lecture. Lecture material focuses on the clinical indication for use of these drugs, their chief mechanisms of action and their major side effect profiles. The current drugs of choice for their respective indications are reviewed. At

the end of the course, the student is expected to be able to predict the chief therapeutic effects and the chief side effects of the drugs within the major drug classes that are most commonly utilized today.

In addition to the basic pharmaceutical courses, within each specialty course (cardiology, gastroenterology, gynecology, etc.) students are taught the therapeutic options for specific conditions. NCNM students are trained to the broadest national scope of practice for an ND, and as such, both naturopathic and allopathic care including surgical and detailed pharmaceutical options are discussed for all conditions.

NCNM uses the following texts: Recommended Texts: Pharmacology, 3rd edition, editors – Harvey and Champe; Lippincott; Principles of Pharmacology 3rd edition, editors Golan et al. Lippincott; Clinical Pharmacology Made Ridiculously Simple, Olson; MedMaster Actions, Interactions and Selected Pharmacologic Agents by Zora DeGrandpre, MS, ND; Goodman & Gilman's, The Pharmacological Basis of Therapeutics, 10th ed; McGraw Hill Drug Facts and Comparisons

4. National University of Health Sciences (NHUS), Chicago, IL

Students in the Doctor of Naturopathic Medicine program at NHUS are required to take 90 hours of basic pharmacology in didactic format. In addition, there are 120 hours of botanical medicine and pharmacognasy which include the pharmacodynamic principals of many plant derived pharmaceutical agents such as anticholinergics and opiates.

Additional pharmacology training is received in the many specialty courses including Evaluation and Management, Internal Medicine/ Emergency Medicine, and Minor Surgery/ Emergency Procedures, which includes suturing, biopsy and the use of topical and regional anesthetics.

In the clinical internship at NUHS, students are instructed on the use of the prescription medications currently used by the clinic's patients under the supervision of an MD internist, including various routes of administration including oral, injectable, and topical. Intravenous therapy is currently only taught through didactic courses although the program is developing clinical training in IV therapy.

5. Southwest College of Naturopathic Medicine (SCNM), Tempe, AZ

SCNM currently requires 96 hours of didactic training in pharmacology, including neuropharmacology, cardiology, respiratory, infectious disease, dermatology, rheumatology, gastroenterology, endocrine pharmacology, and other areas. Students graduating and passing the clinical board exams are qualified family practice physicians who are able to safely prescribe many different standard treatments generally used in family practice, including controlled substances. ND students generally receive minimal clinical experience in pharmaceutical prescription during clinical training, though they can seek additional training with physicians

who prescribe pharmaceutical medications.

Graduating ND students are not qualified to prescribe in specialty areas, even though the standard DEA number would permit legal prescriptions. This includes neuropsychiatry, oncology, advanced cardiology, HIV and tuberculosis treatments, and several other areas, without substantial further training. IV administration of nutritional medicines is taught in the clinical setting.

ADMINISTRATIVE RULES FOR NATUROPATHIC PHYSICIANS

PART 1. GENERAL INFORMATION ON LICENSURE OF NATUROPATHIC PHYSICIANS

1.1 THE PURPOSE OF LICENSURE

To protect the public health, safety and welfare, the Vermont Secretary of State has the duty to license and regulate naturopathic physicians. Vermont Statutes Annotated Title 26, Chapter 81("Chapter 81").

1.2 LAWS THAT GOVERN LICENSURE

Chapter 81 governs the issuance of licenses and the regulation of professional practice for naturopathic physicians. Chapter 81 also authorizes rulemaking authority to carry out these regulatory duties. In enforcing Chapter 81, the Director of the Office of Professional Regulation (the "Director") follows the Administrative Procedure Act (Vermont Statutes Annotated, Title 3 §§801-849), Vermont Open Meeting Law (Vermont Statutes Annotated, Title 1 §§ 311- 314), Access To Public Records (Vermont Statutes Annotated, Title 1 §§ 315-320), and Professional Regulation (Vermont Statutes Annotated, Title 3 §§ 121-131).

These laws set forth the rights of applicants, licensed naturopathic physicians, and the public. The complete text of these laws is available at most libraries and town clerks' offices. "Vermont Statutes Online" is available at <http://www.leg.state.vt.us>. The text of statutes and administrative rules governing naturopathic physician practice is available at <http://www.vtprofessionals.org>.

PART 2. INFORMATION FOR APPLICANTS

2.1 APPLICATION

Applications and information about licensure requirements are available from the Office of Professional Regulation ("Office"). An applicant must submit a completed application form with all supporting documentation and the fee to the Office.

The Office reviews applications only after the supporting documentation is received, including evidence of a degree and examination results, as required in Rule 2.2, or evidence of a license in another jurisdiction and its licensing standards, as required by 26 V.S.A. §4129.

Initial licenses issued within 90 days of the renewal date will not be required to renew or pay the renewal fee. The license will be issued through the next full license period. Applicants issued an initial license more than 90 days prior to the renewal expiration date will be required to renew and pay the renewal fee.

2.2 QUALIFICATIONS FOR LICENSURE AS A NATUROPATHIC PHYSICIAN

(a) **Degree requirement:** The degree required is a doctoral degree in naturopathic medicine from a program accredited by the Council on Naturopathic Medical Education (CNME), or a degree determined by the Director to be essentially equivalent and which meets educational standards essentially equivalent to those established by the CNME.

(b) **Licensing Examination:** The Director, or the Director's designee, administers a written examination on naturopathic medicine. The Director currently uses the Naturopathic Physicians Licensing Examinations (NPLEX). To be eligible for licensure as a naturopathic physician in Vermont, an applicant must have passed the NPLEX and the Minor Surgery Clinical Elective Examination. The passing score and the minimal competency requirements for the NPLEX are established by NPLEX. The Director, or the Director's designee, shall administer the licensing examination at least twice a year at a time and place set well in advance.

(c) Applicants under this section who have not actively practiced the profession or who have not been enrolled in an approved naturopathic program during the two years immediately preceding the submission of their application must complete the continuing education requirements required by Rule 3.2 prior to receipt of a Vermont license.

PART 3. INFORMATION FOR NATUROPATHIC PHYSICIANS

3.1 RENEWING LICENSURE BIENNIALLY

Licenses renew on a fixed biennial schedule: September 30 of the even-numbered years.

Before the expiration date, the Office will mail a renewal application and notice of the renewal fee to the latest address on file with the Office. A license will expire automatically within 14 days if the renewal application and fee are not returned to the Office by the expiration date.

Licensees possessing a special license endorsement to practice naturopathic childbirth must submit proof of current cardiopulmonary resuscitation certification for adults and newborns and for neonatal resuscitation biennially, with each license renewal. See Rule 3.7(b) below. Such licensees must also file with the Director a written plan for consultation with other health care providers for emergency transfer and transport of an infant or a maternity patient, or both, to an appropriate health care facility. The written plan must be submitted to the Director on an approved form with the initial application for the naturopathic childbirth special license endorsement and with subsequent renewals. See Rule 3.7(d) below.

3.2 CONTINUING EDUCATION REQUIREMENTS

(a) As a condition of license renewal, naturopathic physicians must complete a minimum of 30 hours of continuing education during the two-year renewal period and must so certify at the time of license renewal. The continuing education requirement does not apply for the renewal period during which a naturopathic physician initially obtained licensure. It will begin with the first full two-year renewal period. Licensees who complete more than the required 30 hours of continuing education may carry-over a total of 10 (ten) hours of continuing education from the preceding licensure renewal period. Licensees seeking the special license endorsement for prescription medications pursuant to 26 V.S.A. §4125(d) may apply credits from the Medical Pharmacology course, or a substantially equivalent course approved by the Director, described in Rule 3.5(a) for two (2) renewal cycles.

(b) A continuing education program means classes, institutes, lectures, conferences, workshops, naturopathic journals, scientific journals, audio, video, or online presentations, and preceptorships. A program shall consist of study covering new, review, experimental, research and specialty subjects within the scope of practice of naturopathic medicine. Excluded are programs that promote a company, individual, or product and programs on practice economics. However, courses specifically dealing with medical

workers compensation or medical recordkeeping in the context of practice economics are acceptable.

(c) A physician-level continuing medical education course is acceptable as a continuing education program. A course is considered physician-level if presented by a physician or other medical professional to a predominantly physician audience. Once a continuing education provider is approved by the Director, the continuing education activity sponsored by that provider is approved for credit and no application to the Director must be made for approval. The Office shall maintain a **List of Approved Providers** which may be obtained from the Office's web site at <http://vtprofessionals.org/>.

(d) Licensees possessing the special license endorsement for prescription medications must complete 10 hours biennially in the pharmacology of legend drugs.

(e) Licensees possessing a special license endorsement to practice naturopathic childbirth must complete 15 hours biennially in naturopathic childbirth. A course in neonatal resuscitation may count toward these 15 hours. Ten of the 15 hours may be applied to general requirements for continuing education.

(f) At the time of license renewal, each licensee must certify on the official renewal form that he or she has complied with the continuing education requirements. The Office may randomly audit licensees to ensure compliance. A licensee who is audited will be notified in writing by the Office and will be required to produce documentation verifying successful completion of the 30 hours of continuing education during the two-year period at issue. A licensee must maintain documentation for at least two years following the renewal period at issue. The Director may require a licensee who cannot produce satisfactory evidence of successful completion to develop and complete a specific corrective action plan within 90 days, prior to renewal.

3.3 CHANGE OF NAME OR ADDRESS

A licensee is responsible for notifying the Office promptly of any changes in name, mailing address, business address or other relevant contact information. See 3 V.S.A. §129a(a)(14).

3.4 PROFESSIONAL STANDARDS

Naturopathic physicians may be disciplined for unprofessional conduct pursuant to 26 V.S.A. §4132(a) and 3 V.S.A. §129a.

3.5 SPECIAL LICENSE ENDORSEMENT FOR PRESCRIPTION MEDICATIONS

(a) The naturopathic pharmacology examination, defined at 26 V.S.A. §4121(13), the passage of which is required for the special prescriptive license endorsement pursuant to 26 V.S.A. §4125(d), shall be the National Board of Medical Examiners ("NBME") subject matter examination in pharmacology, or the examination(s) given in the Medical Pharmacology course taught within the Department of Pharmacology through Continuing Medical Education at the University of Vermont's College of Medicine, or a substantially equivalent examination approved by the Director after consultation with the Commissioner of Health. In order to obtain the special license endorsement which shall authorize a naturopathic physician to prescribe, dispense, and administer prescription medicines, an otherwise qualified naturopathic physician will be required to pass the NBME pharmacology examination, or the Medical Pharmacology course examination(s) at the University of Vermont, or a substantially equivalent examination approved by the Director, after consultation with the Commissioner of Health. Approval for a substantially equivalent examination may be obtained by applying to the Office at anytime but no later than 90 days before the

alternate course begins.

(b) For no less than one year after receiving the special license endorsement, and until the first one hundred (100) drug prescriptions are issued, prescriptions shall be reviewed by an objective and independent supervising physician licensed under Chapter 23 or 33 of Title 26, or a naturopathic physician licensed under Chapter 81 of Title 26. The supervising physician shall possess an unencumbered license and have been prescribing and administering prescription drugs without limitation for five years or more in Vermont. The supervising physician shall evaluate the naturopathic physician's ability to:

(1) safely prescribe and administer prescription drugs within the naturopath's scope of practice;

(2) comply with federal and state statutes; and

(3) comply with the applicable administrative rules of the Vermont Board of Pharmacy.

(c) The naturopathic and supervising physicians shall have a formal written agreement. The agreement shall address the requirements of subsection (b) of this rule. The agreement shall be available for inspection upon request by the Office.

(d) A naturopathic physician who satisfies the supervision requirement in subsection (b) of this rule shall notify the Office that this requirement has been met and file a certificate of completion signed by the supervisor.

(e) The Director may waive the prescription review requirement in subsection (b) of this rule if the newly endorsed naturopathic physician can show that they have substantial experience in prescribing prescription medicines under the laws of another jurisdiction that has standards and qualifications for a naturopathic physician to prescribe prescription medications at least equal to those required under these rules.

(f) The use of prescription medications in a manner that has not been approved by the FDA is referred to as "off-label." In addition to the use of prescription medications in a manner approved by the FDA, a naturopathic physician who has appropriate competency, training and experience may prescribe medications in an "off-label" manner in conformance with generally accepted standards of practice, including safety and efficacy, for both allopathic and naturopathic physicians.

3.6 ADVERTISING

(a) 26 V.S.A. §4122 lists five designations that a naturopathic physician licensed in Vermont may use. The five designations are: N.D., Doctor of Naturopathic Medicine, Naturopathic Doctor, Doctor of Naturopathy, and Naturopathic Physician. Licensees must prominently feature at least one of the five designations in any advertising.

(b) A licensee who complies with the law in this way may then use the designation "Dr." in the advertisement. The purpose of this rule is to prevent deceptive advertising and to inform the public that the licensee is a naturopathic physician licensed under Title 26, Chapter 81 and not another health care licensee.

(c) The terms "board certified" and "diplomate" imply that the licensee has completed an advanced level of training. A licensee advertising either term or similar terms must state the area of specialty, and the private credentialing organization that issued the specialty certification. The purpose of this rule is to provide the

public with complete and accurate information about the licensee's credentials and level of training.

3.7 NATUROPATHIC CHILDBIRTH

No licensee may practice naturopathic childbirth without first obtaining a special endorsement on his or her license. To obtain this endorsement, a licensee must:

(a) Show evidence of completion of a naturopathic childbirth or midwifery program from an approved naturopathic college or hospital and furnish a signed log showing evidence that sections (1), (2) and (3) of this subsection have been completed under the direct supervision of a licensed practitioner with specialty training in obstetrics or natural childbirth.

(1) The licensee must have taken part in the care of 50 cases each in prenatal and postnatal care. One case may qualify for both areas of care.

(2) The licensee must have observed and assisted in the intrapartum care and delivery of 50 natural childbirths in a hospital or alternative birth setting 3 of which must have occurred within the last two years. A minimum of 26 of these births must be under the supervision of a naturopathic physician. No more than 10 of the 50 births may be under the supervision of a medical doctor (allopathic or osteopathic physician). No more than 10 of the births may be observation only. A labor and delivery that starts under the care of a naturopathic physician and includes hospitalization shall count as a birth.

(3) The course work must consist of at least 200 hours in naturopathic childbirth.

(b) Hold a current cardiopulmonary resuscitation certification for adults and newborns and for neonatal resuscitation. The Director will accept courses in external cardiopulmonary resuscitation which are approved by the Vermont Heart Association or the American Red Cross and for courses in neonatal resuscitation approved by the American Academy of Pediatrics (AAP).

(c) Pass a specialty examination in naturopathic childbirth approved by the Director. The Director, or designee, will administer the specialty examination in naturopathic childbirth at least once each year if applications are pending. A licensee may sit for this examination in another state and have the results of the examination transferred to this state.

(d) File with the Director a written plan for consultation with other health care providers for emergency transfer and transport of an infant or a maternity patient, or both, to an appropriate health care facility. Licensees must submit the plan to the Director on an approved form with the initial application for a naturopathic childbirth endorsement and with every subsequent renewal of the endorsement.

(e) Applicants under this section requesting a naturopathic childbirth endorsement who have not passed the naturopathic childbirth exam within the two years preceding the application shall show evidence of completion of the continuing education requirements required by this section.

(f) Licensees possessing a naturopathic childbirth endorsement must, as a condition of renewal:

(1) obtain 15 hours in naturopathic childbirth continuing education during each two-year renewal period. A course in neonatal resuscitation may count toward these 15 hours. Ten of the 15 hours may be applied to general requirements for continuing education. See Rule

3.2 above (continuing education requirements).

(2) submit proof of current cardiopulmonary resuscitation certification for adults and newborns and for neonatal resuscitation biennially, with each license renewal. See subsection (b) above.

(3) have performed 3 natural childbirths in the preceding two year renewal period.

(g) Licensing or disciplinary action by an Administrative Law Officer or judicial authority shall be deemed to have an equal effect upon a special endorsement to practice naturopathic childbirth issued to a licensee, unless specifically provided otherwise in the licensing or disciplinary action. When the subject of a licensing or disciplinary proceeding relates specifically to the practice of naturopathic childbirth by a licensee who possesses a special endorsement, the licensing or disciplinary action may, instead of affecting the entire scope of the licensee's practice, suspend, revoke, condition, or restrict only the licensee's authority under the special endorsement.

3.8 INFORMED CONSENT FOR NATUROPATHIC CHILDBIRTH

(a) Before accepting a client for prenatal and natural childbirth, the naturopathic physician must first obtain a written informed consent. Informed consent must be shown in a written statement and signed by the ND and the client to whom care is to be given, in which the ND certifies that full disclosure has been made and acknowledged by the client of the following:

(1) The naturopathic physician's credentials.

(2) A copy of the written plan for consultation, emergency transfer, and transport.

(3) A description of the procedures, benefits, and risks of home birth.

(b) The informed consent form must be filed in the client's chart, and a copy must be provided to the client.

3.9 SCOPE AND PRACTICE STANDARDS FOR NATUROPATHIC CHILDBIRTH

(a) Prenatal Care:

(1) Information: The client will be presented accurate information conforming to the requirements of informed consent and also including but not limited to:

(A) Financial charges for services.

(B) Services the ND provides, and the advantages and disadvantages of home birth.

(C) Client responsibilities.

(D) Values and ethics of practice.

(E) Information on emergency consultation, transfer, and transport.

(F) Choices regarding prenatal lab testing, including but not limited to sexually transmitted

diseases, blood type and antibody screen, CBC, rubella, HIV, Hepatitis B, and urinalysis.

(2) History and Physical Assessment: At the initial prenatal visit, a personal and health history will be obtained, including medical history, family history, current pregnancy history, nutritional history, and physical assessment, including review of systems and prenatal care.

(3) On-going Prenatal Care: Will be conducted in such a way as to promote the health of the client and baby, screen for problems, develop a relationship with the client and family, exchange information, and do a physical assessment of the prenatal health.

(4) Prenatal visits should occur every four weeks through the 32nd week, every two weeks until the 36th week, and weekly thereafter. The prenatal visit includes:

(A) Physical evaluation including weight, blood pressure, urine screen, fetal heart tones, fundal heights, fetal growth, fetal position and presentation.

(B) Discussion during these visits includes: recent illnesses, social or emotional problems, diet, supplements, exercise for pregnancy, birth preparation, partner's role, transport arrangements, newborn care, postpartum care, and parenting.

(5) Parents' Responsibilities:

(A) Obtain all supplies on birth list.

(B) Have an accessible telephone.

(C) Have adequate light, heat, water, cleanliness, and accessibility.

(D) Post all emergency phone numbers.

(E) Make child care arrangements.

(F) Arrange for help after the birth.

(6) Naturopathic Physician's Responsibilities:

(A) Alert parents to signs of labor and when to call.

(B) Alert parents to signs of complications that necessitate immediate contact with the naturopathic physician.

(C) Be on call or have on-call arrangements if out of town.

(D) Arrange for a birth assistant.

(E) Make a home visit before the 37th week.

(F) Maintain appropriate equipment for assessing maternal, fetal, and newborn well being, carry anti-hemorrhagic agents, supplies to maintain asepsis, and emergency resuscitation

equipment.

(G) Maintain a record of the care provided and data gathered for each client, subject to the federal medical records laws and those of the State of Vermont regarding accessibility and confidentiality.

(7) Discontinuation of Services: During prenatal care, a naturopathic physician shall evaluate a client and baby and determine continuing appropriateness for the home birth. All concerns shall be shared with the client. If an impasse is reached between what is deemed appropriate by the naturopathic physician and the client or family, it is the right of the ND to refuse or discontinue service and to make appropriate referrals when indicated for the protection of the client, baby, and naturopathic physician.

(b) Labor, Birth, and Immediate Postpartum:

(1) Labor: During labor and birth, the naturopathic physician shall use all of the resources available to assure and enhance the well being of the mother and baby.

(2) The naturopathic physician's labor responsibilities include:

(A) Assessing the well being of the laboring woman and baby, fetal heart tones, blood pressure, maternal temperature, position and presentation of the baby, and client's attitude, ability, and energy to cope with labor. A vaginal examination will be performed as necessary to assess progress of labor. Aseptic technique shall be observed with use of OSHA and VOSHA regulations relevant to home birth.

(B) Provide adequate fluid and nutrition throughout the labor, provide support and encouragement during the birth process, assist with delivery of the placenta, manage interpartum hemorrhage, and perineal repair as needed.

(3) Immediate Care of Newborn: Following the birth the naturopathic physician shall:

(A) Maintain a warm environment for the baby.

(B) Assess newborn using APGAR scoring and provide appropriate care; continue assessment of newborn vital signs.

(C) Encourage and support breast feeding or proper nutrition and feeding habits.

(D) Conduct a newborn exam, offering vitamin K and eye prophylaxis.

(4) Immediate Postpartum Care: Following the birth, the naturopathic physician shall remain with the client and baby until both are stable and secure and at least two hours have passed since the birth. During this time, the naturopathic physician shall assess maternal well being, bleeding, blood pressure, and uterine size and consistency, examine the perineum, and repair if necessary. Assess the client's ability to urinate and be ambulatory. Postpartum instructions shall be given including information on normal postpartum bleeding, appropriate size and consistency of uterus, perineal care and hygiene, rest and nutritional requirements, breast feeding, newborn care, and indications which warrant contacting the naturopathic physician.

(c) Postpartum Follow-up Care: Postpartum visits are recommended at 24 hours, day 3, one week, three weeks and six weeks, with phone consultation as necessary. During these visits, the mother is assessed for normal postpartum recovery and health, breast feeding status, uterine status, lochia status, normal bowel and urinary output, nutritional status and emotional status. The baby is assessed for overall well being, normal nursing or feeding habits, jaundice of the newborn, activity level, growth, vital signs, bowel and urinary patterns, umbilical assessment, and neurological evaluation. A blood sample for newborn metabolic screening shall be obtained after 24 hours and submitted as required by the Vermont Department of Health newborn screening program.

(d) Final Postpartum Visit: A six to eight week final visit for mother and baby. At this time, the naturopathic physician shall make inquiries concerning breast feeding, feeding habits, bleeding, activity level, family adjustments, and sexual activity, perform a gynecological exam with a pap smear, and discuss family planning or birth control. Provisions shall be made for ongoing well child care.

3.10 WRITTEN PLAN FOR CONSULTATION, EMERGENCY TRANSFER, AND TRANSPORT

(a) The naturopathic physician recognizes that there are certain conditions when medical consultation or transfers, or both, are advisable. Each naturopathic physician practicing naturopathic childbirth must develop a written plan for consultation with other health appropriate care providers, including at least one M.D. or D.O., for emergency transfer and transport of an infant or mother to the appropriate health care facility. The written plan must be submitted to the Director on an approved form with the initial license application and with every subsequent license renewal.

(b) Prenatal Medical Conditions: If the following medical conditions present during prenatal care, the naturopathic physician shall consult with the appropriate health care provider:

- (1) Possible ectopic pregnancy.
- (2) Multiple gestation.
- (3) Persistent breech presentation at 36 weeks.
- (4) Signs and symptoms of preeclampsia.
- (5) Suspected post-maturity.
- (6) Polyhydramnios and oligohydramnios.
- (7) Indications that the fetus has died in utero.
- (8) Development of any medical condition potentially detrimental to the pregnancy or the well being of the fetus.
- (9) Hyperthyroidism currently treated by medication.
- (10) Acute Toxoplasmosis, Rubella, Cytomegalovirus, or Parvovirus infection, where the client is currently symptomatic.
- (11) Second or third trimester bleeding.

(12) History of intrauterine death after 20 weeks gestation, or stillbirth due to a situation which might recur.

(13) Previous myomectomy.

(14) Tuberculosis.

(c) Transfer: If the following conditions become apparent during prenatal care, the naturopathic physician shall transfer the client to hospital care for the birth. The naturopathic physician may continue to give co-care and accompany the mother at the birth.

(1) Placenta previa or placental abruption.

(2) Preeclampsia.

(3) Transverse fetal position.

(4) Testing positive for HIV.

(5) Suspected premature labor, less than 36 weeks of pregnancy.

(6) Premature labor (gestation less than 36 weeks).

(7) Thrombosis.

(8) Primary or active Herpes simplex cervical or vaginal lesion at the time of delivery.

(9) Premature rupture of membranes at 37 weeks or less with a positive GBS.

(d) Labor and Birth Transfer: If the following conditions become apparent during labor, birth, or immediate postpartum, the naturopathic physician shall facilitate transfer to a hospital setting if time allows or consult with an OB/GYN to determine whether and when transfer is advisable:

(1) Malpresentation.

(2) Multiple gestation.

(3) Fetal distress as indicated by fetal heartbeat monitoring or gross meconium staining.

(4) Client distress.

(5) Prolapsed cord.

(6) Uncontrolled maternal hemorrhage or retained placenta.

(7) Signs of maternal or fetal infection.

(8) All stage 4 and any maternal perineal lacerations beyond the naturopathic physician's ability to

repair.

(9) APGAR score of less than seven at ten minutes or fetal distress not responding to CPR.

(10) Any newborn whose vital signs are absent or exhibiting signs of respiratory distress.

(11) Obvious congenital anomalies.

(12) Active A hepatitis.

(13) Thrombosis.

(e) Decision-making Conflicts: If the client chooses to remain at home against the medical advice of the naturopathic physician during the interpartum period, the naturopathic physician may refer them to an alternative birth provider. If the birth is imminent, the naturopathic physician will leave only if the naturopathic physician has made reasonable attempts to assure that the client is not unattended (i.e., calling an ambulance).

3.11 UNCOMPLICATED CHILDBIRTH

(a) Uncomplicated naturopathic childbirth is the provision of care, support and education to healthy women during the childbearing cycle, including normal pregnancy, labor, childbirth and the postpartum period. There are certain pre-existing medical conditions which may prevent the ability to have a natural home birth assisted by a naturopathic physician.

(b) If a history of any of the following disorders or situations is found to be present at the initial interview or if any of the following disorders or situations becomes apparent through history, examination, or laboratory report as prenatal care proceeds, the naturopathic physician must not assume or continue to take responsibility for the client's pregnancy and birth care. For clients already under care, it is the responsibility of the naturopathic physician to arrange for orderly transfer of care to a licensed M.D. or D.O.

(1) Uncontrolled insulin dependent diabetes mellitus.

(2) Uncontrolled epilepsy.

(3) Active non-A hepatitis.

(4) HIV positive.

(5) Current alcohol or drug addiction.

(6) Rh sensitivity with positive antibody titer.

(7) Previous cesarean delivery, except as provided for in Rule 3.14, below.

3.12 PREVIOUS CESAREAN DELIVERY

The following requirements must be met for vaginal birth after cesarean (VBAC). In addition, prenatal consultation is advised when available.

- (a) The naturopathic physician must obtain records to ascertain that the client had only one documented previous lower uterine segment cesarean section with uterine closure of more than one layer.
- (b) There must be at least 18 months from the client's cesarean to the due date of the current pregnancy.
- (c) The client must obtain ultrasound documentation to determine that the location of the placenta is not previa or is not low and anterior.
- (d) Signed informed consent must be present in the client's chart. See Appendix A.
- (e) The naturopathic physician must perform fetal auscultation at least every 15 minutes during active labor and more frequently if necessary and at least every five minutes during the second stage of labor and more frequently if necessary.
- (f) The birth site must be located within 30 minutes' transport time from a hospital emergency room.
- (g) A naturopathic physician must be accompanied by another licensed physician or midwife.
- (h) No labor induction or augmentation of any kind must be done. Specific examples of labor induction or augmentation prohibited by this section include administration of pitocin or its congeners, or stimulation of the release of pitocin by nipple stimulation, or the use of prostaglandin preparations. This section does not prohibit the use of calmative, sedative or analgesic preparations that are not primarily intended to induce or augment labor, and that are included in the naturopathic physician formulary when, in the judgment of the naturopathic physician, their use for their calmative, sedative or analgesic effects is indicated.
- (i) Pre-admission forms must be completed for the client before labor, for the hospital to which the client may possibly be transferred.
- (j) Prenatal records for the client must be sent before labor to the back-up system for the birth (hospital, labor and delivery unit, or physician practice).

Effective date: November 1, 2013