State of Vermont
Office of the Secretary of State

Office of Professional Regulation
1 National Life Drive, North Floor 2
Montpelier, VT 05620-3402

[phone] 802-828-1505
[fax] 802-828-2496
www.sec.state.vt.us

James C. Condos, Secretary of State
Brian H. Leven, Deputy Secretary

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.