

MINNESOTA HEALTH-RELATED LICENSING BOARDS

COUNCIL OF HEALTH BOARDS



**Review of Legislative Request:
Health Occupation Review**

**Naturopathic Doctors
(HF4205/SF3232)**

December 2006

**Review of Legislative Request:
Health Occupation Review**

**Licensure of Naturopathic Doctors
(HF4205 / SF 3232)**

Application submitted by:

Leslie Vilensky, N.D.
President, Minnesota Association of Naturopathic Physicians
905 Jefferson Avenue, Suite 202
Saint Paul, MN 55102

Review Panel for the Council of Health Boards:

- John King, Board of Veterinary Medicine, Chair
- Joanne Schulman, DVM, Board of Veterinary Medicine
- Stephanie Lunning, Board of Physical Therapy
- Corinne Ellingham, Board of Physical Therapy
- Laurie Mickelson, Board of Dietetics and Nutrition
- Marnie Moore, Board of Dietetics and Nutrition
- Larry Spicer, Board of Chiropractic Examiners
- Rich Tollefson, Board of Chiropractic Examiners
- Rob Leach, Board of Medical Practice
- Richard Auld, Board of Medical Practice
- Alfred Anderson, MD, Board of Medical Practice
- Tom Hiendlmayr, Minnesota Department of Health

Referred to the Council of Health Boards by:

Senator Becky Lourey

Staff to the Subcommittee:

Cindy Greenlaw Benton
Health-Related Licensing Boards
Administrative Services Unit

Public meeting dates:

September 7, 2006
September 27, 2006
October 18, 2006
November 3, 2006
December 6, 2006

Review Comments:

The subcommittee of the Council of Health Boards was charged with the responsibility of reviewing the legislative proposal providing for licensing of naturopathic physicians in Minnesota. Minnesota Statutes 214.001, Subd. 4, states that the chair of a standing committee in either house of the legislature may request information from the Council of Health Boards regarding proposals relating to the regulation of health occupations. Minnesota Statute 214.025 states that the health-related licensing boards may establish a Council of Health Boards consisting of representatives of the health-related licensing boards and the Emergency Medical Services Regulatory Board. When reviewing legislation or legislative proposals relating to the regulation of health occupations, the Council shall include the commissioner of health or a designee.

The panel reviewed the application through means of a ratings worksheet. Ratings were based upon the materials provided with the application, with limited reliance on knowledge of, or assumptions about, the professions by the subcommittee. The worksheets contained 60 items in the general topic areas: Description of the Occupation; Safety and Efficacy; Government and Private Sector Recognition; Education and Training; Practice Model & Viability of Profession; and Regulatory Framework. The proposal submitted by the proponent for Naturopathic Doctor Licensure was reviewed according to these 60 items for thoroughness of response and provision of information. The Council has assessed the degree to which the responses to the Council's questions supported the application for establishing licensure.

The Council reviewed the proposal with a view toward providing the Legislature with an objective evaluation of information regarding the proposal and to describe those areas, if any, that were supportive of licensure of the occupation, and which were not. The subcommittee met to organize the review process, review the worksheets and to discuss the proposal on September 7 and 27, October 18, and November 3, 2006.

In general, this subcommittee found that, as presented, the responses given to the questionnaire, although generally responsive to the questions posed, indicated that there are considerations that are not addressed, for which the Legislature may want to request additional information or clarification. The proponents also submitted responses to supplemental questions from the subcommittee. Although the proponents have responded to the questions, the Council finds that in some important aspects, the Legislature may require additional information or clarification.

It is not the role of this Council to either recommend or to withhold recommendation of proposed legislation, but to analyze submissions pertaining to proposed legislation and to offer factually based conclusions and other possible areas of inquiry in order for the legislature to determine whether to grant licensure to an occupation.

Additional research is suggested, which would inquire into areas for which insufficient information was provided by the proponent of this proposal.

An Executive Summary of major issues for legislative consideration may be found at the end of this report.

A. Description of the Occupation

Overall, the committee returned several times to a question about the apparent overlap of the practice of naturopathic medicine with other occupations, and believes that the Legislature may wish to inquire into the exact standards of practice. As described by the proponents, the scope of practice is quite broad, encompassing functions that are within the practice of other regulated health professions, among them, Chiropractic, Dietetic and Nutrition Practice, Nursing, Medical Practice, Pharmacy, Podiatric Medicine, and Physical Therapy; and would also include broad prescribing authority. That is, there are questions as to whether the practice of naturopathy is an occupation that is a different and unique entity from other health professions, or which provides a unique service not otherwise available from currently licensed practitioners.

Regarding the proposed scope of practice in Appendix A, the legislation does not contain limiting language typical of Practice Acts for regulated professions, which would indicate that the practice of naturopathy is not, e.g., the practice of medicine, chiropractic, etc. The proposed scope of practice also does not contain sufficient information to establish the unique character of naturopathy as opposed to other occupations with which it overlaps.

Within the proposed scope of practice is language noting the authority of naturopathic doctors to prescribe therapeutic devices, which could be used or possessed only by licensed individuals. However, in reviewing the educational requirements that would be imposed through the legislation, the committee noted that the course of education does not reflect training in, or use of, such devices.

The proposed scope of practice also contains language stating that the scope of practice includes, but is not limited to, the provision of a long list of services. Such language is unusual for a delineated scope of practice of a regulated occupation.

The Council notes that the proposed legislation anticipates that disciplinary action would be in accordance with the provisions of the Medical Practice Act, which governs the disciplinary actions of the Minnesota Board of Medical Practice. The legislation does not explicitly state what would constitute grounds for discipline of naturopathic practitioners.

Even after obtaining testimony and responses to additional questions, the Council found that many of the services that naturopaths currently perform, as well as additional services they seek to perform, are regulated and provided by members of other occupations, and there is a lack of standards for practice of these services by naturopaths. The proponents note that the occupation would fall within the governance of the Minnesota Board of Medical Practice; under a Naturopathic Advisory Council within the Medical Practice Board. The Council of Health Boards, however, believes that

ambiguity remains as to whether the Medical Practice Act fully addresses the scope of practice matters pertaining to naturopathic practice.

The Council questioned the extent of authority for this profession, if licensed, to delegate tasks, such as phlebotomy, and whether such authority to delegate should be limited in some respect; there is currently no mention of delegation within the proposed statute itself.

The proponents indicate that approximately 25 individuals in Minnesota would fall within the coverage of the proposed legislation, i.e., would be eligible for licensure under this bill.

B. Safety and Efficacy

Although the occupation addressed issues regarding safety and efficacy, the Council found a decided lack of objective data regarding the safety and efficacy of the profession.

The Office of Complementary and Alternative Health Care Practices (OCAP) at the Minnesota Department of Health regulated unlicensed health care practitioners, including naturopaths. Of 50 “non-massage therapy” complaints, OCAP has received 15 complaints concerning persons using “naturopath” or a similar title. The initial allegations in these complaints included violation of professional boundaries, failure to refer, using a restricted title, puncturing the skin, diagnosing, advising client to discontinue prescription medication, and failure to comply with a previous order of the Commissioner. There have been four public disciplinary orders resulting from investigation of these 15 complaints, with orders including a revocation of practice; an order to cease drawing blood, making diagnoses and using the term “doctor”; an order to cease using medical devices restricted by federal law; and an order to provide information about medical device use, refer clients as appropriate, submit quarterly reports for one year concerning all client symptoms and completion of a professional boundaries course. Six of 15 the complaints involved individuals who were graduates of accredited North American naturopathic colleges; one complaint was about a graduate of a European college of naturopathy; one about a graduate of an unaccredited college of naturopathy; and seven about individuals with no indicated specific training or education in naturopathy.

Under the proposed naturopathic licensing legislation, some of these allegations would not be violations of law. However, the legislature should consider whether the complaints discussed above are evidence of conduct needing regulation and enforcement of standards.

The proponents noted that literature pertaining to the occupation is evolving, and is currently more observational than scientific, and includes established practices of the profession. The naturopathic profession is aware of the need to establish the efficacy of some of its practices, e.g., homeopathy.

The proponents of the legislation offered journal citations regarding the efficacy of naturopathic practices. The committee noted that all but one of the studies cited were from naturopathic journals, and all but one were written in the 1990s. However, these studies were of specific modalities already in use by other professions, rather than studies on the general practice of Naturopathy itself. Although there is a lack of data regarding safety and efficacy, the Council notes that a lack of data does not necessarily translate to a practice being either safe or unsafe. It is anticipated that studies will continue to be done, and the occupation will evolve.

Studies have also been done by other professions pertaining to items contained within the naturopathic scope of practice, which is expected to continue.

The Legislature has previously expressed interest in evidence-based health practice, and may want to weigh the evidence of efficacy of naturopathy. The Council has not assessed nor determined the safety and risk of various naturopathic devices and practices; this remains to be determined and examined by the profession to examine in collaboration with other professional practitioners.

Additional concerns included lack of clarity in regard to assuring competence of practitioners who have received the required education, but who have not been professionally licensed to perform some of the functions for which they would now be licensed under the legislation. The proponents of the legislation stated that the request for licensing implicitly presupposes that practitioners do exist who are not competent. The proponents also noted that all treatment modalities done by other occupations and the research that is done by other fields is used by naturopaths.

The proposed legislation calls for “informed consent” from patients “after advising the patient of the licensee’s qualifications including education, license information, and outline of the scope of practice of licensed naturopathic doctors in Minnesota.” This informed consent language is not congruent with that typically found in Practice Acts, in that it does not require practitioners to apprise patients of risks, benefits or alternatives of treatment.

In addition to standard recordkeeping requirements, the legislation would require that records of minors be retained for seven years or until the minor’s 19th birthday, whichever is longer. The legislature may wish to consider whether this is an appropriate length of time for retention of such documents.

The Council also questioned an assertion in response to written questions, in which the proponents of the legislation stated that:

“The worst thing one can say about homeopathy [practiced by naturopaths] is that any positive effects may simply be the result of a placebo phenomenon. Compare this to aspirin, which kills thousands of children annually, or Tylenol, which kills thousands more from liver failure.”

The Council is not offering recommendations on what practices are safe or unsafe, and it is beyond the scope of the Council to do so. The Legislature may wish to obtain input from stakeholders in other occupations in regard to these practices, as well as safety and risk of devices, scope of practice, and, in particular, prescribing authority.

C. Government and Private Sector Recognition

After reviewing statements contained within the documents submitted by the proponents and opponents, the Council detected a discernible split among persons who practice under the general category of “naturopath” and those who seek licensure as “naturopathic doctors”; the split is quite stark, in that one group seeks occupational regulation (this group is supportive of specific educational requirements), and the other group opposes regulation via licensure (and is not supportive of specific educational requirements). (The primary differences between these two groups can be found below, under “Education and Training”.) In determining whether this profession is ripe for licensure, the Legislature will want to determine whether a consensus can be reached among the groups, or whether the profession is described sufficiently to provide licensure for those who wish to seek it, and would also allow enforcement against those who are not licensed and practicing within the scope of naturopathic practice. It should be noted that at this time there is not a consensus among two major groups representing naturopathy, as to whether the legislation should go forward, and what exactly should be contained in the legislation.

The legislation as proposed anticipates the existence of certification in specialty areas, however, the only specialty noted is that of naturopathic childbirth. It is unclear whether other specialty areas are anticipated; if other specialty areas are intended to be included, they have not been mentioned in the legislation, nor have specific training or educational requirements for additional specialties been included in the statute. If specialties are to be included, specific language will be required to be contained within the statute.

The occupation is unable to provide specific information on the number of clinic patient visits made to members of the occupation per defined time period. The Council requested this information to assess the current level of demand in Minnesota for naturopathic services, albeit of limited scope.

The legislative proposal pertaining to this occupation requests licensure, but the proposed regulatory scheme is more in the nature of title protection, i.e., registration. Licensure includes independent practice and exclusive right to practice. The proposed legislation authorizes independent practice and exclusive use of titles, but not exclusive right of practice.

The proposed legislation provides for licensure by reciprocity; the term “reciprocity” has become obsolete and the general term for the notion of accepting credentials from other states with proof of competency is “endorsement”.

The subcommittee noted that the legislation contains no reference as to who may own a practice; such limitations are regularly provided in practice acts pertaining to other health occupations.

D. Education and Training

The Legislature is encouraged to review the adequacy of the training / educational requirements for the occupation. While conducting its review, the Council noted the substantial overlap in scope of practice between that anticipated in the legislation and that performed by other health professions. In light of the substantial educational / training requirements that exist for each of the other regulated health professions, the Council was not completely apprised as to the level of education provided to naturopaths that would permit them to practice the same disciplines as those in other health fields, without the concomitant education in each of the fields.

As referenced above, there are differences between groups practicing Naturopathy, with one major group supportive of the legislation and another in opposition to the proposal; one difference among the groups is related to the area of education. The proponents of the legislation have graduated from programs accredited by the Council on Naturopathic Medical Education (CNME). The opponents appear to have varying levels of education.

A review of the proposed legislation indicates that “the practice of naturopathic medicine by students enrolled in an approved naturopathic medical college” [if under supervision of a licensed physician, osteopath, chiropractor, or naturopathic doctor] would not be prohibited or restricted. This provision does not note whether this includes students in their first year of study, in internships, or students in the clinical portion of training.

Additionally, educational opportunities are not totally standardized across the states for the occupation.

In regard to assuring proficiency and competency, the subcommittee noted that if the scope of practice requested by the occupation is granted, it will be far expanded from current practice, and proficiency in the broad scope of practice must be assured; practitioners who have been working in Minnesota have not been practicing under the proposed broad scope of practice, including, e.g., prescribing and administering drugs; ordering imaging studies; and ordering or performing electrocardiograms, ultrasound, phlebotomy, and clinical laboratory tests. How the Board would ensure this competency is unknown; such matters might ultimately be determined by the civil liability system. The occupation will also need to address issues pertaining to continuing competency as scope of practice expands.

E. Practice Model and Viability of Profession

The legislation proposes the Medical Practice Board have an advisory council to review and regulate the activities of the occupation. According to the proposal, the profession has been open to treatments, experimentation, and innovation. The prescribing authority would permit drug use (off label) for any purpose; the proposal and the profession have not noted any consideration of limitations on innovation; it is anticipated that other stakeholders may seek limits on this authority.

Some ambiguity exists as to the number of practitioners who would be able to meet the proposed eligibility criteria, i.e., the written responses to the questionnaire on behalf of the proponents indicated that 100% of practitioners (approximately 25) would be able to meet the licensing criteria; however, the regulation actually seeks to exclude a number of persons who also hold themselves out to be practitioners of naturopathy. The number of these practitioners is uncertain. The legislation as proposed does not exclude this group of practitioners from pursuing their occupations, but would set a certain standard for licensed practitioners.

The legislative proposal, if enacted, would remove the licensed practitioners (as well as those who cannot meet the established criteria) from the jurisdiction of the Office of Complementary and Alternative Practice (OCAP). Cases that would previously have been under OCAP will be referred to the Board, which has cease and desist authority.

F. Regulatory Framework

The subcommittee did not receive sufficient information to determine the cost of regulation. The size of the group that would be regulated is estimated by the proponents to consist of only 25 practitioners. Based on experience as health occupation regulators, the Council is dubious regarding cost-effectiveness, and recommends that the Legislature closely examine this component of the proposal. There is insufficient information to determine the anticipated supply of practitioners, or the demand for naturopathic practitioners. The proponents indicate that the cost of regulation would be negligible; this is contrary to the experience of that of the regulators on the Council. There is also insufficient information on number of visits used; the profession also indicated that some third-party insurers cover naturopathic treatment, and others do not.

The Council has made no determination on the efficacy of naturopathic treatment as a discipline, nor of competency of practitioners. Although various health practitioners perform various components of some of the areas proposed to be within the scope of practice of naturopaths, not all components proposed are covered within any of the currently licensed professions. The Legislature will be required to determine whether the proposal offers sufficient clarity, whether sufficient evidence exists to support efficacy of the practice, and whether the public will be protected by this licensing proposal.

The subcommittee reviewed the proposed fees, and was unable to determine whether the proposed fees would be sufficient to support the cost of regulation of the occupation; fees may not be at an appropriate level, and would need to be based on sound financial principles; this could be determined by the licensing / credentialing authority.

Section 6 of the proposed legislation pertains to action on applications for licensure. This section should be reviewed for compliance with current health licensing regulations found in Chapter 214.

The current effective date of the legislation is July 1, 2007; this date may need to be reviewed in light of legislative action and timelines.

The current legislation includes no reference in the Conforming Amendments section to participation in a health professionals service program to protect the public from persons regulated by boards who are unable to practice with reasonable skill and safety by reason of illness, use of alcohol, drugs, as a result of any psychological condition, etc. This participation is a standard provision of other regulated health professions. This omission could be remedied and included in the proposed legislation.

Additional Comments

The Council recognizes that quality of care can benefit by regulation. In the case of the proposed legislation, the protection is limited to regulation of a particular subgroup of naturopathic practitioners; the legislation would serve to differentiate a small number of naturopathic doctors from other naturopathic practitioners. The title of “naturopathic doctor” would be limited to those persons with specific education as defined in the statute (diploma from an approved naturopathic program). References to approved and accredited programs were presumed by the Council of Health Boards to be approved by the United States Department of Education.

Remaining to be resolved are issues regarding other occupational stakeholders, and the appropriate limits on non-licensed practitioners. There may be a public benefit in attaching the title “naturopathic doctor” to some practitioners, in that a certain level of education and training would be held by such title holders. Those who seek the title “naturopathic doctor” are not, however, the only persons who hold themselves out as naturopathic practitioners; there is a group of practitioners who oppose licensing of the occupation. The public may find it difficult to differentiate among those who are not similarly qualified to those who seek licensure. The legislature will need to determine whether the current system of nonregulation causes harm, or whether regulation will meet the need for the public to assess a health profession. The legislature will need to determine the extent of public benefit of licensure as proposed in this legislation.

Additional questions remain pertaining to the unique character of naturopathy, i.e., whether the practices are different from those of other regulated professionals.

Even after reviewing all materials, and hearing statements from the occupation, the Council was uncertain as to how competency of practitioners who would potentially be “grandfathered” into licensure would be assured.

It was noted that under the legislation, those who are licensed to practice naturopathy are also permitted to sell nutritional supplements to patients for a profit; this is not permitted by those professionals who are licensed dietitians and nutritionists.

The Council believes that it must call attention to questions raised regarding “minor office procedures”, defined within the legislation as follows:

Minor office procedures. "Minor office procedures" means the use of operative, electrical, or other methods for the surgical repair and care incidental to superficial lacerations and abrasions, superficial lesions, and the removal of foreign bodies located in the superficial tissues and the use of antiseptics and local anesthetics in connection with such methods, except that it shall not include general or spinal anesthetics, major surgery, surgery of the body cavities, or specialized surgeries such as plastic surgery, surgery involving the eye, or surgery when tendons are involved.

The Council requested additional information from the proponents regarding the type of surgery that naturopaths do, and how minor and major surgery could be differentiated. That is, major surgical procedures are not defined within the legislation. The occupation indicated, when responding to a written question, that major surgical procedures include such procedures as “orthopedical or heart bypass surgeries” would not be included. However, the legislature may want to determine whether the proposed statute sufficiently describes what surgical procedures are permitted and which are prohibited. Stakeholders will also be involved in addressing critical scope of practice issues.

Executive Summary

Description of the Occupation:

- The scope of practice is quite broad, encompassing functions that are within the practice of other regulated health professions, as well as broad prescribing authority.
- The proposed scope of practice contains language stating that the scope of practice includes, but is not limited to, the provision of a long list of services. Such language is unusual for a delineated scope of practice of a regulated occupation.

Safety and Efficacy:

- The Council found a decided lack of objective data regarding the safety and efficacy of the profession. The Legislature has previously expressed interest in evidence-based health practice, and may want to weigh the evidence of efficacy of naturopathy.
- The Legislature may wish to obtain input from stakeholders in other occupations in regard to naturopathic practices, as well as safety and risk of devices, scope of practice, and, in particular, prescribing authority.

Government and Private Sector Recognition:

- There is a discernible split among naturopathic practitioners regarding whether the State should or should not licensure naturopaths. In determining whether this profession is ripe for licensure, the legislature will want to determine whether a consensus can be reached among the groups.
- The proposed legislation requests licensure, but the suggested regulatory scheme is more consistent with title protection than licensure.

Education and Training:

- The Legislature is encouraged to review the adequacy of the training / educational requirements for the occupation, including non-restricted practice of naturopathy by students in an approved naturopathic medical college (if under supervision of a licensed physician, osteopath, chiropractor, or naturopathic doctor).

Practice Model and Viability of Professions:

- Under the proposed legislation, the Medical Practice Board would have an advisory council to review and regulate the activities of the licensed naturopathic doctors.
- Some ambiguity exists as to the number of practitioners who would be able to meet the proposed eligibility criteria, although estimated by proponents as approximately 25 persons. The number of other persons, who also hold themselves out to be practitioners of naturopathy, and who would not meet licensing requirements, is unknown.

Regulatory Framework:

- The size of the group that would be regulated is estimated by the proponents to consist of only 25 practitioners. The Council is dubious regarding cost-effectiveness of licensing this number of practitioners, and recommends that the Legislature closely examine this component of the proposal.
- The Legislature will need to determine whether the proposal offers sufficient clarity, whether sufficient evidence exists to support efficacy of naturopathic practice, and whether the public will be protected by this licensing proposal.

Appendix A

Article 1, Section 2 of S.F. 3232 contains the proposed scope of practice.

Sec. 2. (a) The practice of naturopathic medicine by a licensed naturopathic doctor includes, but is not limited to, the following services:

(1) using, administering, prescribing, or dispensing for preventive and therapeutic purposes: food, extracts of food, nutraceuticals, vitamins, minerals, amino acids, enzymes, botanicals and their extracts, botanical medicines, herbal remedies, homeopathic medicines, all dietary supplements and nonprescription drugs as defined by the federal Food, Drug, and Cosmetic Act, glandulars, protomorphogens, lifestyle counseling, hypnotherapy, biofeedback, dietary therapy, electrotherapy, ultrasound, galvanic therapy, naturopathic physical medicine, oxygen, therapeutic devices, barrier devices for contraception, and minor office procedures;

(2) performing or ordering for diagnostic purposes physical and official examinations, electrocardiograms, ultrasound, phlebotomy, clinical laboratory tests and examinations, and physiological function tests;

(3) ordering diagnostic imaging studies including x-ray, ultrasound, mammogram, bone densitometry, and referring the studies to an appropriately licensed health care professional to conduct the study and interpret the results;

(4) prescribing nonprescription medications and therapeutic devices or using noninvasive diagnostic procedures commonly used by physicians in general practice;

(5) utilizing routes of administration that include oral, nasal, auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular;

(6) prescribing or performing naturopathic physical medicine; and

(7) prescribing all legend and schedule III, IV, and V controlled substances.

(b) A licensed naturopathic doctor may prescribe any of the following:

(1) hormones, including human growth hormone; thyroid hormones, including synthetics, armour, T3 and T4; natural estrogens; progesterone; testosterone; dehydroepiandrosterone (DHEA); pregnenolone; hydrocortisone; adrenocorticotrophic hormone (ACTH); and oxytocin;

(2) prostaglandins;

(3) silver nitrate;

(4) lidocaine;

(5) birth control pills and contraceptive barrier devices;

(6) antibiotics, including penicillins, cephalosporins, macrolides, tetracyclines, quinolones, nitrofurantoin, clindamycin, trimethoprim, cotrimoxazole, fosfomycin, and linezolid;

(7) antifungals, including nystatin and azoles;

(8) antiparasitics;

(9) antidiarrheals;

(10) diuretics;

(11) epinephrine;

(12) procaine;

- (13) medications used to treat diabetes, including insulins, sulfonylureas, meglitinides, thiazolidinediones, alpha-glucosidase inhibitors, and biguanides;
- (14) oxygen;
- (15) antihistamines;
- (16) short-acting beta-2 agonists including albuterol;
- (17) mast cell stabilizers including cromolyn sodium;
- (18) selective estrogen receptor modifiers;
- (19) bisphosphonates;
- (20) heavy metal therapies: EDTA, DMPS, and penicillamine;
- (21) nootropic drugs, including hydergine (ergoloid mesylate), selegiline, piracetam, and bromocriptine; and
- (22) nonhemorrhagic drugs.