# 2005 SUNR-SE REV-E

### Colorado Department of Regulatory Agencies Office of Policy, Research and Regulatory Reform

### Naturopathic Physicians



### STATE OF COLORADO

**DEPARTMENT OF REGULATORY AGENCIES** 

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Bill Owens Governor

October 14, 2005

Members of the Colorado General Assembly c/o the Office of Legislative Legal Services State Capitol Building Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado Department of Regulatory Agencies has completed its evaluation of the sunrise application for regulation of naturopathic physicians and is pleased to submit this written report. The report is submitted pursuant to section 24-34-104.1, Colorado Revised Statutes, which provides that the Department of Regulatory Agencies shall conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

The report discusses the question of whether there is a need for the regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm, and whether the public can be adequately protected by other means in a more cost-effective manner.

Sincerely,

Tambor Williams
Executive Director

Tambo Williams

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### The Sunrise Process

### Background

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:

- (I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
- (II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence; and
- (III) Whether the public can be adequately protected by other means in a more cost-effective manner.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation. Applications received by July 1 must have a review completed by DORA by October 15 of the year following the year of submission.

### Methodology

DORA has completed its evaluation of the proposal for regulation of naturopathic physicians. During the sunrise review process, DORA performed a literature search, contacted and interviewed the applicant, reviewed licensure laws in other states, conducted interviews of administrators of those programs, and interviewed other groups of healthcare practitioners. DORA attended a meeting between the Colorado Medical Society and the Colorado Association of Naturopathic Physicians. Also, DORA facilitated a meeting between proponents and opponents of regulation. In order to determine the number and types of complaints filed against naturopaths in Colorado, DORA contacted the Office of the Attorney General, and the Colorado Board of Medical Examiners.

### **Proposal for Regulation**

The Colorado Association of Naturopathic Physicians (Applicant) has submitted a sunrise application to the Department of Regulatory Agencies (DORA) for review in accordance with the provisions of section 24-34-104.1, Colorado Revised Statutes (C.R.S.). This occupational group is known as Doctors of Naturopathy, N.D., naturopaths, naturopathic practitioners, naturopathic physicians, Doctors of Naturopathic Medicine, and Naturopathic Medical Doctors.

The Applicant proposes a state licensure program for naturopathic physicians that would define a scope of practice, establish clear titles that the public understands, and allow for discipline of practitioners. The Applicant seeks regulation in order to enable the public to clearly differentiate between the various members of the naturopathic profession in regards to training and qualifications, and to allow naturopathic physicians a scope of practice and authorization to practice.

The Applicant further argues that Colorado needs regulation of naturopathic physicians for the following reasons:

- The public should not be required to become experts in medical education and detection of false credentials in order to access health care.
- Regulation should provide clear avenues for public complaint, a functional disciplinary
  process by which the public can register complaints, allow the state to control
  inappropriate practice, and ensure that practitioners are afforded due process.

The following components would characterize the recommended licensure program:

- Program administered by the Division of Registrations located within DORA.
- Establishment of minimum education standards, including a degree from a naturopathic medical college accredited by the Council on Naturopathic Medical Education (CNME).
- Passing scores on the Naturopathic Physicians Licensing Examinations (NPLEX).
- Defined scope of practice.

The Applicant previously submitted sunrise applications in 1993 and 1998. Comparable to the current application, the previous applications proposed a licensure program that required a degree from a CNME-accredited naturopathic medical college and successful passage of the NPLEX. The 1993 sunrise review concluded that the Applicant had not shown that the public was being substantially harmed by the unregulated practice of naturopathic physicians. In addition, the number of naturopathic physicians in Colorado comprised such a small number (20) that a regulatory program would place an unreasonable burden on practitioners because the licensing fee would have been approximately \$1,500 per year. Although the sunrise review conducted in 1993 recommended against regulation, a bill for full regulation and licensure of naturopathic physicians was introduced in the General Assembly.

The 1998 sunrise review delineated the benefits of regulation and discussed the potential public confusion regarding the education and training of persons in Colorado who refer to themselves as naturopathic physicians, naturopathic medical doctors, Doctors of Naturopathy, and N.D. Furthermore, the 1998 sunrise review maintained that if the General Assembly determined that regulation of naturopathy was warranted, two regulatory models (title protection and licensure) would be reasonable to consider.

### Profile of the Profession

### **Historical Perspective**

Naturopathy is a system of health care based on the philosophy that the human body has the power to heal itself by restoring its natural balance. Naturopathy encompasses an evolving system of natural therapeutics that includes hydrotherapy, homeopathy, nutritional therapy, botanical medicines, psychology, physiotherapy, and spinal manipulation.

Natural medicine grew out of the alternative healing systems of the 18th and 19th centuries, but traces its philosophical roots to the Hippocratic school of medicine (circa 400 B.C.). Naturopathic medicine has been practiced in the United States and in Europe throughout history. Conventional medicine and naturopathy were at one time quite similar in their use of medicinal plants, diet therapies, and hydrotherapy treatments. Only within the last 40-50 years has conventional medicine diverged from this path.

The naturopathic profession has a 100-year history in North America. Naturopathy evolved in the late 19th century from the work of Dr. Benjamin Lust, a German physician who came to the United States in 1892 to spread the practice of hydrotherapy. Naturopathy grew to include all natural methods of healing, including the use of botanical medicines, homeopathy, nutritional therapy, and manipulative therapies. The term "naturopathy" was coined for this evolving system of natural therapies in 1895 by Dr. John Scheel of New York City, to describe his method of health care.

Naturopathic medicine was popular and widely available throughout the U.S. well into the early part of the 20th century. Around 1920, from coast to coast, there were a number of naturopathic medical schools, thousands of naturopathic physicians, and a large number of patients using naturopathic therapies.

Naturopathic medicine went into decline, along with most other natural health professions, after the 1930s. Dr. Benjamin Lust's death, conflict between various schools of natural medicine (homeopathy, Eclectics, Physio-Medicalism, herbalism, naturopathic medicine, and others.), the rise of medical technology, and the use of "miracle drugs" like antibiotics were all contributing factors. By the 1970s, however, the American public was inspired to look for "new" options and alternatives to conventional medicine. Naturopathy and all of complementary alternative medicine began to enter a new era of rejuvenation. <sup>1</sup>

### The Naturopathic Physician

In states that regulate naturopathic physicians, they function as primary care physicians and have attended four-year graduate level naturopathic medical schools. They study holistic and nontoxic approaches to therapy with a strong emphasis on disease prevention and optimizing wellness. Naturopathic physicians encourage the self-healing abilities of the individual through the education and promotion of therapeutic methods and modalities. Their training with respect to modalities includes a focus on nutrition, botanical medicine, homeopathy, hydrotherapy, physical manipulation, pharmacology, and minor surgery. Some naturopathic physicians have additional training in natural childbirth and/or acupuncture. The American Association of Naturopathic Physicians defines naturopathic medicine as "a distinct system of primary health care - an art, science, philosophy and practice of diagnosis, treatment, and prevention of illness." <sup>3</sup>

The practice of naturopathy is based on the philosophy that can be summarized as: "helping the body heal itself in the least invasive, most fundamentally curative manner possible. This approach is not tied to any particular therapy or modality, but rather is oriented to a rational blend of vitalistic and mechanistic principles working with the whole person, and educating the patient in the ways of health."<sup>4</sup>

<sup>1</sup> 

<sup>&</sup>lt;sup>1</sup> University of Maryland Medical Center, <a href="http://www.umm.edu/altmed/ConsModalities/Naturopathycm.htm">http://www.umm.edu/altmed/ConsModalities/Naturopathycm.htm</a>: accessed July 19, 2005.

<sup>&</sup>lt;sup>2</sup> Holly J. Hough et al., *Profile of a Profession: Naturopathic Practice*. San Francisco: Center for the Health Professions, University of California, 2001.

<sup>&</sup>lt;sup>3</sup> The American Association of Naturopathic Physicians, "AANP Definition of Naturopathic Medicine Position Paper;" available from <a href="http://www.naturopathic.org/news/positions/definition\_naturopathic\_medicine.aspx">http://www.naturopathic.org/news/positions/definition\_naturopathic\_medicine.aspx</a>: accessed December 12, 2004.

<sup>4</sup> Randall Bradley, N.D., Philosophy of Naturopathic Medicine. Pizzorno: Murray & Bradley, 1985.

There are six principles that naturopathic physicians consider to be fundamental in defining naturopathic medicine. They are:

### 1. The Healing Power of Nature:

Naturopathic medicine recognizes an inherent healing process in the person that is ordered and intelligent. The body is capable of healing itself. The role of the naturopathic physician is to identify and remove obstacles to healing and recovery and to facilitate and augment this inherent natural tendency of the body.

### 2. Identify and Treat the Cause:

Naturopathic physicians seek to identify and remove the underlying causes of illness, not merely eliminate or suppress symptoms.

### 3. First Do No Harm:

Naturopathic physicians follow three guidelines to avoid harming patients:

- 1. Utilize methods and medicinal substances that minimize risks of side effects, using the least force needed to diagnose and treat.
- 2. Avoid, when possible, the harmful suppression of symptoms.
- 3. Acknowledge and work with the individual's self-healing process.

### 4. Doctor as Teacher:

Naturopathic physicians recall that the origin of the word "doctor" is the Latin word, "to teach." A fundamental emphasis in naturopathic medicine is patient education.

### 5. Treat the Whole Person:

Naturopathic physicians attempt to take into consideration all the factors that make up patients' lives and affect their health and well-being.

### 6. Prevention:

Naturopathic medicine emphasizes the prevention of disease, assesses risk factors, and makes appropriate interventions with patients to prevent illness.

Naturopathic physicians believe that health results from the harmonious functioning of all parts of a person. Therapy is directed at the whole person and at the underlying cause of illness, such as the patient's lifestyle, diet habits, and emotional state.

Naturopaths take a holistic approach to healing. In diagnosing ailments, naturopathic physicians take medical histories, order laboratory tests, and perform physical examinations. Treatment methods include nutritional advice, the use of homeopathic remedies, herbs and botanical medicines, vitamin and mineral therapy, physiotherapy, hydrotherapy, psychological counseling, stress management, and spinal manipulation. In regard to spinal manipulation, naturopathic physicians differ from chiropractors in that chiropractors may specialize in one therapeutic approach while naturopathic practice usually includes a broad range of drugless therapies.

One treatment method, homeopathy, based on the principle that "like cures like," is a treatment in which the patient receives tiny dosages of natural substances that in larger dosages would cause the same symptoms as the ailment. It is based upon the observed relationship between a remedy's ability to produce signs and symptoms in a healthy individual and the same remedy's ability to cure a sick patient with similar signs and symptoms. Homeopathic remedies are derived from a wide variety of plant, mineral, and chemical substances. The 1938 Federal Food, Drug, and Cosmetic Act gave legal status to homeopathic remedies. These remedies are recognized as drugs in the *Homeopathic Pharmacopoeia of the United States*. Homeopathic remedies are available from practitioners, pharmacists, and health food stores, as well as manufacturers who sell directly to the public.

Hydrotherapy, another method of treatment used by naturopathic physicians, is defined as the use of water in any of its forms for the maintenance of health or the treatment of disease. Water at various temperatures is used for therapeutic purposes. For example, the physiotherapy departments of many hospitals have heated hydrotherapy pools for treatment. Alternate treatments with hot and cold water are used to stimulate the circulation of the blood. Naturopathic physicians may also recommend hydrotherapy for its revitalizing properties during convalescence.

### **Education and Training**

All naturopathic medical college programs are residential (students attend classes and laboratories in person) and have four-year academic programs. The U.S. Department of Education (U.S. DOE) recognizes the Council on Naturopathic Medical Education (CNME) as the programmatic accrediting agency for the residential naturopathic medical colleges. The CNME requires four years of graduate level study in medical sciences and naturopathic therapeutics. The CNME received federal recognition from the U.S. DOE in 1987 and acted as the institutional accrediting agency for naturopathic programs for the next 13 years.

In 1999, the U.S. DOE staff and the National Advisory Committee on Institutional Quality and Integrity (NACIQI) requested that CNME's application for renewal of recognition be denied. The recommendation was based on evidence that CNME did not respond appropriately to violations of its standards at Southwest College of Naturopathic Medicine (SCNM). Between 1997 and 1998, SCNM experienced significant financial and administrative difficulties. Although the CNME stated that it had closely followed the situation and urged school officials to correct the problems, the U.S. DOE staff and a majority of NACIQI members concluded that CNME had failed to issue a timely order to show cause why SCNM should not have its candidacy for accreditation ended. The U.S. DOE withdrew its recognition of the CNME on January 16, 2001. In September 2003, CNME regained its U.S. DOE recognition with a renewal date set for 2005. In June 2005, NACIQI voted to recommend that the U.S. DOE grant re-recognition of the CNME for three years.

The first two years of graduate study in naturopathic medical colleges focus on the standard medical sciences (e.g., anatomy, physiology, pathology, biochemistry, immunology, embryology, and related areas), with specialty courses required in pediatrics, obstetrics, cardiology, dermatology, neurology, urology, and other clinical sciences. During this period of study, students also begin their training in diagnostic procedures (physical examination, laboratory testing, and diagnostic imaging).

During the third and fourth academic years, clinical methods of naturopathic medicine are presented in preventive medicine, pediatrics, geriatrics, gynecology, obstetrics, physical medicine, neurology, endocrinology, cardiology, pulmonology, urology, dermatology, immunology, case management, intravenous therapy, and practice management. The focus on therapeutic interventions intensifies, covering the broad range of diverse natural treatment modalities such as clinical nutrition and diet, botanical medicine, homeopathy, naturopathic physical medicine, hydrotherapy, counseling, and health psychology. During this clinical phase, students are also trained in pharmacology, consistent with a naturopathic scope of practice and in minor office procedures, such as removal of superficial lesions and suturing of minor lacerations.

In addition, during the third and fourth years of the naturopathic medical program, students participate in clinical internships, which consist of 1,500 hours of treating patients under the supervision of licensed naturopathic and conventional medical physicians. At the National College of Naturopathic Medicine in Portland, Oregon for example, clinical training hours comprise 1,525 of the total 5,188 hours of instruction.

Though not required for graduation, if an individual wishes to gain more clinical experience, he or she may enter a naturopathic postdoctoral residency program. The SCNM, for example, has developed an integrated residency program, whereby residents are exposed to private practice, community clinics, research, and teaching environments. In addition, affiliation agreements with area hospitals and medical clinics offer access to hospital facilities, including emergency rooms. The Cancer Treatment Centers of America offer a full-time, two-year naturopathic residency program at its Midwestern Regional Medical Center. The program highlights general medicine with a strong emphasis on naturopathic oncology. Currently, Utah is the only state requiring a one-year residency prior to obtaining a license.

There are three naturopathic medical colleges in the United States accredited by the Commission on Accreditation of the CNME and one college that is a candidate for accreditation. These colleges include Bastyr University in Seattle, Washington; National College of Naturopathic Medicine in Portland, Oregon; the Southwest College of Naturopathic Medicine in Scottsdale, Arizona; and the University of Bridgeport in Bridgeport, Connecticut (candidacy status). A minimum of three years of undergraduate premedical study from an accredited college or university is a prerequisite for entry to an accredited naturopathic medical college.

<u>Bastyr University</u> was founded in 1978 to train naturopathic physicians with a scientific approach. Since then, degree programs in nutrition, acupuncture and Oriental medicine, applied behavioral science, psychology, exercise science, and herbal sciences and health have been added. In addition to accreditation by CNME, Bastyr is accredited by the Commission on Colleges of the Northwest Association of Schools and Colleges. The Bastyr University AIDS Research Center was established in October 1994, under a cooperative grant from the National Institute of Health's National Institute of Allergy and Infectious Disease and the National Center on Complementary and Alternative Medicine.

Founded in 1956, the <u>National College of Naturopathic Medicine</u> (NCNM) is the oldest naturopathic medical school in North America. The Naturopathic Physician (N.D.) degree accredited by the CNME is a four-year graduate program that prepares graduates for licensure and the general practice of naturopathic medicine. NCNM was the first naturopathic institution to develop a residency program certified by the CNME. The program has site residencies in six states and 18 residents for the 2003-2004 academic year. Over 50 percent of the licensed naturopathic physicians practicing in the United States are graduates of NCNM. In June 2005, NCNM received accreditation from the Northwest Commission on Colleges and Universities. The accreditation was backdated to the beginning of the academic year commencing on September 1, 2004.

The Doctor of Naturopathic Medicine program began at the <u>Southwest College of Naturopathic Medicine & Health Sciences</u> (SCNM) in 1992. The SCNM is approved by the Arizona Naturopathic Physicians Board of Medical Examiners and the Arizona Board for Private Post-Secondary Education and accredited by the CNME. Additionally, the college has candidacy status with the Higher Learning Commission of the North Central Association of Colleges and Schools. The residency program at SCNM is a post graduate, formal education program that offers the participant the opportunity to gain a wide range of clinical experiences in the area of family practice medicine. SCNM has a number of preceptorship opportunities for graduates. A preceptorship, as opposed to a residency position, allows a graduate (licensed or unlicensed) to practice under a licensed naturopathic physician in a clinical setting.

The Doctor of Naturopathic Medicine (N.D.) degree program offered at the <u>University of Bridgeport</u> was licensed by the state of Connecticut Department of Higher Education in May 2000, and granted Candidacy Status from the CNME in March 2001.

### **Examinations**

In 1985, in response to a need for the development of standards for licensing naturopathic physicians, a group of licensed naturopathic physicians created Naturopathic Physicians Licensing Examination (NPLEX). NPLEX contracted with the National Assessment Institute to do the initial development of the examination. A questionnaire was sent to licensed naturopathic physicians nationwide to determine which functions of diagnosis and treatment were being encountered in practice, and to assess the level of frequency and criticality associated with each aspect. A set of seven (7) clinical examination blueprints were developed, on which the NPLEX is based. Two "Add-On" examinations (in Homeopathy and Minor Surgery) were also made available to jurisdictions that required demonstrated competence in these areas.

The National Assessment Institute set standards for test development, administration, item review, and scoring, all of which are followed today. NPLEX has contracted with other organizations (including Columbia Assessment Services and the Washington State Department of Health) to provide the examination production and scoring services. Gradually, NPLEX, Inc. has taken over more of the responsibility for this process.

For the purposes of the Applicant's request for licensure, the psychometrician from the Division of Registrations reviewed the examination development, scoring, and security of NPLEX. A summary and total analysis may be found in Appendices A and B beginning on page 40.

### **Summary of Current Regulation**

### The Colorado Experience

From 1923 until it closed in the 1960s, the University of Natural Healing Arts and its College of Naturopathy was located in Denver and trained naturopathic doctors, physical therapists, and chiropractors. The school offered a four-year, in-residence dual chiropractic and naturopathic degree program. Currently, there are no four-year programs in Colorado accredited by an agency recognized by the U.S. Department of Education that offer Doctor of Naturopathic Medicine degrees. There are no laws to regulate the practice of naturopathic physicians, or to establish standards for scope of practice.

For example, in Colorado, there is a practicing Doctor of Naturopathic Medicine with a diploma from the Colorado University of Naturopathic Medicine. His diploma is embossed with a seal from the Colorado Alternative Medical Regulatory Board. A copy of this diploma "establishes confirmation of certification, accreditation, and license endorsement in a single authenticating document." Research was initiated to further compile information on the Colorado University of Naturopathic Medicine and the Colorado Alternative Medical Regulatory Board. The only information available on the Colorado University of Naturopathic Medicine was found on the state websites of both Michigan and Oregon, which list colleges and universities whose degrees are not accepted by the state civil service as satisfying any educational requirements. Furthermore, the State of Oregon proclaims that a degree from this entity is invalid for use in state or licensed employment in Oregon and the use of such degrees can result in criminal prosecution or civil penalties depending on the circumstances of the use. Moreover, the Colorado Alternative Medical Regulatory Board has no affiliation with any State of Colorado regulatory authority.

Although the sunrise review conducted in 1993 recommended against regulation, a bill for full regulation and licensure of naturopathic physicians was introduced in the General Assembly, indicating that the Joint Sunrise/Sunset Committee found that regulation was necessary. The 1998 Sunrise Review of Naturopathic Physicians maintains: "While it is not clear whether the sunrise criteria for regulation have been satisfied, there are reasons to consider regulation of naturopathic physicians." Furthermore, the review states that if the Colorado General Assembly determines that the regulation of naturopathic physicians is necessary, a licensing scheme administered by the Director of the Division of Registrations could provide adequate public protection.

### Sloan's Lake Managed Care

Sloans Lake Managed Care provider network is comprised of approximately 10,500 individual providers. In its capacity as a Preferred Provider Organization (PPO), Sloan's Lake provides managed care services to insurance carriers and corresponding employer groups. It is among the first managed care companies offering alternative care. Alternative care offered in the network includes acupuncture, ayurvedic medicine, Chinese medicine, herbology, homeopathy, massage therapy, mind/body interventions, and naturopathic medicine. The criteria that Sloan's Lake Managed Care uses for credentialing Naturopathic Doctors includes the following:

- Completion of a four year Council on Naturopathic Medical Examination (CNME) accredited doctoral program in Naturopathic Medicine;
- Passing scores on the Naturopathic Physicians Licensing Examination (NPLEX);
- Current license to practice in a state which regulates the practice, with no pending investigations or action by that state's licensing board; and
- Completion of a one year residency program or a minimum of five years experience in full time practice.

### Colorado Association of Naturopathic Physicians

There are approximately 84 naturopathic physicians in Colorado who have graduated from CNME-accredited colleges. Of these 84, 74 maintain licenses in states that have a regulatory program to license naturopathic physicians. Of these 74 naturopathic physicians, 45 are professional members of the Colorado Association of Naturopathic Physicians (CANP). CANP, established in 1985, is a professional association of naturopathic physicians formed to promote the merits of naturopathic medicine in Colorado and to work towards a law that would enable its members to practice. The American Association of Naturopathic Physicians (AANP) recognized the CANP as a constituent organization in the fall of 1987. Active members in the CANP must hold either a valid license to practice naturopathic medicine in a state with a board of examiners recognized by the AANP or hold a degree of Doctor of Naturopathic Medicine from a naturopathic medical college approved by the CNME.

### Regulation In Other States

The legal status of naturopathy varies from state to state. In some states, the practice of naturopathy, though not regulated, is protected through court rulings or attorney general opinions. In most states, naturopathic physician status is unprotected or unclear. Two states, Florida and Nevada, have repealed regulation of this profession. Nevada ceased licensing naturopathic physicians in 1987 (in Nevada naturopathic physicians were required to be supervised by medical doctors). Although naturopathic licensing in Florida was discontinued in 1959, there are still laws and a board regulating those naturopaths still practicing. Florida allows naturopathic physicians licensed prior to program termination dates to continue to practice. In Tennessee and in South Carolina, the practice of naturopathy is illegal. Tennessee law, for example, provides that the practice of naturopathy is a Class B misdemeanor, but renders this prohibition inapplicable to "persons who comply with the regulatory laws of the state with respect to the practice of the various healing arts." Without a similar textual qualification, however, a South Carolina statute prohibits the practice of naturopathy and subjects offenders to a fine not to exceed \$500 or imprisonment for a period not exceeding one year, or both.

The multiplicity of therapies and techniques that typically comprise the statutory definition of naturopathy may often fall within the scope of practice for other professions. The Montana Naturopathic Practice Act expressly acknowledges this fact by recognizing that many of the therapies used by naturopathic physicians, such as the use of nutritional supplements, herbs, foods, homeopathic preparations, and such physical forces as heat, cold, water, touch, and light, are not the exclusive privilege of naturopathic physicians, and their use, practice, prescription, or administration by persons not licensed to practice naturopathic medicine is not prohibited by this practice act.

Currently, 15 states and the District of Columbia license naturopathic physicians: Alaska, Arizona, California, Connecticut, Florida, Hawaii, Idaho, Kansas, Maine, Montana, New Hampshire, Oregon, Utah, Vermont, and Washington. In several states, licensed naturopathic physicians must also qualify for a certificate to practice natural childbirth, acupuncture, or to dispense a natural substance or device. The following highlights the regulatory programs found in the 15 states.

<u>Alaska's</u> law places several restrictions on the practice of naturopathy. A person who practices naturopathy may not prescribe a prescription drug, perform surgery, or use the word "physician" as a title. There are currently 36 licensed naturopathic doctors in Alaska.

Arizona's Naturopathic Physicians Board of Medical Examiners (Arizona Board) was established in 1935. Arizona remains the state with the third highest number of licensed naturopathic physicians (400). The Arizona Board has the statutory authority to adopt rules for recognizing naturopathic specialties. The Arizona Board has approved training programs in four specialty areas and has issued certificates to at least 16 naturopaths in the specialty of family medicine. Additionally, the Arizona Board has assembled a formulary of more than 460 items that naturopathic physicians may dispense including both prescription drugs and some controlled substances.

In 2000, the Arizona Board underwent a performance audit. The review concluded that terminating the Arizona Board would not significantly harm the public's health and safety since the practice of medicine would continue to be regulated by the Allopathic Board of Medical Examiners. Naturopaths could continue to perform many traditional activities, but would no longer be allowed to act as primary medical care providers. However, the review further stated that terminating the Arizona Board could harm the public's welfare by potentially limiting access to alternative medical care. Subsequently, there was no action taken by the Arizona legislature to repeal the Arizona Board.

<u>California's</u>. The Bureau of Naturopathic Medicine (Bureau) within the Department of Consumer Affairs was established to administer the Naturopathic Doctor's Act and was authorized to collect fees and receive license applications beginning January 1, 2004. This act authorizes the creation of an advisory committee comprised of three licensed naturopathic doctors, three licensed physicians, and three public members. The committee's first meeting was convened on December 13, 2004. Additionally, a naturopathic formulary advisory committee was formed and a naturopathic childbirth attendance advisory committee was created to issue recommendations concerning the practice of naturopathic childbirth attendance.

The scope of practice for licensed naturopathic doctors includes diagnosis and treatment of patients, including the authority to order lab tests and prescribe most drugs subject to supervision of a medical or osteopathic physician. Licensed naturopathic doctors may perform minor procedures, such as treating lacerations and removing moles and growths.

The program began accepting license applications in January 2005. Currently there are 129 licensed naturopathic doctors in California.

<u>Connecticut's</u> law, which was enacted in 1920, does not allow licensed naturopathic physicians to perform minor surgery, prescribe drugs, or practice obstetrics and gynecology. The statute requires that naturopathic physicians maintain professional liability insurance. There are currently 196 licensed naturopaths in Connecticut.

<u>District of Columbia</u> In May 2004, final approval was given to the Naturopathic Medicine Licensing Amendment Act of 2004 to license naturopathic physicians as primary care providers. The act recognized naturopathic physicians who have completed four-years of naturopathic medical college training and successfully passed the NPLEX. Prior to the passage of this act, the District of Columbia had a registration program for naturopaths. A person registered to practice naturopathy was entitled to use the title "Doctor of Naturopathy." The only requirements for registration were that applicants must be at least 18 years of age and not have been convicted of a crime of moral turpitude that bears directly on the applicant's fitness to be registered. The practice specifically excluded the use of x-rays, performing any surgical procedure, injecting any substance into a person by needle, or performing any invasive procedure.

As of September 2005, the District of Columbia had not promulgated any rules or issued any licenses.

Florida's licensing authority for naturopathic physicians was abolished in 1959 and licensees who were licensed at that time were allowed to continue practicing naturopathic medicine. Draft legislation proposed by the Florida Naturopathic Physician Association was introduced in 2004 to reestablish regulation of naturopathic medicine through licensure and to create the Board of Naturopathic Medicine within the Department of Health. A 2004 Sunrise Report on Proposed Licensure of Naturopathic Physicians, by the Florida House of Representatives, Committee on Health Care, concluded that while there is evidence for support of licensure based on the existence of accredited training programs and licensure examinations, there is no documented evidence of substantial risk from not licensing naturopathic physicians. Moreover, there is potential risk from licensing naturopathic physicians and allowing them to provide a broad range of primary care services.

<u>Hawaii</u> has regulated naturopathic physicians since 1925. There are currently 81 licensed naturopaths. Originally, the Board of Health was responsible for conducting examinations and issuing licenses. In 1969, the regulation was transferred to the Department of Regulatory Agencies, now the Department of Commerce and Consumer Affairs. The regulation of naturopathy was reviewed in 1978 and 1985, with continued regulation recommended in both instances.

<u>Idaho</u> became the 15th state in 2005 to create a licensure program for naturopathic physicians. The legislation is a full scope and title protection act. The law requires the creation of a formulary council to determine pharmaceutical privileges for naturopathic physicians.

<u>Kansas</u> passed legislation during the 2002 legislative session to regulate the practice of naturopathic medicine. The bill, signed into law in May 2003, provides registration for naturopathic doctors, rather than licensing, yet requires educational and testing requirements. Naturopathic medicine is defined to include such procedures as venipuncture, naturopathic acupuncture, and minor office procedures. Naturopathic doctors may not perform surgery, practice obstetrics, administer ionizing radiation or prescribe, dispense or administer any controlled substances or any prescription-only drugs except those listed on the naturopathic formulary adopted by the Kansas board.

<u>Maine's</u> Board of Complimentary Health Care Providers regulates 19 naturopathic doctors. Naturopathic doctors have the exclusive right to the use of the terms "naturopathic doctors," "naturopathic," "naturopath," "doctor of naturopathic medicine," "Doctor of Naturopathy," "naturopathic medicine," "naturopathic health care," "naturopathy," and "N.D." Use of the term "physician" by a licensee is prohibited. Naturopathic Doctors have a limited scope of prescriptive authority.

<u>Montana's</u> Naturopathic Health Care Practice Act was enacted in 1991 to regulate lay midwives and naturopathic physicians. Naturopathic physicians are authorized to perform minor surgery, attend a natural childbirth if in possession of a certificate of specialty practice, and prescribe certain drugs as established by the natural substance formulary list. When the program first began there were only five licensed naturopathic physicians in the state, however, as of August 2005, there were 66.

<u>New Hampshire's</u> Naturopathic Health Care Practice Act was enacted in 1994. Specialty certificates in naturopathic childbirth and acupuncture are offered. Doctors of naturopathic medicine with specialty certification in naturopathic childbirth are authorized to use oxytocin and pitocin. There are currently 36 licensed naturopathic physicians in New Hampshire.

<u>Oregon</u> first began licensing naturopathic physicians in 1927, although they were able to practice before then under an exemption in the Osteopathic Practice Act. The total number of licensed naturopathic physicians in Oregon equals 636, ranking second for licensees in a state. Oregon also has the most encompassing law as practitioners are allowed to prescribe drugs, perform minor surgery, and practice natural childbirth with a certificate of special competency.

<u>Utah's</u> Naturopathic Physicians Licensing Board was created in 1996. The board currently issues five different categories of licenses: naturopath, naturopath including surgery/obstetrics, naturopathic physician, temporary naturopathic physician, and naturopathic controlled substance. In order to perform naturopathic childbirth, a licensee must satisfy the standards of the American College of Naturopathic Obstetricians or its successor.

<u>Vermont's</u> licensed naturopathic physicians may order, prescribe, dispense, and administer certain medications of mineral, animal, or botanic origin and must adhere to the Naturopathic Physician Formulary Rules promulgated by the Vermont Department of Health. Licensees may not practice naturopathic childbirth unless they have obtained a special endorsement that requires specific education; training; passage of an examination; and actual childbirth assistance, participation, and observation.

<u>Washington</u> has regulated naturopathic physicians since 1919, as part of its law created to regulate professions engaged in "drugless healing." The law was substantially amended in 1988 to reflect the current practice of naturopathic physicians. The total number of licensed naturopathic physicians in Washington is 650, ranking first for licensees in a state.

tables provide regulatory information, legal scope of practice, and licensing requirements for naturopathic physicians in the regulations promulgated by the legislative and licensing bodies in the various jurisdictions that license them. The following Legal scopes of practice accompany licensing acts. Naturopathic physicians often must adhere to different sets of laws and United States.

Table 1
Regulatory Information for Other States

State	Year Law	Type of Law	Title(s)	Regulatory Body	Number of	Complaint
	בוומכופת			Department of Community and	FICELISCES	Only 1 or 2 since
Alaska	1986	License	Naturopathic Doctor	Economic Development, Division	36	1986 with no
				of Occupational Licensing		discipline
						2002 - 36
			Doctor of Naturopathic	Naturonathic Physicians Board of		2003 - 30
Arizona	1935	License	Modicine	Medical Evaminers	432	(5 unlicensed)
			0	Modical Evaluations		2004 – 26
						(7 unlicensed)
California	2003	License	Naturopathic Doctor	Bureau of Naturopathic Medicine,	129	A/A
				State Board of Naturopathic		2002 - 1
Connecticut	1920	License	Naturopath	Examiners, Department of Public	196	2003 - 1
			-	Health		2004 - 1
District of Columbia	2004	License	Naturopathic Physician	Department of Health	A/N	N/A
Florida⁺	A/N	N/A	N/A	N/A	A/N	N/A
:: D Z	1005	i	Naturanthic Dhysician	State Board of Examiners in	ά	0 since 1008
nawali	1920	רוכפוואם	Naturopatine Filysteian	Naturopathy	0.1	0 2000
Idaho*	2005	License	Naturopathic Physician	State Board of Naturopathic Medical Examiners	N/A	N/A
Kansas	2002	Registration	Naturopathic Doctor	State Board of Healing Arts	6	None
Maine	1995	License	Naturopathic Doctor	Board of Complimentary Health Care Providers	19	N/A
Montana	1991	License	Naturopathic Physician	Board of Alternative Health Care	99	2003 - 2 2004 - 3
New Hampshire	1994	License	Doctor of Naturopathic Medicine	Naturopathic Board of Examiners	36	2002 - 0 2003 – 0
N/A - Not Available	ø					

<sup>+</sup> Florida abolished new licensing of naturopaths in 1959, but the state continues to renew licenses and regulate those naturopaths who were

licensed prior to July 1, 1959. \* Idaho law effective 7/01/2005.

State	Year Law Enacted	Type of Law	Title(s)	Regulatory Body	Number of Licensees	Complaint Activity
Oregon	1927	License	Doctor of Naturopathy Naturopathic Physician	Board of Naturopathic Examiners	989	2001 – 30 2002 – 23 2003 – 15 2004 – 13
Utah	1996	License	Doctor of Naturopathic Medicine Naturopathic Physician	Naturopathic Physicians Licensing Board	8	1-2 since 2002
Vermont	1996	License	Naturopathic Physician	Office of the Secretary of State, Office of Professional Regulation	102	1 since 2003
Washington	1919	License	Doctor of Naturopathic Medicine	Department of Health	650	2003 - 15

Table 2

### Scope of Practice in Other States

		1	I					,
\eartetrics\ Արցին ան Մահերույն	Yes, but cannot oversee childbirth	Yes	Yes – additional education and certification required	9 N	Yes –passage of a specialty examination, written agreement with a licensed obstetrician, and 100 coursework hours, internship or preceptorship required	Y/N	ХeУ	
Х-Кау	Yes	S 0	Yes	Yes	Yes	N/A	8	
Electrotherapy	Yes	Yes	Yes	Yes	Yes	N/A		
noitsluqinsM	Yes	Yes	o Z	Yes	Yes	A/A	Yes	
Physiotherapy	Yes	Yes	Yes	No	o Z	N/A	Yes	
Нуdrotherapy	Yes	Yes	Yes	Yes	, ∀es	N/A	Yes	
Dietetics	Yes	Yes	Yes	Yes	Yes	A/A	Yes	
Perform Limited Minor Surgery	o <sub>N</sub>	Yes	No – Bureau required to review, issue and report to legislature by January 1, 2006	9N	Yes	A/N	No	
Prescriptive ViirohtuA	οN	Yes – must pass an additional state examination	Yes – Limited. Bureau required to review, issue, and report to legislature by January 1, 2006	°N	Yes	A/N	No	
Practice Under Supervision of Licensed MD Only	oN	ON.	O Z	No	O Z	V/N	٥N	olde
ejsj2	Alaska	Arizona	California	Connecticut	District of Columbia	Florida	Hawaii	PINA NO TON

\esirteteO ygolosenyƏ	Yes - a special competency certificate for naturopathic childbirth is required	Yes – limited to contraception	Yes – limited to contraception	Yes – limited to contraception unless additional credentialing is obtained	Yes – limited to contraception unless additional credentialing is obtained	Yes – additional credentialing required	Yes – additional credentialing required	Yes – additional credentialing required	Yes – gynecology exams only
Х-Кау	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Electrotherapy	N/A	Yes	N/A	Yes	Yes	Yes	Yes	Yes	Yes
noitsIuqinsM	N	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Physiotherapy	o Z	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Нудгої негару	Yes	Yes	N/A	Yes	Yes	Yes	Yes	Yes	Yes
Dietetics	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Perform Limited Minor Surgery	Yes	ХeУ	Sə	Yes	ON N	ON	ХЭ	SӘД	Yes
Prescriptive Viinority	Yes – limited	Yes – limited	Yes – limited	Yes – limited	Yes – limited	Yes – limited	Yes - limited	Yes - limited	Yes - limited
Practice Under Supervision of Licensed MD Only	O Z	ON	oN	o Z	o Z	oN O	oN O	No	No
ətst2	Idaho	Kansas	Maine	Montana	New Hampshire	Oregon	Utah	Vermont	Washington

Table 3

## Licensing Requirements in Other States

	Education Requirements	Examination Requirements	Mandatory Continuing Education	Professional Liability Insurance
Alaska	Graduate from a four-year school that is accredited by or is a candidate for accreditation by the Council on Naturopathic Medical Education	NPLEX	N	No, but must disclose lack of insurance
Arizona	Graduate from a school that is accredited by or is a candidate for accreditation by the Council on Naturopathic Medical Education or a school that is accredited by or is a candidate for accreditation by an agency approved by the Council on Higher Education; and complete approved internship, preceptorship or clinical program	NPLEX and a jurisprudence examination developed by the Arizona Board. If the practitioner wishes to prescribe drugs, he/she must take a 60-hour course and pass an examination developed by the Arizona Board.	Yes – 30 hours per year, including 10 hours in pharmacology	o Z
California	Graduate from a school that is accredited by the Council on Naturopathic Medical Education	NPLEX	Yes – 60 hours every two years, including 20 in pharmacotherapeutics.	Yes
Connecticut	Graduate from a school approved by the state board. Educational program must last at least 64 weeks	Examination prescribed by the Department of Public Health	No	Yes – at least \$500,000 per occurrence, with aggregate not less than \$1.5 million
District of Columbia	Graduate from a school that is accredited by the Council on Naturopathic Medical Education	NPLEX	No	No
Florida	N/A	N/A	N/A	N/A
Idaho	Graduate from an approved naturopathic medical program approved by the Board	Have passed a competency-based examination approved by the Board.	Required for annual renewal	ON.
Hawaii	Graduate from school accredited by or that is a candidate for accreditation by a regional or national accrediting body recognized by the U.S. Department of Education	NPLEX <u>and</u> an examination on homeopathy	N	o N
ACI:C: A TOIN AVIA	-14-1:-			

N/A – Not Available.

	Education Requirements	Examination Requirements	Mandatory Continuing Education	Professional Liability Insurance
Kansas	Graduate from an approved school that offers a degree of doctor of naturopathy or naturopathic medicine and that requires a fouryear, full-time resident program of academic and clinical study	NPLEX	Yes – 50 hours per year	Yes
Maine	Graduate from school accredited by or that is a candidate for accreditation by a regional or national accrediting body recognized by the U.S. Department of Education	NPLEX	Yes – 25 hours per year, including 7 hours in pharmacology	No, but must disclose lack of insurance
Montana	Graduate from a school that is accredited by or is a candidate for accreditation by the Council on Naturopathic Medical Education or another accrediting agency recognized by the U.S. Department of Education, or a school that has been approved by the board	NPLEX	Yes – 15 hours per year, including 5 hours in pharmacology	No
New Hampshire	Graduate from a school that is accredited by or is a candidate for accreditation by the Council on Naturopathic Medical Education or another accrediting agency recognized by the U.S. Department of Education, or a school that has been approved by the board	NPLEX	Yes – 150 hours every three years	ON N
Oregon	2 years liberal arts & sciences study, plus graduate from an state board approved naturopathic school	NPLEX	Yes – 25 hours per year, including 5 in pharmacology	No
Utah	Graduate from a school that is accredited by or is a candidate for accreditation by the Council on Naturopathic Medical Education plus 12 months of clinical experience	NPLEX	Yes – 24 hours every two years	No
Vermont	Graduate from a school that is accredited by or is a candidate for accreditation by the Council on Naturopathic Medical Education	NPLEX	Yes – 30 hours every two years	N
Washington	Graduate from a school approved by the Secretary of Health that issues a doctorate degree and requires at least 200 postgraduate hours in the study of mechanotherapy	NPLEX <u>and</u> a state jurisprudence examination	Yes – 20 hours per year	°Z

### **Analysis and Recommendations**

Public Harm

The first sunrise criterion asks:

Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument.

The Colorado Association of Naturopathic Physicians (Applicant) argues that harm can come to consumers through improper diagnosis, improper dispensing of medicine, inappropriate application of therapies, and failure to recognize conditions requiring referral. To support their claim that regulation of naturopathic physicians is needed to protect the public, the Applicant provided the following case studies regarding actual or potential harm. A review of these cases reveals that some naturopaths are alleged to have caused significant harm, while others are alleged to have engaged in inappropriate conduct.

### Case 1A: 17-Year Old Female in Wheatridge, Colorado Experienced Cardiac Arrest. (Rocky Mountain News, July 20, 2004)

A health care practitioner who referred to himself as a naturopathic medical doctor performed a procedure called photoluminescence or ultraviolet blood irradiation. In such a process, blood is removed from the body, passed under ultraviolet light, and injected back into the body. The procedure is purported to combat illness by increasing oxygen in the blood, stimulating the immune system, and fighting viruses and toxins.

Following the blood treatment, the 17-year old female went into cardiac arrest and was rushed to a local hospital in critical condition. Physicians at the hospital where the female was treated reported that she had had a heart attack possibly triggered by an air bubble or embolism, anaphylactic shock, or a contaminated product.

The practitioner was arrested on charges of practicing medicine without a license, criminal impersonation, assault, and theft. The practitioner's naturopathic degree was awarded by a correspondence course offered by the Herbal Healer Academy located in Mountain View, Arkansas. In addition, this practitioner exhibited a license from the Federal Intermediary Council on Alternative Medicine in Washington, D.C., as a naturopathic medical doctor and a diploma from the Colorado University of Naturopathic Medicine.

Case 1B: Questionable Medicine: Criminal Charges Focus Spotlight on Alternative Healing, Wheatridge, Colorado. (*Rocky Mountain News*, September 25, 2004, p.23A and February 8, 2005.)

On several occasions, the naturopathic medical doctor described in Case 1A treated a 19-year old male patient with a photoluminescence procedure for his terminal cancer. The treatments were promoted as being able to fight disease and cancer by killing toxins and mutated cells in the blood and by stimulating the body's immune system to fight disease. After each treatment, the patient's blood oxygen level content declined significantly. During the final treatment that involved taking blood from the patient's body, his blood oxygen plummeted to 17. A healthy level would be in the high 90s. The patient died the next day. The family believes that their son was deprived of his last few months of life because of this treatment that was provided by the naturopathic medical doctor. The practitioner faces charges of manslaughter for his treatment of this 19-year old male patient.

Case 2: Naturopath Guilty in Diabetic's Death. (Citizen-Times.com, (Ashville Citizen-Times: Voice of the Mountains) April 16, 2002, <a href="http://orig.citizen-times.com">http://orig.citizen-times.com</a>

An eight-year old female in Ashville, North Carolina who was an insulin dependent diabetic, was the patient of an unlicensed naturopath. The naturopath's credential included board certification in clinical naturopathy from the American College of Naturopathy. This certification is not affiliated with any four-year medical program recognized by the U.S. Department of Education. The naturopath recommended that the child cease taking insulin. Subsequently, an autopsy determined that the child died of high blood sugar levels brought on by insulin deprivation. The practitioner was found guilty of practicing medicine without a license and involuntary manslaughter.

Case 3: Adult Female Treated for Breast Cancer. (Letter from Dr. Paul Reilly, ND, L.Ac dated June 26, 2004, Cancer Treatment Center of America, Seattle, Washington)

An adult female was being treated for breast cancer by an unlicensed naturopathic doctor in Idaho. She was repeatedly told by the practitioner that she was improving. Her condition deteriorated such that she visited the Cancer Treatment Center of America (CTCA) in Seattle, Washington. CTCA is a network of cancer treatment hospitals and facilities. Its approach combines the latest medical, surgical and radiological therapies with supportive therapies like nutrition, mind-body medicine, physical therapy, naturopathy, and spiritual wellness. When the patient was evaluated at CTCA, it was determined that the cancer had destroyed the entire breast and had penetrated into the underlying muscle and bone.

Dr. Reilly reported in his letter that he had seen other patients with large weeping lesions that became infected and necrotic because they delayed treatment on the advice of unlicensed ND's in other states who assured them they were improving despite all evidence to the contrary.

Case 4: Licensed Naturopathic Doctor in Arizona Convicted of 185 Counts of Illegal Distribution of Controlled Substances. (*Arizona Republic*, May 13, 2004, December 22, 2004)

In 2004, a licensed naturopathic doctor in Scottsdale, Arizona was convicted in federal court of 185 counts of illegal distribution of controlled substances and was sentenced to 12 years in prison and three years of supervised release for distributing the drugs over an 18-month period. The practitioner was convicted of knowingly and intentionally distributing controlled substances outside his legitimate practice and without legitimate medical purposes. The U.S Attorney's Office reported that evidence at the trial indicated 10 patients and 2 undercover Drug Enforcement Agents posing as patients received over 10,000 doses of prescribed narcotics. It was determined that the drugs dispensed, which included OxyContin, Percocet, Vicodin and morphine sulfate, were not medically necessary.

Case 5: Van Nuys "Faith Healer" Sentenced to Nine Years in State Prison. (Los Angeles County District Attorney's Office Release, February 9, 2004, <a href="http://da.co.la.ca.us/mr/020904b.htm">http://da.co.la.ca.us/mr/020904b.htm</a>), Los Angeles Times, February 10, 2004, pg. B4.

A 54-year old male in California consulted a naturopathic faith healer seeking treatment for a persistent skin disorder. After being injected with vitamins and an anti-inflammatory drug, the man went into convulsions and later died. The faith healer was subsequently sentenced to nine years in prison for practicing medicine without a license and injecting drugs into a man who later died.

Case 6: Utah Man Charged in Cancer Patient's Death. (Deseret Morning News, November 21, 2004), (In the Fourth District Court of Utah County, State of Utah, November 15, 2004, Case No. 041404455)

A Canadian practitioner of alternative medicine who periodically visited Utah to see patients was charged with three third-degree felonies involving practicing medicine without a license. If convicted on all three accounts, he faces up to 15 years in prison. According to court documents: (a) the practitioner allegedly treated a Utah woman who had breast cancer and subsequently died in October 2004; (b) the methods utilized included a "muscle test," a "body scan" device, and homeopathic products; and (c) the woman was advised to eat apricot pits and have her amalgam fillings removed. The practitioner allegedly determined that her cancer developed because of gangrene and mercury poisoning in her teeth. The practitioner applied for a Utah naturopathic license in 1997, but was denied because he lacked appropriate qualifications.

### Case 7: Colorado Woman with Thyroid Condition Became Dangerously III After Following Advice of a Naturopath. (Letter from Patient in Durango, August 5, 2004)

A 47-year old woman visited a naturopathic doctor in Durango because she was experiencing a persistent feeling of malaise for several months. This practitioner presented to the public as a Doctor of Naturopathy on the basis of her national certification and board certification by the American Naturopathic Medical Certification and Accreditation Board. The practitioner's disclosure statement declared that she would not advise any patient to quit any prescription medication. However, according to the patient, the practitioner stated that she could cure the thyroid disease and that there would no longer be a need for the hormone medication that she had been taking for 20 years.

Results from a diagnostic machine utilized by the naturopath indicated that the patient's thyroid and pituitary glands were malfunctioning and that she had Epstein-Barr virus. She was given a detailed schedule to wean herself from the thyroid medication. Despite complaints of increasing fatigue, the practitioner continued to tell the patient that her thyroid was functioning and she did not need the prescription medication. Evaluations were based on the results from the diagnostic machine. No lab work was ordered. Due to increasing fatigue and other symptoms, the patient visited an endocrinologist who evaluated her thyroid function and subsequently determined that her thyroid was in the dangerous and critical range. Under treatment through her endocrinologist, the patient recovered. The patient wrote to the naturopathic doctor to complain about her treatment outcome, but the practitioner denied making any suggestion to stop the thyroid medicine and refused to take any responsibility for the patient's condition.

### Case 8: Federal Agents Raid "Natural Healing" Office in Rhode Island. (*The Providence Journal*, January 8, 2005 and June 18, 2005)

The Providence Journal reported that the office of a practitioner in Rhode Island was raided in January 2005 and again in April 2005 by Food and Drug Administration and Internal Revenue Service agents who seized equipment and dietary supplement products. It was reported that a complaint from a state medical board official purported that the practitioner was practicing medicine without a license. He continued to practice until the Health Department suspended the practice in June 2005 maintaining that the practitioner was an immediate danger to the public. Evidence was submitted by the Health Department indicating that the practitioner had presented himself as a naturopathic doctor and a medical doctor. At the hearing, the practitioner agreed to accept the Health Department's suspension of his natural healing practice.

Case 9A: Adult Female Patient Instructed to Cease Taking Thyroid Medicine. (In the Fourth District Court of El Paso County, State of Colorado, 2005, Case No. 2005CV2881)

In July 2004, a Colorado woman visited a naturopathic physician who is licensed as a naturopathic physician in Montana, and as an acupuncturist in Colorado. The practitioner held himself out to the public as having extensive clinical experience in proctology, homeopathy, minor surgery, hemorrhoid treatment, spinal manipulation, and laboratory diagnostics. The patient informed the practitioner of her under active thyroid that had been persistent for the previous eight years. The patient alleged that the naturopathic physician sold the patient "USP" Armour thyroid medicine (pig gland), for which prescribing authority (medical license) is required in Colorado. Within a month, the patient suffered from hot flashes, hair loss, fluid retention, weight gain, and fatigue. A blood test was performed at the office of the endocrinologist, who reported that the results indicated a very low thyroid level. The endocrinologist indicated that the implications for not taking prescription thyroid medication in the long-term could be fluid retention, weight gain, sluggishness, rise in cholesterol levels, myxedema, and heart attacks. An injunction by the Colorado Board of Medical Examiners was imposed on the naturopathic physician for engaging in the unlicensed practice of medicine.

The final disposition (September 1, 2005) of this case between the Colorado State Board of Medical Examiners and the naturopathic physician (defendant) included the following terms: (1) the defendant will not engage in the practice of medicine as defined in section 12-36-106, et seq., C.R.S., (2) the defendant will not perform any kind of surgical operation (as defined in the permanent injunction) upon a human being, and (3) the defendant agreed not to practice proctology, surgery, the writing of or dispensing of prescriptions for prescription drugs, intravenous therapy, vitamin and mineral injections, topical anesthesia injections, and obstetrics.

Case 9B: Adult Male Treated for Hemorrhoids. (In the Fourth District Court of El Paso County, State of Colorado, 2005, Case No. 2005CV2881)

In March 2002, a male patient presented to a hospital emergency room in Colorado with complaints of painful hemorrhoids. The emergency room physician evaluated the patient, determined that the situation was not an emergency, and diagnosed that the patient suffered from inflamed hemorrhoids. The physician prescribed Demerol, Visataril, and a topical anesthetic to relieve the discomfort, and recommended that the patient have a surgeon remove the hemorrhoids at a later date. Later that same day, the patient visited a naturopathic clinic for removal of the hemorrhoids. The naturopathic physician performed outpatient surgery by removing the hemorrhoids. The practitioner held himself out to the public as having extensive clinical experience in proctology, homeopathy, minor surgery, hemorrhoid treatment, spinal manipulation, and laboratory diagnosing. An injunction was imposed on the naturopathic physician for engaging in the unlicensed practice of medicine (see case #9A for the final disposition).

Of the cases described previously, five cases involved three Colorado practitioners and six cases occurred in other states. Of the three Colorado practitioners, two who identified themselves as naturopathic practitioners had not graduated from Council on Naturopathic Medical Education-accredited institutions. Only one of the Colorado practitioners held a license in a state that licenses naturopathic physicians. The majority of these illustrations of physical harm or potential harm were caused by individuals who would not be allowed to represent themselves as naturopathic physicians or naturopathic medical doctors if the licensing scheme submitted was adopted by the General Assembly.

### Need for Regulation

The second sunrise criterion asks:

Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence.

There are currently 84 naturopathic physicians practicing in Colorado who have graduated from CNME-accredited naturopathic medical colleges. Since they are unregulated, they cannot perform the full range of services that they are trained to perform, because some services could be interpreted as the practice of medicine, the practice of physical therapy, or the practice of chiropractic therapy.

There are other problems for the practitioner and the patient in the current system. Without licensure, naturopathic physicians have a more difficult time procuring malpractice insurance that would provide additional safeguards to the public. Currently, three carriers write policies for naturopathic physicians practicing in states with licensing laws, only one writes limited coverage for those practicing in states without licensing laws. Nor can they be reimbursed under most insurance plans.

The lack of licensing presently may inhibit full cooperation between naturopathic medicine and other health care providers. As the system currently operates, if a referral is necessary, the naturopathic physician may find the medical doctor reluctant to consult on that referral, since the naturopathic physician lacks legal authority to practice. In fact, some practices that naturopathic physicians engage in may be included in the definition of the "practice of medicine."

- □ The "practice of medicine" is defined as holding out one's self to the public within this state as being able to diagnose, treat, prescribe for, palliate, or prevent any human disease, ailment, pain, injury, deformity, or physical or mental condition… [§12-36-106(1)(a), Colorado Revised Statutes].
- Suggesting, recommending, prescribing, or administering any form of treatment, operation, or healing for the intended palliation, relief, or cure of any physical or mental disease, ailment, injury, condition ... [§12-36-106(1)(b), C.R.S.].
- □ Performing any kind of surgical operation upon a human being...[§12-36-106(1)(e), C.R.S.]

The current lack of regulation restricts naturopathic physicians' ability to consult with other health professionals and to utilize community diagnostic and treatment services, such as laboratory work and diagnostic x-rays.

Naturopathic physicians focus on prevention as the key to better health. Regulation of naturopathic physicians would increase access to primary health care practitioners and encourage wellness and preventive care.

Few people have the time or expertise to investigate a health care practitioner's education or credentials. One of the purposes of regulation is to assure a minimal level of education and competency. State regulation assists the consumer in choosing a provider with appropriate training and skills by issuing licenses only to those the state deems minimally competent.

### **Public Confusion**

There are numerous correspondence schools and distance education programs easily accessible on the Internet that offer Doctor of Naturopathy degrees. These schools have different standards and graduation/certification requirements (see Appendix C on page 55). Adding to this confusion, naturopaths often refer to themselves by varying titles, such as "naturopathic physician", "naturopathic medical doctor", "Doctor of Naturopathy", and "N.D."

In addition, the distinction between other forms of alternative medicine is not necessarily known or fully understood by the public. For example, many members of the public do not know the difference between a homeopath and a naturopath. Regulation of naturopathic physicians may help to increase public awareness and assist the public in determining which qualifications to look for in a practitioner.

The term "naturopathic physician" is largely reserved by states with licensure programs for those who have gone to a four-year accredited naturopathic medical college. There are also educational programs for those who refer to themselves as "traditional naturopaths" that offer "N.D." or Naturopathic Doctor degrees. These programs are not accredited by an accrediting agency recognized by the U.S. Department of Education. According to a review of the naturopathic profession by the State of California, *Profile of a Profession: Naturopathic Practice*, in states that license naturopathic physicians, the titles "naturopathic physician," "naturopathic doctor," and even "naturopath" may be protected by statute for use only by those who have completed the four-year naturopathic physician program.

In addition to the plethora of titles and educational programs that exist in the arena of naturopathy, there are several organizations that represent themselves as the legal authority for licensing naturopaths. For example the Colorado Alternative Medical Regulatory Board (CAMRB) appears to distribute a document periodically that affirms that CAMRB, under legal authority of the Colorado Department of Regulatory Agencies (DORA), functions in cooperation with DORA. This is untrue.

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<sup>&</sup>lt;sup>5</sup> Holly J. Hough et al., *Profile of a Profession: Naturopathic Practice*. San Francisco: Center for the Health Professions, University of California, 2001.

To add to the public's confusion, during the course of this review, the Naturopathic National Council Inc., which represents itself as a national licensing agency for traditional naturopaths, contacted DORA and the Colorado Office of the Attorney General, in addition to attorneys general throughout the United States. The documentation submitted purports to establish the Naturopathic National Council Inc.'s jurisdiction over the branch of medicine of traditional naturopathy by providing occupational licenses to traditional naturopaths that includes, but is not limited to Doctor of Naturopathy, nutritional consultants, and herbalists. Furthermore, the Council states that the Naturopathic National Council, Inc. has jurisdiction over the title Doctor of Naturopathy, (N.D.) and they intend to use this title in practice in Colorado.

### Alternatives to Regulation

The third sunrise criterion asks:

Whether the public can be adequately protected by other means in a more costeffective manner.

One consideration in establishing a new regulatory program is whether the costs of regulation limit the number of providers. To determine the costs of any new program various expenditures must be analyzed. The following expenditures are most often associated with other DORA professional licensing programs: personal services, operating budget, indirect costs, investigations, legal services, administrative law judges, leased space, and information technology services.

Licensure generally gives a professional an economic monopoly to persons who meet the qualifications established by the Legislature. Additionally, the regulatory structure can restrict the types of activities of those providers regulated. Limitations on scope of practice and the activities the practitioner is qualified for, or otherwise may provide, may reduce market and provider organization flexibility and efficiency.

National and state naturopathic physician associations argue that because naturopathic medicine emphasizes prevention, patient participation, and less technologically advanced treatments, it is a cost effective alternative to conventional medicine.

### Colorado Consumer Protection Act

Current Colorado statutes provide some protection in the form of the Colorado Consumer Protection Act (CPA). There are currently persons in Colorado using the title "Ph.D. in Naturopathy" in Colorado who may be in violation of the CPA, (§ 6-1-707(1)(a), C.R.S.). The CPA states that persons engaged in deceptive trade practices when they claim, either orally or in writing, to possess an academic degree or an honorary degree of the title associated with that degree, unless the person has been awarded the degree from an institution that is:

- accredited by a regional or professional accrediting agency recognized by the U.S.
   Department of Education or the Council on Post-secondary Accreditation;
- provided, operated, and supported by a state government or any of its political subdivisions or by the federal government;

- a school, institute, college, or university chartered outside the United States, the academic degree from which has been validated by an accrediting agency approved by the U.S. Department of Education; or
- a religious seminary, institute, college, or university, which prepares students for a religious vocation, career, occupation, profession, or lifework.

In addition, the CPA states that persons may not use "Dr.", "Ph.D.", "Ed.D.", "D.N.", or "Th.D" or any other title that signifies they have a doctorate degree, unless their degree falls under the auspices of the four previously mentioned criteria. None of the doctorate degrees from the correspondence and distance education programs (see Appendix C on page 55) satisfy these criteria. The education, training, and philosophy of these distance education programs are substantially different from that of the CNME graduates. There is potential for confusion for the Colorado resident trying to differentiate among the various persons calling themselves naturopaths, naturopathic physicians, doctor of naturopathy, N.D., Ph.D. in naturopathy, or naturopathic medical doctors.

The Colorado Office of the Attorney General has initiated consumer protection actions on behalf of the State of Colorado against individuals who have offered a product or service to treat or cure a disease. Those actions were brought under the Deceptive Trade Practices Act that can be found in section 6-1-105, C.R.S. While the CPA offers some protection to the public against the illegal use of degree titles, a formal regulatory program would offer greater protection and more consistent and thorough oversight.

### Conclusion

The Purpose and Implications of Regulation of Health Professions

The traditional reasons given for the regulation of health care professions are to prevent non-diagnosis, misdiagnosis, non-treatment and mistreatment by unqualified medical providers. The aims of the regulatory mechanism are: 1) protecting the public from the dangers of unskilled practitioners and unsound treatment or advice; and 2) protecting the public from reliance on unskilled practitioners, as well as directing them to proper medical care.<sup>6</sup>

There are reasons to consider regulation of naturopathic physicians: it is possible that the public is confused by the common use of the various forms of the term "naturopath;" it is possible that the practice of some naturopaths who refer to themselves as "doctors" are in violation of the Colorado Consumer Protection Act; and the use of naturopathic and alternative medicine continues to be utilized by Colorado consumers, thus requiring some level of regulatory oversight. The potential regulation of any health profession has numerous implications for consumers, providers, and society as a whole. Sometimes in discussions of the implications of regulation, the interests of consumers and providers conflict, while at other times, they coincide.

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<sup>&</sup>lt;sup>6</sup> M.H. Cohen, "Holistic Health Care: Including Alternative and Complementary Medicine in Insurance and Regulatory Schemes." *Arizona Law Review.* 38, 1 (Spring 1996):83-164.

### Reasons for Utilizing Complementary Alternative Medicine (CAM)

According to one study, most users of alternative therapies believe they have explored the full utility of conventional Western approaches. "Most have chronic illnesses (e.g. cancer, HIV infection, or AIDS, arthritis, chronic pain, sinusitis, migraines) for which Western medicine can usually offer only symptomatic relief or palliation, not definitive treatment. Alternative therapies are often used in combination with the appropriate conventional approaches, as a way of enhancing and complementing them. Sometimes alternative approaches are used instead of conventional therapies when the latter have proved ineffective or have produced deleterious side effects." <sup>7</sup>

As noted earlier in this sunrise review, a potential for public harm exists in the unregulated practice of naturopathy. What is more, this potential harm arises in the realm of public health, which is arguably more important than other areas of potential harm, such as pecuniary damage.

### **Opposition to Licensure**

Not everyone agrees that Complementary Alternative Medicine (CAM) represents an appropriate form of medical care. To some, many of the therapies considered to be CAM represent unscientific treatments that may at best be benign and at worst harmful (National Council Against Health Care Fraud, 1994). The argument made against CAM is that if these therapies were to be proven scientifically valid, they would be adopted by allopathic medicine, and would become mainstream. Although these opponents of CAM often admit that there are some CAM therapies that have been demonstrated to be effective, they maintain that supporting or validating all CAM allows unscrupulous practitioners to prey on unsuspecting patients who may be directed away from truly helpful medical treatments. Critics of CAM point to the relative lack of rigorous, controlled effectiveness studies, and call for caution in evaluating the usefulness of a therapy until more scientific evaluation can be conducted.

However, practices that were once considered alternative, such as massage therapy, acupuncture, chiropractic manipulation, and therapeutic application of nutrition, have become more accepted within mainstream medicine. Many acute care, long-term care, and ambulatory care clinics are beginning to offer CAM.

During the sunrise review process, DORA made every effort to elicit information and comments from all interested parties. Several opponents of licensure for naturopathic physicians responded to the sunrise application by submitting opposition papers and letters to DORA. The Coalition for Natural Health, the National Council Against Health Fraud, Colorado Family Physicians, Colorado Dental Association, Colorado Chiropractic Association, and the American Naturopathic Medical Association submitted documents.

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<sup>&</sup>lt;sup>7</sup> J.S. Gordon, M.D. "Alternative Medicine and the Family Physician." *American Family Physician*. 54, 7 (1996):2205-2212.

### **Coalition for Natural Health**

There are a significant number of practitioners in Colorado who refer to themselves as "traditional naturopaths." In their report, <u>Profile of a Profession: Naturopathic Practice</u>8 the Center for Health Professions at the University of California describes this group as:

practitioners who adhere to the strictest definition of natural healing and do not incorporate surgical, non-natural pharmaceutical or obstetrical care into their practices. They may focus their work on one or more of the various modalities that comprise naturopathic healing. They have a much more varied set of pathways for entry into practice and training ranges from self instruction and apprenticeship to formal course of study.

Practitioners of naturopathy are currently in debate about the definition of naturopathy and the training requirements for entry to the profession. This disagreement is articulated by two different associations: The American Association of Naturopathic Physicians (AANP), which represents providers of "naturopathic medicine" and the Coalition for Natural Health, which is a non-profit organization purportedly representing thousands of individuals nationwide to promote the holistic approach to health and to ensure that natural health alternatives remain widely accessible to the public. The mission of the CNH is to educate the public to the true meaning of traditional naturopathy, to educate legislators to the efficacy of natural health and traditional naturopathy, and to prevent legislation that would prohibit practitioners of natural health modalities including traditional naturopaths from practicing now and in the future. The CNH submitted a 31-page document to DORA in opposition of licensure.

CNH states that "traditional naturopaths" do not use procedures that are common to medical care, such as prescribing drugs and pharmaceuticals, performing invasive surgical procedures, and delivering babies. Instead, they focus on health and education, teaching their clients how to create internal and external environments that are conducive to good health.

Furthermore, the CNH contends that naturopathic physicians seek protection from legal prosecution because they know that the scope of practice they seek constitutes the practice of medicine. On the other hand, traditional naturopaths can provide traditional naturopathic services to the public in Colorado – now, without licensure – because traditional naturopaths do not practice medicine.

The Applicant submitted a response to the CNH's oppositional document. In their document, the Applicant notes that the greatest risk for the residents of Colorado is that diploma mills, distance learning programs, and other unaccredited programs that issue Doctorate of Naturopathy degrees severely lack curriculum, provide no clinical training, and promote the practice of medicine among their graduates despite this lack of training. Also, the Applicant maintains that many of the schools of traditional naturopathy pose a risk to the public, as evidenced by the cases of harm documented in the application and this sunrise report.

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<sup>&</sup>lt;sup>8</sup> Holly J. Hough et al., *Profile of a Profession: Naturopathic Practice.* San Francisco: Center for the Health Professions, University of California, 2001.

<sup>&</sup>lt;sup>9</sup> Coalition for Natural Health, Response by the Coalition for Natural Health, Inc. to the 2004 Naturopathic Physicians Sunrise Application, 2005.

### **National Council Against Health Fraud**

The National Council Against Health Fraud (NCAHF), comprised of health professionals, educators, researchers, attorneys, and consumers, is a non-profit voluntary health agency focusing on health misinformation, fraud, and quackery as public health problems.

The Colorado Area Coordinator of the NCAHF submitted several articles in addition to a 20-page commentary to DORA urging the denial of licensure for naturopathic physicians. Several key points that it made are listed below:

- Naturopathic education has only the appearance of that of a standard medical school.
   A foundation in basic sciences does not qualify anyone to practice medicine.

   Naturopathic education in diagnosis and treatment is not evidence-based and bears no resemblance to standard medical school education.
- Naturopaths are a public health risk, particularly to children. They advise the public against fluoridation, pasteurization, and immunization.
- A principal danger to the public of licensing naturopaths is the false sense of security that the public is given regarding the competence of a licensed naturopath to practice medicine as opposed to naturopathy.
- There are no standard naturopathic treatments for specific conditions in the sense that anything is ruled out. Naturopaths are taught to diagnose and treat patients with invalidated, irrational, and potentially dangerous methods. They use their patients as guinea pigs. All divert patients away from evidence-based care.

### **Colorado Family Physicians**

Colorado Family Physicians (CFP) represents the Colorado Association of Family Medicine Residences and the Colorado Association of Family Physicians. Its letter states:

The Colorado Association of Naturopathic Physicians application for licensure may ultimately have merit, if it leads to ensuring patient safety by introducing into the naturopathic approach to health care procedures that are scientifically proven to be efficacious and not harmful to consumers of health care.

The concerns of CFP regarding two issues in CANP's application is discussed in the summary below.

### 1. The Consumer's Perception of the Health Care Provider

The naturopathic physician's use of family medicine, primary care physicians, and family physicians is grossly misleading. Furthermore, the education and clinical experience of naturopathic physicians inadequately prepares them to recognize and treat early manifestations of serious illnesses that occur among ambulatory patients or acute and complex presentations.

## 2. Scope of Practice

A defined scope of practice is an essential element in protecting patients. Unscientific naturopathic beliefs pose irrational challenges to proven public health measures. Practices within the proposed scope of practice for naturopaths are already included in the legal scope of practice for family medicine. Licensing naturopathic physicians as independent primary care physicians will deteriorate standards of health care, expose the public to the inevitable risk of inferior medical service, and cause further confusion to the health consumer.

## **Colorado Dental Association**

In a letter presented to DORA, the Colorado Dental Association expressed its opposition to licensing naturopaths because,

when a supposed 'profession' immerses itself in pseudoscience, uses quackery to further its income and puts the public at medical risk (intravenous hydrogen peroxide injections), that is not in the best interest of any community.

Furthermore, the letter stated that naturopaths are against the use of water fluoridation and the use of amalgam restorations (silver-colored fillings).

The letter further expounds that fluoridation has been listed as one of the ten great public health achievements of the 20th century by the Centers for Disease Control and Prevention, and amalgam restorations have been proven to be a safe and effective restorative material for decayed teeth.

## **Colorado Chiropractic Association**

The Colorado Chiropractic Association (CCA) submitted a letter to the Colorado Board of Chiropractic Examiners that was forwarded to DORA. CCA expressed concern that the website of many naturopathic physicians that are linked to the Colorado Chapter of the Association of Naturopathic Physicians website, advertise that they perform manipulation. CCA believes that the use of this advertising misleads and endangers the public. They contend that naturopathic physicians should not be performing manipulation without a license from the Board of Chiropractic Examiners.

## **American Naturopathic Medical Association**

Founded in 1981, the American Naturopathic Medical Association's website describes the association as a nonprofit, scientific, educational organization dedicated to exploring new frontiers of mind, body, medicine and health. Membership is available to individuals with Doctor of Naturopathy (N.D.) or Doctor of Naturopathic Medicine (N.M.D.) degrees, as well as other health care fields. The members subscribe to the motto "Doctor do no harm." The President Emeritus submitted a letter to DORA strongly opposing the licensure of naturopathic physicians because they "lack the education to offer anything beyond natural non-invasive therapies." Furthermore, the letter states that naturopathic physicians from four-year resident schools are misleading the public into believing they are trained like medical doctors.

## **Benefits of Regulation**

Regulation of a health profession could, at least in theory, have a number of benefits. First, the regulation might improve the quality of care consumers receive, as unqualified or unethical providers are eliminated. Consumers could be protected from unknowingly seeking care from an untrained or unskilled provider. Second, consumers may have access to more information on what type of training should be expected of a provider of a certain type of care. Consumers might have better ability to seek out providers with appropriate training and skills. In addition, they create databases, which facilitate the monitoring of practitioner geographic distribution and specialty, which can assist public health agencies in planning. Third, providers who are regulated would not be subject to legal action for practicing within the scope of their profession.

The report from the Pew Commission<sup>10</sup> articulates the following principles for a health care workforce regulatory system:

- Promoting effective health outcomes and protecting the public from harm;
- Holding regulatory bodies accountable to the public;
- Respecting consumers' rights to choose their health care providers from a range of safe options;
- Encouraging a flexible, rational and cost-effective health care system that allows effective working relationships among health care providers; and
- Facilitating professional and geographic mobility of competent providers.

One problem identified in this report is the unsafe practice of unregulated naturopathic physicians or other "healers" referring to themselves as naturopaths, naturopathic medical doctors, and N.D.s.

The foundation principle that applies to the creation of new occupational regulation in Colorado is whether there is evidence that Colorado citizens are being harmed absent regulation, and that the imposition of new regulation will alleviate that harm in the most cost-effective manner.

The Applicant has demonstrated that Colorado citizens have been harmed, including death, at the hands of one practitioner, and the applicant has established that the potential for future harm, as found across the nation, exists in Colorado.

As discussed previously in this report, 15 states currently license naturopaths. For the most part, those 15 states regulate naturopathy consistent with the sunrise proposal of the Applicant. Further, the experience of these states shows that the regulatory scheme is successful.

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<sup>&</sup>lt;sup>10</sup> Christine M. Gragnola and Elizabeth Stone, MD, *Considering the Future of Health Care Workforce Regulation*, Pew Health Professions Commission, San Francisco: Center for the Health Professions, University of California, 1995.

The negative impact on Colorado citizens as a result of Colorado's *status quo* is twofold. First, this state's citizens are denied access to a complimentary health care modality. That is so because most of the elements of a naturopathic scope of practice may violate any number of existing practice acts including medical practice and chiropractic. Therefore, the 70 or so practitioners who would qualify for licensure under the applicant's proposal could find themselves out of business at any point that a regulatory board might choose to exert its authority. In fact, during the course of this review, the professional association representing chiropractors filed a complaint with the Board of Chiropractic Examiners alleging that some naturopaths advertise to perform manipulation.

Second, Colorado consumers are presently at a disadvantage when choosing a naturopath. This situation is created because anyone can refer to himself or herself as a naturopath, doctor of naturopathy or any other title, regardless of training, or in the absence of any training at all. This, in fact, is one of the assertions made in the case concerning the death of a patient.

As this report has discussed, there is opposition to the creation of a regulatory program for naturopathic physicians as described in the sunrise application. The CNH has thoroughly laid out its opposition to the sunrise proposal. The Applicant's proposal would impact some people who advertise as naturopaths. However, this review finds that the concerns of those practitioners represented by the CNH do not outweigh the public policy concerns raised by the Applicant regarding naturopathic practice. The primary consideration leading to this finding is the extremely disparate training and education that allows entry as a practitioner. Without meaningful accreditation, one cannot reasonably assess the skill and knowledge of the practitioner (See discussion "Public Confusion" on page 28 of this report).

The Colorado membership of CNH is unknown. Without proper data regarding CNH membership, this review is unable to estimate the economic impact, if any, which would result from regulation of naturopaths. As examples, one cannot estimate the number of clients or patients that CNH members treat. There is no information available showing the variety of treatments employed nor the outcomes of treatments. Nor is it clear what titles these practitioners use to advertise. For these reasons, this review does not support CNH's position that Colorado should take no action because any action would be detrimental to its membership.

An argument raised in opposition to the Applicant's proposal is a broad assault upon the efficacy of naturopathic practice. This opposition makes little or no distinction between groups or philosophies lumping all naturopathy into the realm of quackery. Many of these arguments are not compelling, but the most sophisticated of them holds that naturopathic practices are not proven effective by medical standards for testing, and, consequently, naturopathic doctors or physicians are not medical doctors.

This review concurs with those premises but differs in the conclusion drawn from them. To dispense with the easiest case, naturopathic doctors are not medical doctors and the application for regulation does not assert that they are, or should be construed as such.

This review concurs with the opponent's position that naturopathic practice may not satisfy the requirement of allopathic medical research standards. This standard, however rigorous and time-tested, is not the standard for regulation of a profession. Colorado currently regulates acupuncture and chiropractic, modalities that may be or once were subject to the same criticisms. The regulatory test for government intervention in consumer choices, and barring clear evidence of fraud, or other compounding factors, is to determine the proper level of education, experience, examination, and subsequent scope of practice. This, coupled with disciplinary authority over practitioners who violate the state's standards constitutes the proper role of government. Ultimately, given a safe market place in which to choose, consumers will make the appropriate decisions more efficiently than will government.

This review therefore is not convinced by the arguments of opponents who believe that naturopathy should not be regulated because of the lack of efficacy of the practice itself.

## **Regulatory Models**

The following three regulatory models are organized in terms of degree of regulatory burden from least burdensome to most extensive.

### Title Protection

A title protection program could be modeled after the title protection provisions (§ 6-1-707(1)(a)(III)(b), C.R.S.) for dieticians found in the Colorado Consumer Protection Act. Following this model, the terms "naturopath," "naturopathic physician," "naturopathic medical doctor," "ND," "doctor of naturopathy," "naturopathic practitioner," "and doctor of naturopathic medicine" would be reserved for those persons who have graduated from an approved naturopathic medical college accredited by the Council on Naturopathic Medical Education (CNME) and have successfully passed the Naturopathic Physicians Licensing Examination (NPLEX). CNME is recognized by the U.S. Department of Education as the national agency for accreditation of naturopathic medical curriculum. Such a regulatory scheme possesses the advantage of offering the public a certain degree of protection and is less restrictive than a licensing program. Under a title protection scheme, enforcement would be taken pursuant to the Colorado Consumer Protection Act (CPA) by the Colorado Office of the Attorney General.

However the CPA has rarely been used to enforce title protection despite the fact that several professions (including dieticians and occupational therapists) are referenced in the CPA. This type of regulation is of limited use as evidenced by the fact that it was not employed in the recent Colorado case involving a practitioner who may well have been in violation of the CPA.

## **Exemption from the Medical Practice Act**

Section 106 of Article 36 of Title 12 of the Colorado Revised Statutes [Medical Practice Act (MPA)] provides exemptions for licensing for specific activities. For example, the Board of Medical Examiners (Board) promulgates rules and regulations specifying the types of services that a qualified athletic trainer may render. Naturopaths could be exempted from the MPA and other health care acts to allow them to practice the full range of their profession (with certain restrictions, if necessary). Additionally, like athletic trainers there would be stated examination and education qualifications, in addition to a scope of practice.

The public may be adequately protected by requiring standardized qualifications for individuals holding themselves out to be "naturopathic physicians." The authority of the Board in section 12-36-106(2), C.R.S., allows the Board to investigate complaints.

## Licensure Program

A licensing scheme administered by the Director of DORA's Division of Registrations should include provisions addressing the following issues:

Title Protection for licensed naturopathic physicians

Title protection will assist the public in identifying those individuals the state has determined to be qualified naturopathic physicians. Individuals who satisfy the educational requirements established by the state would be permitted to use the titles "Licensed Naturopathic Physician," "Naturopath" or any derivative thereof. The protected titles would be reserved for those persons with the following credentials:

- (1) Graduated from an approved naturopathic medical college accredited by, or with a curriculum equivalent to, the accreditation standards of the CNME, and
- (2) Passed a licensure examination that conforms to the standards approved by the Director of the Division of Registrations.
- A definition of the scope of practice for naturopathic physicians

By defining the practice of naturopathy, it will be clear which practitioners fall within the scope of the licensing program.

Restricting the practice of licensed naturopathic physicians

The restrictions on the practice of "Licensed Naturopaths" could prohibit:

- Prescribing or giving a prescription drug or a controlled substance
- Engaging in minor surgery
- Practicing obstetrics

- The program would be cash-funded and located within the Office of the Director of the Division of Registrations.
- Licensed Naturopaths may be exempted from the Medical Practice Act and other health care acts to allow them to practice the full range of their profession (with the restrictions above).
- Full range of disciplinary actions against licensed naturopathic physicians, including civil penalties.
- The Director of the Division of Registrations could be granted the authority to convene a Naturopathic Advisory Committee.

A licensing scheme would offer the public the greatest level of regulatory protection. Only those individuals who have fulfilled the requirements for licensure would be allowed to engage in the scope of practice for naturopathic physicians, thus ensuring a minimum level of competency.

Recommendation: This sunrise review concludes that the evidence supports regulation of naturopathic physicians in Colorado. The three options proposed include licensure, title protection, or exemption from the Medical Practice Act.

If it is determined not to implement one of these three options, this will leave in effect, Colorado's *status quo* as discussed.

# Appendix A – Summary of the Psychometric Evaluation of the NPLEX Exam

# Naturopathic Physician Licensing Examinations (NPLEX): Compliance with Standards For Educational and Psychological Testing<sup>11</sup> - Executive Summary

The Colorado Office of Examination Services (OES) within the Department of Regulatory Agencies, Division of Registrations performed a psychometric review of the NPLEX Part II—Core Clinical Science Series Examinations. The NPLEX Part II—Core Clinical Science Series Examinations consist of eight multiple-choice examinations that are intended to measure the skills and technical knowledge that an entry-level naturopathic physician needs to practice safely. There also are three additional multiple-choice examinations in the Part II-Clinical Add-On Series. The Part II-Core Clinical Science Series is required by every jurisdiction that regulates the naturopathic profession. A licensing/regulatory authority also may require any or all three examinations in the Part II-Clinical Add-On Series.

The psychometric review conducted by the OES reviewed evidence about (1) the knowledge and skills identified by NPLEX for credential-worthy performance as a naturopathic physician, (2) the content purported to be assessed by NPLEX Part II—Core Clinical Science Series Examinations, (3) test construction, (4) standard setting and equating/linking of different forms of a test, (5) reliability and errors of measurement, (6) test administration, (7) scoring, (8) attention to fairness, and (9) score reporting and records. The results of the psychometric review are discussed in the report that follows. Overall, findings led to the following key observations:

# > Do the NPLEX Part II Clinical Licensing Examinations Measure Clinical Competence?

The NPLEX Part II clinical licensing examination program utilizes multiple-choice item formats to measure "technical knowledge" associated with the naturopathic physician profession.

- ✓ Per the NPLEX 2003 Technical Manual, Item #6, p. 19: <u>"Limitations of a multiple choice examination:</u> "With more than 1000 examinees being tested each year, NPLEX cannot employ formats which could more appropriately test clinical competence (e.g., essay examinations, model patients)."
- ✓ To date, there is little generalizable evidence that the NPLEX Part II clinical licensing examinations actually measure clinical competence. This concern may be alleviated to some degree if the educational programs, which now receive programmatic accreditation from the Council of Naturopathic Medical Education (CNME), can demonstrate that students fulfill sufficient clinical requirements and are tested by independent entities in their clinical competence before they sit for the current NPLEX Part II clinical licensing examinations.

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<sup>&</sup>lt;sup>11</sup> American Educational Research Association, American Psychological Association, & National Council on Measurement in Education. (1999). <u>Standards for Educational and Psychological Tests</u>. Washington, DC: American Educational Research Association.

✓ Until recently, the CNME also served as the <u>institutional</u> accrediting body for naturopathic schools. While the institutional accreditation role recently has been shifted appropriately to regional accrediting bodies recognized by the United States Department of Education and the four U. S. naturopathic colleges currently either are in a candidacy status or have attained 5-year institutional accreditation by one of the recognized regional accrediting bodies, the previous dual accreditation role assumed by CNME (programmatic and institutional) may call into question whether development of the naturopathic profession to date has unfolded via independent higher learning experiences that lead to unbiased theories of science and practice that produces replicable results.

# > To What Extent Does Construct Under-Representation and/or Measurement Imprecision Threaten the Validity of Test Score Interpretations?

Each Part II clinical licensing examination contains 50% new items that have not been pre-tested. Many of the clinical licensing examination parts contain only 50 multiple-choice items in total. Items are analyzed before they are scored; however, if new items do not perform as desired, then the test may not adequately represent the universe of generalization it was intended to represent when it was developed (e.g., new items may have more than one correct answer (accept multiple options) or they may be flawed in ways that render them useless (all options need to be accepted).

- ✓ Any reliability coefficient using the data will likely overstate matters because the testing conditions facet is effectively "fixed" in that the test is given in one administration every six months and the reliability coefficient is based on the "internal consistency" in which all of the items measure a common characteristic of the examinee (e.g., technical knowledge) on that test administration occasion. Thus, error variance is likely to be understated by the NPLEX clinical licensing examinations.
- ✓ Any interpretation of a test score or a comparison of test scores from the NPLEX II clinical licensing examinations must be made with an acute awareness of the standard error of measurement. Although the magnitude of errors of measurement decreases as the reliability coefficient increases, errors of appreciable size can still be found with reliability coefficients that are considered to be high (e.g., .90 or .95). The thirteen years of NPLEX examination statistics presented in the 2003 NPLEX Technical Manual, Appendix E, and examined in pages 7-9 of the following psychometric analyses indicate that the band within which we can be reasonably sure an examinee's true score lies can be variable and somewhat concerning if we are drawing conclusions about technical knowledge of a candidate based on his/her particular test score.

# > Are the NPLEX Part II Clinical Licensing Examinations Adequate for Licensing Decisions if Colorado Required Regulation of Naturopathic Physicians?

The NPLEX Part II Clinical Licensing Examinations have many acceptable psychometric characteristics, including but not limited to evidence of: (1) careful test construction, (2) appropriate test administration, (3) attention to scanning accuracy, (4) psychometric analysis before final test scores are computed, (5) attempts to determine pass/fail cut-points that are independent from the distribution of scores for a test session, (6) adequate explanation of score conversions, and (7) good documentation about the NPLEX tests and test guides that help examinees know what to expect and how to prepare for the NPLEX examinations.

It is feasible that measures of the technical knowledge needed for safe practice, such as those provided by the NPLEX Part II licensing examinations, can provide the assurances required for public protection if:

- 1. The clinical competence of naturopathic physicians can be assured via educational or other programs that demonstrate unequivocally that the graduate can perform safely a scope of practice in which reasonable potential for therapeutic gains in a patient's medical condition out-weighs the risk of treatment methods. [See §12-36-117(3)(a), C.R.S. in the Medical Practice Act that defines "alternative medicine" for the purposes of that section]; and
- 2. The educational programs that are programmatically accredited by CNME lead to a naturopathic physician degree that is granted through institutions of higher learning that hold accreditation status from an independent regional accrediting body recognized by the U. S. Department of Education.

## Appendix B – Psychometric Evaluation of the NPLEX Exam

## STATE OF COLORADO

#### OFFICE OF EXAMINATION SERVICES

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## **Department of Regulatory Agencies**

Tambor Williams
Executive Director

## Division of Registrations

Rosemary McCool Director

> Bill Owens Governor

# Naturopathic Physician Licensing Examinations (NPLEX): Compliance with Standards For Educational and Psychological Testing<sup>1</sup> Executive Summary

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The psychometric review conducted by the CO OES reviewed evidence about (1) the knowledge and skills identified by NPLEX for credential-worthy performance as a naturopathic physician, (2) the content purported to be assessed by NPLEX Part II—Core Clinical Science Series Examinations, (3) test construction, (4) standard setting and equating/linking of different forms of a test, (5) reliability and errors of measurement, (6) test administration, (7) scoring, (8) attention to fairness, and (9) score reporting and records. The results of the psychometric review are discussed in the report that follows. Overall, findings led to the following key observations:

## > Do the NPLEX Part II Clinical Licensing Examinations Measure Clinical Competence?

The NPLEX Part II clinical licensing examination program utilizes multiple-choice item formats to measure "technical knowledge" associated with the naturopathic physician profession.

- ✓ Per the NPLEX 2003 Technical Manual, Item #6, p. 19: "Limitations of a multiple choice examination: "With more than 1000 examinees being tested each year, NPLEX cannot employ formats which could more appropriately test clinical competence (e.g., essay examinations, model patients)."
- ✓ To date, there is little generalizable evidence that the NPLEX Part II clinical licensing examinations actually measure clinical competence. This concern may be alleviated to some degree if the educational programs, which now receive <u>programmatic</u> accreditation from the Council of Naturopathic Medical Education (CNME), can demonstrate that students fulfill sufficient clinical requirements and are tested by independent entities in their clinical competence before they sit for the current NPLEX Part II clinical licensing examinations.
- Until recently, the CNME also served as the <u>institutional</u> accrediting body for naturopathic schools. While the institutional accreditation role recently has been shifted appropriately

<sup>&</sup>lt;sup>1</sup> American Educational Research Association, American Psychological Association, & National Council on Measurement in Education. (1999). <u>Standards for educational and psychological tests</u>. Washington, DC: American Educational Research Association.

to regional accrediting bodies recognized by the United States Department of Education and the four U. S. naturopathic colleges currently either are in a candidacy status or have attained 5-year institutional accreditation by one of the recognized regional accrediting bodies, the previous dual accreditation role assumed by CNME (programmatic and institutional) may call into question whether development of the naturopathic profession to date has unfolded via independent higher learning experiences that lead to unbiased theories of science and practice that produces replicable results.

## > To What Extent Does Construct Under-Representation and/or Measurement Imprecision Threaten to the Validity of Test Score Interpretations?

Each Part II clinical licensing examination contains 50% new items that have not been pretested. Many of the clinical licensing examination parts contain only 50 multiple-choice items in total. Items are analyzed before they are scored; however, if new items that do not perform as desired, then the test may not adequately represent the universe of generalization it was intended to represent when it was developed (e.g., new items may have more than one correct answer (accept multiple options) or they may be flawed in ways that render them useless (all options need to be accepted).

- ✓ Any reliability coefficient using the data will likely overstate matters because the testing conditions facet is effectively "fixed" in that the test is given in one administration every six months and the reliability coefficient is based on the "internal consistency" in which all of the items measure a common characteristic of the examinee (e.g., technical knowledge) on that test administration occasion. Thus, error variance is likely to be understated by the NPLEX clinical licensing examinations.
- Any interpretation of a test score or a comparison of test scores from the NPLEX II clinical licensing examinations must be made with an acute awareness of the standard error of measurement. Although the magnitude of errors of measurement decreases as the reliability coefficient increases, errors of appreciable size can still be found with reliability coefficients that are considered to be high (e.g., .90 or .95). The thirteen years of NPLEX examination statistics presented in the 2003 NPLEX Technical Manual, Appendix E, and examined in pages 7-9 of the attached psychometric analyses indicate that the band within which we can be reasonably sure an examinee's true score lies can be variable and somewhat concerning if we are drawing conclusions about technical knowledge of a candidate based on his/her particular test score.

#### Are the NPLEX Part II Clinical Licensing Examinations Adequate for Licensing Decisions if Colorado Required Regulation of Naturopathic Physicians?

The NPLEX Part II Clinical Licensing Examinations have many acceptable psychometric characteristics, including but not limited to evidence of: (1) careful test construction, (2) appropriate test administration, (3) attention to scanning accuracy, (4) psychometric analysis before final test scores are computed, (5) attempts to determine pass/fail cut-points that are independent from the distribution of scores for a test session, (6) adequate explanation of score conversions, and (7) good documentation about the NPLEX tests and test guides that help examinees know what to expect and how to prepare for the NPLEX examinations.

It is feasible that measures of the technical knowledge needed for safe practice, such as those provided by the NPLEX Part II licensing examinations, can provide the assurances required for public protection if:

- The clinical competence of naturopathic physicians can be assured via educational or other programs that demonstrate unequivocally that the graduate can perform safely a scope of practice in which reasonable potential for therapeutic gains in a patient's medical condition out-weighs the risk of treatment methods (C.R.S. §12-36-117 (3) (a)); and
- The educational programs that are programmatically accredited by CNME lead to a naturopathic physician degree that is granted through institutions of higher learning that hold accreditation status from an independent regional accrediting body recognized by the U. S. Department of Education.

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#### Introduction

There are two distinct "Parts" to the Naturopathic Physician Licensing Examinations (NPLEX) examinations:

- The NPLEX-Part I (Basic Science Examinations) consist of five multiple-choice examinations
  that may be taken by students who attend a naturopathic medical college approved by the
  programmatic accrediting agency (Council on the Naturopathic Medical Education [CNME]).
  These examinations are intended to measure whether students have the knowledge foundation
  needed to enter the clinical phase of their training. The five exams are: (1) Anatomy, (2)
  Physiology, (3) Biochemistry, (4) Microbiology & Immunology, and (5) Pathology.
- 2. The NPLEX-Part II (Core Clinical Science Series Examinations) consist of eight multiple choice examinations that are intended to test the skills and knowledge an entry-level naturopathic physician needs to practice safely. The eight examinations are: (1) Physical and Clinical Diagnosis, (2) Lab Diagnosis & Diagnostic Imaging, (3) Emergency Medicine & Public Health, (4) Pharmacology, (5) Botanical Medicine, (6) Nutrition, (7) Physical Medicine, and (8) Counseling, Behavioral Medicine & Health Psychology. There also are three additional multiple-choice examinations in the Part II-Clinical Add-On Series (Homeopathy, Minor Surgery, Acupuncture).

The Part II—Core Clinical Science Series is required by every jurisdiction that regulates the naturopathic profession. A licensing/regulatory authority also may require any or all three examinations in the Part II—Clinical Add-On Series. The psychometric review conducted by the Office of Examination Services focuses on the NPLEX Part II—Core Clinical Science Series Examinations.

The North American Board of Naturopathic Examiners (NABNE) is the international (U.S./Canadian) examining board. The NABNE oversees and sets exam policies, approves applicants to take the NPLEX examinations, and oversees administration, proctoring, scoring, and reporting of the NPLEX examinations. The Naturopathic Physicians Licensing Examinations is the organization that analyses and writes the new examinations on a biannual basis, analyzes results every six months, and scores the NPLEX examinations.

#### Psychometric Evaluation of the NPLEX-Part II Clinical Licensing Examinations

The information presented herein was determined with reference to the most recent *Standards for Psychological and Educational Testing*<sup>2</sup>. Specifically, the summary that follows was conducted from the perspective of modern validity theory as described in the recent *Standards*:

"Evolving conceptualizations of validity no longer speak of different types of validity but speak instead of different lines of validity evidence, all in the service of providing information relevant to a specific intended interpretation of test scores. Thus, many lines of evidence can contribute to an understanding of the construct meaning of test scores." (AERA et al., 1999, p. 5).

### **Unified Concept of Validity**

Validity is "the degree to which evidence and theory support the interpretations of test scores entailed by proposed uses of tests" (AERA et al., 1999, p. 9). According to the Standards (AERA, et al., 1999, p. 9), "validity" is the most fundamental consideration in developing and evaluating tests.

Validation is the process of developing sound arguments for and against proposed test uses and interpretations (AERA et al., 1999; Cronbach, 1988; Haertel, 1999; Kane, 1992, 2001, 2002; Messick, 1989). Plausible rival hypotheses are formulated and tested to determine "whether a test measures less

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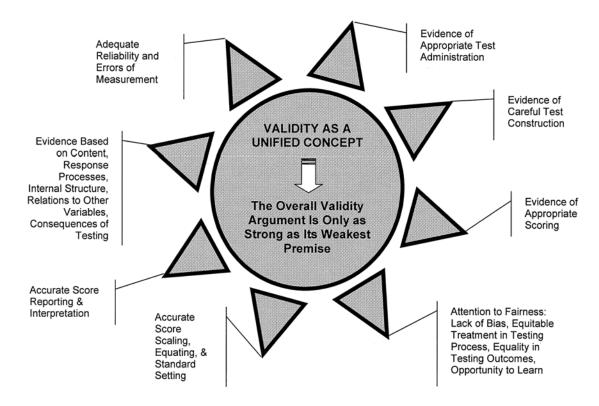
<sup>&</sup>lt;sup>2</sup> American Educational Research Association, American Psychological Association, & National Council on Measurement in Education. (1999). <u>Standards for educational and psychological tests</u>. Washington, DC: American Educational Research Association.

or more than its proposed construct." (AERA et al., 1999, p. 10). Embracing the scientific ideal requires a balanced approach in the validation process so that efforts strive to understand and disclose all evidence about tests and testing practices.

Validity as a unified concept means that an argument for a particular interpretation of a test score is only as strong as the weakest evidence used to support the implied inference (Kane, Crooks, & Cohen, 1996). Haertel (1999, p. 5) summed it up well when he said, "Massive evidence in support of one proposition really doesn't buy us much if evidence for some other key proposition is lacking."

Figure 1 depicts validity as a unified concept and presents sources of validity evidence. The sources of validity evidence are complex and depend on the propositions in validity arguments. The psychometric evaluation of the NPLEX-Part II: Core Clinical Science Series Examinations takes into consideration the sources of validity evidence and the validity research agenda as described in the documentation provided by the NABNE in regards to the NPLEX clinical licensing examinations.

Figure 1. Unitary Concept of Validity & Sources of Validity Evidence<sup>3</sup>



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<sup>&</sup>lt;sup>3</sup> McCallin, R. C. (in press). Test administration. In S. M. Downing & Haladyna, T. M. (Eds.), <u>Handbook of test development</u> (Part V). Hillsdale, NJ: Erlbaum.

The psychometric evaluation of the validity propositions and evidence offered by the NABNE about the NPLEX–Part II: Core Clinical Science Examinations is premised on the information contained in the NPLEX Technical Manual<sup>4</sup>, the NPLEX Part II–Blueprints and Preparation Guide<sup>5</sup>, and information posted on the NABNE web site at: <a href="http://www.nabne.org/html/part2.html">http://www.nabne.org/html/part2.html</a>. The summary table that follows outlines key factors associated with evaluating the usefulness of the NPLEX licensing examinations for licensing decisions.

## <u>Table 1. Exam Program Evaluation: Naturopathic Physicians Licensing Examinations</u> Part II—Clinical NPLEX Examinations

#### AERA/APA/NCME Standard (Page Citation)

#### JOB ANALYSIS

#### Standard 14.14:

The content domain to be covered by a credentialing test should be defined clearly and justified in terms of the importance of the content for credential-worthy performance in an occupation or profession. A rationale should be provided to support a claim that the knowledge or skills being assessed are required for credential-worthy performance in an occupation and are consistent with the purpose for which the licensing or certification program was instituted. (p. 161)

The comment following this standard emphasizes its relevance:

Some form of job or practice analysis provides the primary basis for defining the content domain. If the same examination is used in the licensure or certification of people employed in a variety of settings and specialties, a number of different job settings may need to be analyzed. Although the job analysis techniques may be similar to those used in employment testing, the emphasis for licensure is limited appropriately to knowledge and skills necessary for effective practice. In tests used for licensure, skills that may be important to success but are not directly related to the purpose of licensure (e.g., protecting the public) should not be included.

#### NPLEX Part II (Clinical)

- > One full-scale job analysis done in 1985.
- > 1996 study updated 1985 results
- > Another update is being conducted in 2004-2005
  - Consider performing full-scale practice analysis about every 5 years, especially if practice grows/changes as theory, science, and/or other developments/innovations emerge
- The NPLEX job analysis research over past 20 years has lead to vast array of topics encompassing the NPLEX content domain.
  - Consider if statistical data reduction techniques may offer means to attain further parsimony in defining practice domain
- The content domain per se does not necessarily establish the robust theoretical foundation that underlies the scope of practice in which reasonable potential for therapeutic gains in a patient's medical condition out-weighs the risks of treatment methods (C.R.S. §12-36-117 (3) (a)).
  - ✓ Consider validity research agenda that leads to generalizable information about (1) relationship between P/F Part II examination performance and safe practice, (2) degree to which performance Part II exams indicates dimensions associated with clinical competence vs. technical knowledge, and (3) the impact NPLEX Part II licensing examinations may have on future naturopathic practice and way candidates and schools prepare for these examinations

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<sup>&</sup>lt;sup>4</sup> NPLEX-Naturopathic Physicians Licensing Examinations: <u>Technical Manual And Guide For Licensing Boards</u>. (Revised May 2003). NABNE/NPLEX: Portland, OR

<sup>&</sup>lt;sup>5</sup> NPLEX-Naturopathic Physicians Licensing Examinations: <u>Part II-Clinical Science Examinations:</u> Blueprints & Preparation Guide. (2004). NABNE/NPLEX: Portland, OR

<sup>&</sup>lt;sup>6</sup> The North American Board of Naturopathic Examiners. <a href="http://www.nabne.org/html/part2.html">http://www.nabne.org/html/part2.html</a>.

AERA/APA/NCME Standard (Page Citation)	NPLEX Part II (Clinical)
TEST SPECIFICATIONS  Standard 3.11:  Test developers should document the extent to which the content domain of a test represents the defined domain and test specifications. (p.45)	➤ Vast array of content domain and % of topic area coverage in test specifications for each exam  ✓ Consider studies that examine extent to which construct under-representation may threaten valid interpretations of performance on clinical licensing tests
TEST DEVELOPMENT  Standard 3.6:  The type of items, the response format, scoring proceduresshould be selected based on the purposes of the tests the qualifications, relevant experiences, and demographic characteristics of the expert judges should also be documented. (p. 44)	Per NPLEX, N of 1000+ examinees per year makes it so "cannot employ formats which could more appropriately test clinical competence (e.g., essay examinations, model patients)." (NPLEX 2003 Technical Manual, p. 19, #6)  Consider studies that examine extent to which construct-irrelevant systematic error due to test item format and/or cognitive requirements of clinical test items threatens validity of interpretations of test scores
Standard 3.7:  The procedures used to develop, review, and try out items, and to select items from the item pool should be documented. (p. 44)	➤ Item developers are practicing naturopathic physicians     ✓ Consider that until recently, all practicing naturopathic physicians graduated from schools that were accredited both institutionally and programmatically by the Council of Naturopathic Medical Education (CNME). In 2003, institutional accreditation responsibilities appropriately shifted to regional accrediting bodies.  Item development proceeds according to detailed "blueprint maps"
Standard 3.9:  When a test developer evaluates the psychometric properties of items, the classical or item response theory (IRT) model used for evaluating the psychometric properties of items should be documented. The sample used for estimating item properties of items should be described and should be of adequate size and diversity for the procedure. The process by which items are selected and the data used for item selection should also be documented (p. 45)	➤ Use classical measurement theory  ➤ Anchor items: 50% of test  ➤ Item analyses are conducted to determine if any items are problematic before final scores are computed  ✓ Consider risks in the associated with using 50% new items on multiple choice Part II—Clinical Exams in which many of the tests have relatively small numbers of total items (many exams contain only 50 items).  ✓ Items that do not perform as desired have potential to narrow meaning of scores that are intended to represent the universe of generalization.  ✓ Any reliability coefficient using the data will likely overstate matters since the testing conditions facet is effectively "fixed" (e.g., only one instance). Thus, error variance likely to be understated.

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AERA/APA/NCME Standard (Page Citation)	NPLEX Part II (Clinical)
Test Development (continued)  Standard 3.22:  Procedures for scoring and, if relevant, scoring criteria should be presented by the test developer in sufficient detail and clarity to maximize the accuracy of scoring. In instructions for using rating scales or for deriving scores obtained by coding, scaling, or classifying constructed responses should be clear. This is especially critical if tests can be scored locally. (p. 47)	<ul> <li>Uses "best answer" dichotomous scoring model</li> <li>Preliminary item analysis used to determine if need to give credit for more than one plausible correct answer</li> </ul>
STANDARD SETTING, RELIABILITY, & ERRORS OF MEASUREMENT  Standard 4.19:  When proposed score interpretations involve one or more cut scores, the rationale and procedures used for establishing cut scores should be clearly determined. (p. 59-60)	<ul> <li>Cut Score Committee (N = 16 Naturopathic Physicians) sets passing standard by assessing "the percentage of minimally competent entry level naturopathic physicians who should be able to answer each individual item correctly—i.e., the average cut score across items becomes the cut score for each examination (see Angoff, 1984).</li> <li>Cut scores determined for each exam administration since 50% of items are new on each form</li> </ul>
Standard 14.15:  Estimates of the reliability of test-based credentialing decisions should be provided.	<ul> <li>Reliability coefficients are provided for the Part II tests</li> <li>Although some reliability coefficients for the Part II exams are likely attenuated due to the numbers of test items on exam forms and restriction in the range of candidate performance, the standard error of measurement (SEM) also should be considered.</li> </ul>
	The Standard Error of Measurement (SEM) expresses the reliability of the test scores in examination score units. A range extending from 2 SEMs above and 2 SEMs below a candidate's obtained score will produce a band within which we can be reasonably sure (19 chances in 20) that the individual's true score will lie.
	<ul> <li>Consider the SEMs presented in Appendix E, Table 4 of the 2003 NPLEX Technical Manual.</li> <li>Average SEM &amp; Pass/Fail Cut Points (Raw scores) across 13 years of NPLEX Statistics show:</li> </ul>
	✓ Physical & Clinical Diagnosis: 150-item test; SEM = 4.51; P/F cut point = 106; ∴ true scores likely within band that ranges from +/- 9.02 points of observed score; <u>Example</u> : Observed score of 106 (Pass) means that true score is likely to fall between 96.98 (Fail) and 115.02 (Pass)

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AERA/APA/NCME Standard (Page Citation)	NPLEX Part II (Clinical)
	Standard Setting, Reliability, and Errors of Measurement (continued)
	✓ Lab Diagnosis & Diagnostic Imaging: 75- items test, SEM = 3.37, P/F cut point = 50, ∴ true scores likely within band that ranges from +/-6.74 points of observed score; Example: observed score of 50 (Pass) means that true score is likely to fall between 43.26 (Fail) and 56.74 (Pass)
	✓ Emergency Medicine: 50-item exam; SEM = 2.59; Pass/Fail cut point = 34; ∴ true scores likely within band that ranges from +/- 5.18 points of observed score; Example: Observed score of 34 (Pass) means that true score is likely to fall between 28.82 (Fail) and 39.18 (Pass)
	✓ Botanical Medicines (50-item exam) + Pharmacology (50-item exam); SEM = 3.24; Pass/Fail cut point = 46; ∴ true scores likely within band that ranges from +/- 6.48 points of observed score; <u>Example</u> : Observed score of 46 (Pass) means that true score is likely to fall between 39.52 (Fail) and 52.48 (Pass)
	✓ Physical Medicine: 50-item exam; SEM = 2.60; Pass/Fail cut point = 34; ∴ true scores likely within band that ranges from +/- 5.20 points of observed score; Example: Observed score of 34 (Pass) means that true score is likely to fall between 28.80 (Fail) and 39.20 (Pass)
	✓ Nutrition: 50-item exam; SEM = 2.57; Pass/Fail cut point = 35; ∴ true scores likely within band that ranges from +/- 5.14 points of observed score; <u>Example</u> : Observed score of 35 (Pass) means that true score is likely to fall between 29.86 (Fail) and 40.14 (Pass)
	✓ Counseling, Behavioral Medicine, & Health Psychology: 50-item exam; SEM = 2.50; Pass/Fail cut point = 35; ∴ true scores likely within band that ranges from +/- 5.00 points of observed score; Example: Observed score of 35 (Pass) means that true score is likely to fall between 30.00 (Fail) and 40.00 (Pass)
	✓ Homeopathy: 50-item exam; SEM = 2.53; Pass/Fail cut point = 34; ∴ true scores likely within band that ranges from +/- 5.06 points of observed score; <u>Example</u> : Observed score of 34 (Pass) means that true score is likely to fall between 28.94 (Fail) and 39.06 (Pass)

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AERA/APA/NCME Standard (Page Citation)	NPLEX Part II (Clinical)
	Standard Setting, Reliability, and Errors of Measurement (continued)
	✓ Minor Surgery: 50-item exam; SEM = 2.72; Pass/Fail cut point = 33; ∴ true scores likely within band that ranges from +/- 5.44 points of observed score; Example: Observed score of 33 (Pass) means that true score is likely to fall between 27.56 (Fail) and 38.44 (Pass)
	✓ Acupuncture: 50-item exam; SEM = 2.57; Pass/Fail cut point = 33; ∴ true scores likely within band that ranges from +/- 5.14 points of observed score; <u>Example</u> : Observed score of 33 (Pass) means that true score is likely to fall between 27.86 (Fail) and 38.14 (Pass)
	Since the reliability coefficient of a test provides an upper limit for the squared correlation between a test and a criterion, the NPLEX Part II—clinical exam results may very well restrict the universe of generalizations about entry-level competence (i.e., results may not adequately account for a good deal of the variance in the test scores).
TEST ADMINISTRATION Standard 5.1:	<ul> <li>Covered in Appendix H (North American Board of Naturopathic Examiners [NABNE] Proctor Manual)</li> </ul>
Test administrators should follow carefully the standardized procedures for administration and scoring specified by the test developer, unless the situation or a test taker's disability dictates that an exception should be made. (p. 63)	
Standard 5.2:  Modifications or disruptions of standardized test administration procedures or scoring should be documented. (p. 63)	<ul> <li>Covered in Appendix H (North American Board of Naturopathic Examiners [NABNE] Proctor Manual)</li> </ul>
Standard 5.3:  When formal procedures have been established for requesting and receiving accommodations, test takers should be informed of these procedures in advance of testing. (p. 63)	Covered in Appendix H (North American Board of Naturopathic Examiners [NABNE] Proctor Manual) and on Web site at: <a href="http://www.nabne.org/html/part2.html">http://www.nabne.org/html/part2.html</a> - Anchor11
Standard 5.5:	> NPLEX publishes preparation guides
Instructions to test takers should clearly indicate how to make responses. Instructions should also be given in the use of any equipment likely to be unfamiliar to test takers. Opportunity to practice responding should be given when equipment is involved, unless use of the equipment is being assessed. (p. 63-64)	NPLEX Web site has information: http://www.nabne.org/html/part2.html - Anchor11

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AERA/APA/NCME Standard (Page Citation)	NPLEX Part II (Clinical)
Test Administration (continued)  Standard 5.6:  Reasonable efforts should be made to assure the integrity of test scores by eliminating opportunities for test takers to attain scores by fraudulent means. (p. 64)	See 2003 Technical Manual, Appendix H     NPLEX Web site has information: <a href="http://www.nabne.org/html/part2.html-Anchor11">http://www.nabne.org/html/part2.html-Anchor11</a>
Standard 8.2:  Where appropriate, test takers should be provided, in advance, as much information about the test, the testing process, the intended test use, test scoring criteria, testing policy, and confidentiality protection as is consistent with obtaining valid responses. (p. 86-87)	NPLEX publishes preparation guides  See NPLEX Web site has information: <a href="http://www.nabne.org/html/part2.html">http://www.nabne.org/html/part2.html</a> - Anchor11
Standard 8.7:  Test takers should be made aware that having someone else take the test for them, disclosing confidential test material, or any other form of cheating is inappropriate and that such behavior may result in sanctions. (p. 88)	<ul> <li>See 2003 Technical Manual, Appendix H</li> <li>See Preparation Guide, 2004</li> <li>NPLEX Web site has information: <a href="http://www.nabne.org/html/part2.html-Anchor11">http://www.nabne.org/html/part2.html-Anchor11</a></li> </ul>
Standard 8.13:  In educational testing programs and in licensing and certification applications, test takers are entitled to fair consideration and reasonable process, as appropriate to the particular circumstances, in resolving disputes about testing. Test takers are entitled to be informed of any available means of recourse." (p. 89-90)	See 2003 Technical Manual, Appendix H     See Preparation Guide, 2004     NPLEX Web site has information: <a href="http://www.nabne.org/html/part2.html-Anchor11">http://www.nabne.org/html/part2.html-Anchor11</a>
Standard 11.11:  If the integrity of a test taker's score is challenged, local authorities, the test developer, or the test sponsor should inform the test takers of their relevant rights, including the possibility of appeal and representation by counsel. (p. 115)	See 2003 Technical Manual, Appendix H     See Preparation Guide, 2004     NPLEX Web site has information: <a href="http://www.nabne.org/html/part2.html-Anchor11">http://www.nabne.org/html/part2.html-Anchor11</a>
SCORING & SCORE REPORTING  Standard 4.1:  Test documents should provide test users with clear explanations of the meaning and intended interpretation of derived score scales, as well as their limitations. (p. 54)	Explained in 2003 Technical Manual     Explained on NPLEX Web site at: <a href="http://www.nabne.org/html/aboutnplex.html-Anchor10">http://www.nabne.org/html/aboutnplex.html-Anchor10</a>

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AERA/APA/NCME Standard (Page Citation)	NPLEX Part II (Clinical)
Scoring and Score Reporting (continued)  Standard 4.2:  The construction of scales used for reporting scores should be described clearly in test documents. (p. 54)  Standard 4.9:	Explained in 2003 Technical Manual     Explained on NPLEX Web site at: <a href="http://www.nabne.org/html/aboutnplex.html-Anchor10">http://www.nabne.org/html/aboutnplex.html-Anchor10</a> Fixeleiged in 2003 Technical Manual
When raw score or derived score scales are designed for criterion-referenced interpretations, including the classification of examinees into separate categories, the rationale for recommended score interpretations should be clearly explained. (p. 56-57)	Explained in 2003 Technical Manual     Explained on NPLEX Web site at: <a href="http://www.nabne.org/html/aboutnplex.html-Anchor10">http://www.nabne.org/html/aboutnplex.html-Anchor10</a> Anchor10
Standard 4.17:  Testing programs that attempt to maintain a common scale over time should conduct periodic checks of the stability of the scale on which scores are reported. (p. 59)	<ul> <li>No information about stability of the 0-100 converted score scale.</li> <li>Since previously used items are not re-used for 2 years and 50% of each exam contains new items, NPLEX should consider inquiries into the stability of the 0-100 scale to make sure that the meaning of the scaled scores does not change over time.</li> </ul>
Standard 5.8:  Test scoring services should document the procedures that were followed to assure accuracy of scoring. The frequency of scoring errors should be monitored and reported to users of the service on reasonable request. Any systematic source of scoring errors should be corrected. (p. 64)	<ul> <li>Candidate answer sheets are machine-scorable and are read by optical mark scanner.</li> <li>Information about data that scanner cannot read is provided on the NPLEX web site at:         <ul> <li><a href="http://www.nabne.org/html/aboutnplex.html#Anchor14">http://www.nabne.org/html/aboutnplex.html#Anchor14</a></li> </ul> </li> </ul>
Standard 5.13:  Transmission of individually identified test scores to authorized individuals or institutions should be done in a manner that protects the confidential nature of the scores. (p. 66)	<ul> <li>Information on Web site indicates examinee test results are sent to examinee &amp; one jurisdiction, as indicated by the candidate on the Application to Test.</li> <li>All scoring is done before data are linked to candidate names (see <a href="http://www.nabne.org/html/aboutnplex.html#Anchor14">http://www.nabne.org/html/aboutnplex.html#Anchor14</a>)</li> </ul>
Standard 5.16:  Organizations that maintain test scores on individuals in data files or in an individual's records should develop a clear set of policy guidelines on the duration of retention of an individual's records, and on the availability, and use over time, of such data. (p. 66)	<ul> <li>Per 2003 Technical manual (p. 11), NABNE serves as the unbiased repository for scores on all NPLEX examinations after August 1988.</li> <li>Official transcripts for scores after August 1988 must come from NABNE.</li> <li>Consider publishing information about score retention &amp; use, if applicable, over time.</li> </ul>

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AERA/APA/NCME Standard (Page Citation)	NPLEX Part II (Clinical)
Scoring and Score Reporting (continued)  Standard 8.5:  Test results identified by the names of individual test takers, or by other personally identifying information, should be released only to persons with a legitimate, professional interest in the test taker or who are covered by the informed consent or the test taker or a legal representative, unless otherwise required by law. (p. 87-88)	<ul> <li>Information on Web site indicates examinee test results are sent to examinee &amp; one jurisdiction, as indicated by the candidate on the Application to Test.</li> <li>All scoring is done before data are linked to candidate names (see <a href="http://www.nabne.org/html/aboutnplex.html#Anchor14">http://www.nabne.org/html/aboutnplex.html#Anchor14</a></li> </ul>
Standard 11.14:  Test users are obligated to protect the privacy of examinees and institutions that are involved in the measurement program, unless a disclosure of private information is agreed upon, or is specifically authorized by law. (p. 116)	<ul> <li>Information on Web site indicates examinee test results are sent to examinee &amp; one jurisdiction, as indicated by the candidate on the Application to Test.</li> <li>All scoring is done before data are linked to candidate names (see <a href="http://www.nabne.org/html/aboutnplex.html#Anchor14">http://www.nabne.org/html/aboutnplex.html#Anchor14</a></li> </ul>

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# Appendix C - Correspondence Schools and Distance Education Programs

The Doctor of Naturopathy degree or certificate offered by correspondence schools and distance education programs differ from the naturopathic medical college graduate degree, in addition to varying within their respective programs. The prerequisites to participate in these programs vary greatly. Students graduating from these programs would not qualify to be licensed naturopathic physicians in states that require licensure to practice. Many of these schools or programs are accredited by the American Naturopathic Medical Accreditation Board, the World Association of Universities and Colleges, and/or the American Association of Drugless Practitioners. The U.S. Department of Education does not recognize any of the abovementioned accreditation boards.

There are a variety of distance education programs that offer N.D., Doctor of Naturopathy and Ph.D. degrees. The following program descriptions are taken from school brochures and Internet sites:

The American Institute of Holistic Theology (AIHT) offers four distance-learning programs in Naturology, each designed to invoke the simple wisdom and bounty of nature in attending to human needs. Offerings include a Bachelor of Science (B.S.), Master of Science (M.S.), Doctor of Naturology, and/or Doctor of Philosophy (Ph.D.) degree. AIHT is accredited by The Certification and Accreditation Board of the American Association of Drugless Practitioners (AADP). The average time of completion for a single degree program is approximately 6-8 months. The website states that students may work at their own pace by completing a course in a matter of weeks, or by taking as long as their schedule requires.

<u>Canyon College</u> offers an online Doctor of Naturopathy degree program that requires the completion of 18 courses. Most courses are designed to be completed within eight to nine weeks. Students may elect to take up to five (5) courses at a time. The Doctor of Naturopathy degree program is accredited by the American Naturopathic Medical Accreditation Board. Each student enrolling in a degree program may apply for and be awarded up to a maximum of fifty percent (50%) of the credits required for a degree in the form of previous life experience credits.

The <u>Clayton College of Natural Health</u> offers several different degree programs in Naturopathy: a single degree program for a Doctor of Naturopathy; two (2) two-degree combination programs for a Bachelor of Natural Health Studies/Doctor of Naturopathy or Bachelor of Holistic Nutrition Studies/Doctor of Naturopathy. In addition, Clayton College offers a Doctor of Naturopathy for healthcare professionals and a Doctor of Naturopathy for medical doctors only. Clayton College is accredited by the World Association of Universities and Colleges (WAUC).

The Doctor of Naturopathy program includes ten (10) required courses including such classes as iridology; alternative approaches to arthritis, manual therapies; and massage, reflexology, and acupressure, along with three electives and a consulting practicum. Students are required to have a bachelor's degree and successfully complete the following prerequisites to enter the Doctor of Naturopathy program: Fundaments of Nutrition, Biology, The Science of Life, Cancer: Prevention and Politics, Introduction to Herbology, Introduction to Homeopathy, Anatomy and Physiology, and Herbology II.

Hallmark College, a state licensed vocational school, offers a three-part program series in naturopathy which includes successful completion of the following programs: Wellness Laboratory Technician, the Naturopathic Counselor, and the Certified Naturopath Program. The Wellness Laboratory Technician Program is a six-month training program that consists of fifteen lessons. The student is trained in all the laboratory instruments, reagents, techniques and skills necessary to own and operate a private, federally certified laboratory. The Naturopathic Counselor program consists of basic chemistry, anatomy and physiology concepts, personal and business development, and history of healthcare. The Certified Naturopathic Program is designed to provide students who have successfully completed the first two parts of the series (the Wellness Technician Program and the Naturopathic Counselor Program) the tools and training needed to become a Certified Naturopath. The program consists of studies in biochemical individuality, biological ionization theory, advanced body energies, insurance basics, nutritional support for disease, and evaluation of the wellness laboratory results, as well as electives which introduce other natural therapies such as homeopathy, herbology, flower essence and emotional stress, reflexology, hormones, and aromatherapy. This program requires a minimum of 1,850 hours.

The <u>Herbal Healer Academy</u> is a private membership organization, offering alternative natural medicines, herbs, homeopathic remedies, tinctures, health books, videos, flower essences, essential oils, soap kits, hair analysis, private N.D. correspondence consultations, ear coning, herbal teas, and more. The website contends that cancer, arthritis, heart problems, diabetes, depression, Lupus, GWS, Fibromyalgia, CFS, and many other conditions have been helped, and in some cases completely healed by the sole use of natural medicine and diet modification. Natural medicine is the logical choice for healing, as it offers no harmful side effects, is reasonably priced, and is easily accessible.

The Herbal Healer Academy offers a complete series on natural medicine correspondence courses in herbology, reflexology, nutrition, acupressure, massage, basic business, anatomy and physiology, homeopathy, death and dying, chronic diseases, hypnotherapy, flower remedies and vibrational medicine. All classes may be completed and paid for separately but, if desired, credit may be awarded towards a Naturopathic Certificate. The curriculum is approved for board certification by the American Naturopathic Medical Certification and Accreditation Board

The <u>International College of Naturopathy</u> offers a Diploma/Certificate of Completion as a "Naturopathic Practitioner" after completing 947 hours of coursework, which includes such classes as anatomy and physiology, biochemistry and endocrinology, naturopathic toxicology, lymphatic system draining and detoxification, therapeutic nutrition, herbology, homeopathy, and aromatherapy. In addition to 13 lessons offered online, students are required to complete a residential laboratory class for 14 hours during a two-day weekend.

The <u>School of Natural Medicine</u> was founded in Cambridge, England and is now based in Boulder, Colorado. The Naturopath ND Study Program offers home study courses in naturopathy. Qualifications are met by completing the home study as well as attending a two week summer school in Boulder, participating in a Clinical Training Graduation Seminar after summer school, and a six-month self-healing module guided by the school's director.

The <u>Trinity College of Natural Health</u> offering a Doctor of Naturopathy (N.D.) is committed to a holistic understanding of man that is taught in the Scriptures. The Trinity School is not designed to provide a vocational curriculum that meets the requirement of any particular state where a license is required. Programs of study are for personal enrichment, self-improvement and focus on a pure, unadulterated lifestyle. Only those who agree with the college's philosophy that physical health is primarily a reflection of God's universal law of cause and effect should apply to the Trinity College of Natural Health. The program includes topical studies in reflexology, anatomy and physiology, acupressure, chemistry of nutrition, homeopathy, medical jurisprudence, body mind connection, children's health and diet and nutrition. The naturopathic program is accredited by the American Naturopathic Medical Certification and Accreditation Board.

Developed in 1989, the <u>University of Natural Medicine</u> offers a Doctor of Naturopathy and a Doctor of Naturopathy for health professionals. Study Phase I of the naturopathic program includes an independent study, practical training, research, case studies, and clinical training. Study Phase II of the naturopathic program includes specialized learning in clinical settings near to the student's residence if possible and desired, or in conjunction with the university's national and international network of affiliate clinics and training facilities. The University is licensed by the New Mexico Commission on Higher Education as a Private Postsecondary Institution of Higher Learning.

The Westbrook University, College of Natural Health Sciences offers a Doctor of Naturopathy (N.D.) requiring 338 credit hours. Westbrook University offers diplomas, certificates, and Associate, Bachelor, Master and Doctorate degrees through distance learning. Incoming credits for life/work experiences may be applied to fulfill many of the requirements. If a student requests credit for life, work, or military experiences; verifications showing the number of years, number of hours of study, and type of experiences must be included. The provision for awarding credit is that the life, work, or military experiences must parallel the studies in which the student will enroll. Westbrook is licensed by the New Mexico Commission on Higher Education. It is accredited by the American Naturopathic Medical Certification and Accreditation Board and the International Association of Schools, Colleges and Universities; neither of which is recognized by the U.S. Department of Education as an official accreditation agency.