



Dora
Department of Regulatory Agencies

Office of Policy, Research and Regulatory Reform

2008 Sunrise Review: Naturopathic Physicians

January 4, 2008



STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES

Office of the Executive Director

D. Rico Munn
Executive Director

1560 Broadway, Suite 1550
Denver, Colorado 80202
Phone (303) 894-7855
V/TDD 711



Bill Ritter Jr.
Governor

January 4, 2008

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 mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunrise reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA 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 DORA 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 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,

D. Rico Munn
Executive Director

Table of Contents

The Sunrise Process	1
<i>Background</i>	1
<i>Methodology</i>	4
Proposal for Regulation	5
<i>Profile of the Profession</i>	6
Summary of Current Regulation	14
<i>The Colorado Experience</i>	14
<i>Regulation In Other States</i>	14
Analysis and Recommendations	23
<i>Public Harm</i>	23
<i>Need for Regulation</i>	33
<i>Alternatives to Regulation</i>	35
<i>Conclusion</i>	37
<i>Recommendation: Regulate those naturopathic practitioners whose practices/activities pose a risk of harming the public and require that competency be demonstrated to engage in regulated practice.</i>	41

The Sunrise Process

Background

Regulation, when appropriate, can serve as a bulwark of consumer protection. Regulatory programs can be designed to impact individual professionals, businesses or both.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation. Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

As regulatory programs relate to businesses, they can enhance public protection, promote stability and preserve profitability. But they can also reduce competition and place administrative burdens on the regulated businesses.

Regulatory programs that address businesses can involve certain capital, bookkeeping and other recordkeeping requirements that are meant to ensure financial solvency and responsibility, as well as accountability. Initially, these requirements may serve as barriers to entry, thereby limiting competition. On an ongoing basis, the cost of complying with these requirements may lead to greater administrative costs for the regulated entity, which costs are ultimately passed on to consumers.

Many programs that regulate businesses involve examinations and audits of finances and other records, which are intended to ensure that the relevant businesses continue to comply with these initial requirements. Although intended to enhance public protection, these measures, too, involve costs of compliance.

Similarly, many regulated businesses may be subject to physical inspections to ensure compliance with health and safety standards.

Regulation, then, has many positive and potentially negative consequences. 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:¹

- (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.

¹ § 24-34-104.1(4)(b), C.R.S.

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 representatives of the Colorado Association of Naturopathic Physicians, reviewed licensure laws in other states, conducted interviews of administrators of those programs, and interviewed other groups of healthcare practitioners. 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 Colorado Office of the Physical Therapy Licensure, the Colorado Office of Acupuncture Licensure, the Colorado Board of Chiropractic Examiners, 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.). The occupational group known as Doctors of Naturopathy, N.D., naturopaths, naturopathic practitioners, naturopathic physicians, Doctors of Naturopathic Medicine, and Naturopathic Medical Doctors can cover a wide swath of practitioners (i.e., those who stock vitamins at the store and who may offer advice on one supplement over another, and those who attend four-year institutions of higher learning). The Applicant seeks to license only a relatively small portion of this larger group.

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 among 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:

- Members of 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 DORA's Division of Registrations.
- 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, 1998 and 2005. Consistent with the current sunrise application, each of 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.

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.

Finally, the 2005 sunrise review found that the unregulated practice of naturopathic physicians had resulted in harm, including at least one fatality. As a result, DORA again recommended that the General Assembly regulate this profession. DORA offered three regulatory alternatives as ideal in addressing the type of harm that had been identified: exemption from the Medical Practice Act; title protection and licensure.

Profile of the Profession

Historical Perspective

Naturopathy and Complementary Alternative Medicine (CAM) represent systems 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 can include hydrotherapy, homeopathy, nutritional therapy, botanical medicines, psychology, physiotherapy, and spinal manipulation.

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.² 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.³

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.⁴

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 Holly J. Hough et al., *Profile of a Profession: Naturopathic Practice*, Center for the Health Professions, University of California, San Francisco, 2001, p. 9.

³ The American Association of Naturopathic Physicians, "AANP Definition of Naturopathic Medicine Position Paper." Downloaded on December 12, 2004, from http://www.naturopathic.org/news/positions/definition_naturopathic_medicine.aspx

⁴ Randall Bradley, N.D., *Philosophy of Naturopathic Medicine*. Pizzorno: Murray & Bradley, 1985.

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 for three additional years to the CNME. Subsequently, the U.S. DOE extended the 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. 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 offers 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.

There are four naturopathic medical colleges in the United States accredited by the Commission on Accreditation of the CNME: Bastyr University in Seattle, Washington; National College of Naturopathic Medicine in Portland, Oregon; SCNM in Scottsdale, Arizona; and the University of Bridgeport in Bridgeport, Connecticut. A minimum of three years of undergraduate premedical study from an accredited college or university is a prerequisite for entry to a CNME-accredited naturopathic medical college.

Bastyr University was founded in 1978 to train naturopathic physicians with a scientific approach. In addition to accreditation by CNME, Bastyr is accredited by the Commission on Colleges of the Northwest Association of Schools and Colleges. Bastyr University graduates approximately 100 naturopathic doctors each year, and the estimated cost of tuition, fees, books and supplies for the 2007-08 academic year is \$25,750.⁵

Founded in 1956, the National College of Naturopathic Medicine (NCNM) is the oldest naturopathic medical school in North America. The Naturopathic Doctor (N.D.) degree program is accredited by the Northwest Commission on Colleges and Universities and the CNME. NCNM graduates approximately 100 naturopathic doctors each year, and the estimated cost of tuition, books and supplies for the 2007-08 academic year is \$22,211.⁶

The Doctor of Naturopathic Medicine program began at SCNM in 1992. SCNM is approved by the Arizona Board for Private Post-Secondary Education and accredited by the Higher Learning Commission of the North Central Association of College and Schools and the CNME. SCNM graduates between 80 and 100 naturopathic physicians each year, and the estimated cost of tuition, books and supplies for the 2007-08 academic year is \$26,140.⁷

The University of Bridgeport is accredited by the Connecticut Department of Higher Education, the New England Association of Schools and Colleges and CNME. The University of Bridgeport graduates between 150 and 200 naturopathic physicians each year, and the estimated cost of tuition for the 2007-08 academic year is \$18,720.⁸

⁵ Bastyr University, Tuition and Fees. Downloaded on November 5, 2007, from www.bastyr.edu/academic/profiles/tuition1.asp?reform=pf&

⁶ National College of Natural Medicine, Financial Policies at NCNM. Downloaded on November 6, 2007, from www.ncnm.edu/academics/financial_policies.php

⁷ *Discover the Nature of Good Medicine: 2007-2008 Course Catalogue*, Southwest College of Naturopathic Medicine, p. 51.

⁸ *University of Bridgeport: Tuition and Fees 2007-2008*.

Examinations

The North American Board of Naturopathic Examiners (NABNE) administers the two-part Naturopathic Physicians Licensing Examinations (NPLEX) twice each year in Portland, Seattle, Phoenix, Bridgeport and Toronto. Importantly, many jurisdictions that regulate naturopathic physicians require licensure candidates to pass the NPLEX. Outside of this formal, regulatory process, passage of the NPLEX does not bestow any kind of credential upon the examinee.

To be eligible to take the NPLEX Part I: Basic Science Examinations, candidates must 1) currently be enrolled in, or have graduated from a CNME-accredited naturopathic medical program, and 2) have completed the basic science coursework in the subjects of anatomy, physiology, biochemistry, genetics, microbiology, immunology and pathology.⁹ In addition, candidates must pay a \$125 application fee and a \$225 examination fee, for a total of \$350.

The NPLEX Part I consists of five separate examinations, or sections, each of which must be passed before the candidate may take the NPLEX Part II. The five examinations comprising the NPLEX Part I are anatomy; biochemistry and genetics; microbiology and immunology; and physiology. Each of these five examinations consists of 50 multiple-choice items that must be completed within 60 minutes.

To be eligible to take the NPLEX Part II: Clinical Science Examinations, candidates must 1) have passed the NPLEX Part I, and 2) graduated from a CNME-accredited naturopathic medical program.¹⁰ In addition, candidates must pay a \$125 application fee and a \$475 examination fee, for a total of \$600.

The NPLEX Part II is a 400-item examination that is administered over the course of three days in half-day sessions. Candidates are given a series of cases and then they must respond to between four and five questions. These questions are divided into three main subjects: diagnosis, modalities and other interventions.

Test questions pertaining to diagnosis address issues involving physical and clinical diagnosis, lab diagnosis and diagnostic imaging.

Test questions pertaining to naturopathic modalities address issues involving botanical medicine, clinical nutrition, physical medicine, homeopathy and psychology.

⁹ *Bulletin of Information and Application for the NPLEX Part I – Basic Science Examinations: February 2008 NPLEX Administration*, North American Board of Naturopathic Examiners, p. 2.

¹⁰ *Bulletin of Information and Application for the NPLEX Part II – Clinical Science Examinations: February 2008 NPLEX Administration*, North American Board of Naturopathic Examiners, p. 2.

Test questions pertaining to other modalities address issues involving pharmacology and emergency medicine.

In addition, there are two elective NPLEX Part II examinations, one in minor surgical procedures and one in acupuncture. Passage of these elective examinations are required by only certain jurisdictions that authorize practice in such areas.

The format of the NPLEX Part II elective examinations is similar to that of the NPLEX Part II Clinical Sciences Examinations in that candidates are provided with a case and then asked a series of questions about that case. However, on the elective examinations, test questions are focused on the subject of the examination.

Each of the NPLEX Part II elective examinations are one hour long and cost \$75 to take.

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.

In Colorado today, there are no laws at the state, local or federal level regulating the practice of naturopathic physicians, or establishing standards for scope of practice.

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 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 and the District of Columbia.

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

**Table 1
Regulatory Information for Other States**

State	Year Law Enacted	Type of Law	Title(s)	Regulatory Body	Number of Licensees	Change in Number of Licensees Since 2005
Alaska	1986	License	Naturopathic Doctor	Department of Community and Economic Development, Division of Occupational Licensing	44	+8
Arizona	1935	License	Doctor of Naturopathic Medicine	Naturopathic Physicians Board of Medical Examiners	538	+106
California	2003	License	Naturopathic Doctor	Bureau of Naturopathic Medicine, Department of Consumer Affairs	269	+140
Connecticut	1920	License	Naturopath	State Board of Naturopathic Examiners, Department of Public Health	219	+23
District of Columbia	2004	License	Naturopathic Physician	Department of Health Board of Naturopathy	N/A	N/A
Florida ⁺	N/A	N/A	N/A	N/A	N/A	N/A
Hawaii	1925	License	Naturopathic Physician	State Board of Examiners in Naturopathy	90	+9
Idaho	2005	License	Naturopathic Physician	State Board of Naturopathic Medical Examiners	12	+12
Kansas	2002	Registration	Naturopathic Doctor	State Board of Healing Arts	21	+12
Maine	1995	License	Naturopathic Doctor	Board of Complementary Health Care Providers	5	-14
Montana	1991	License	Naturopathic Physician	Board of Alternative Health Care	73	+7
New Hampshire	1994	License	Doctor of Naturopathic Medicine	Naturopathic Board of Examiners	57	+21

N/A – Not Available

⁺ 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.

State	Year Law Enacted	Type of Law	Title(s)	Regulatory Body	Number of Licensees	Change in Number of Licensees Since 2005
Oregon	1927	License	Doctor of Naturopathy Naturopathic Physician	Board of Naturopathic Examiners	774	+138
Utah	1996	License	Doctor of Naturopathic Medicine Naturopathic Physician	Naturopathic Physicians Licensing Board	28	+20
Vermont	1996	License	Naturopathic Physician	Office of the Secretary of State, Office of Professional Regulation	148	+46
Washington	1919	License	Doctor of Naturopathic Medicine	Department of Health	877	+227

**Table 2
Scope of Practice in Other States**

State	Practice Under Supervision of Licensed MD Only	Prescriptive Authority	Perform Limited Minor Surgery	Dietetics	Hydrotherapy	Physiotherapy	Manipulation	Electrotherapy	X-Ray	Obstetrics/ Gynecology
Alaska	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes, but cannot oversee childbirth
Arizona	No	Yes – must pass an additional state examination	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
California	No	Yes – limited	No – Prohibited from acts involving sutures.	Yes	Yes	Yes	No	Yes	Yes	Yes – additional education and certification required
Connecticut	No	No	No	Yes	Yes	No	Yes	Yes	Yes	No
District of Columbia	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes – passage of a specialty examination, written agreement with a licensed obstetrician, and 100 coursework hours, internship or preceptorship required
Florida	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Hawaii	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes

N/A – Not Available.

State	Practice Under Supervision of Licensed MD Only	Prescriptive Authority	Perform Limited Minor Surgery	Dietetics	Hydrotherapy	Physiotherapy	Manipulation	Electrotherapy	X-Ray	Obstetrics/ Gynecology
Idaho	No	Yes – limited	Yes	Yes	Yes	No	No	N/A	Yes	Yes - a special competency certificate for naturopathic childbirth is required
Kansas	No	Yes – limited	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes – limited to contraception
Maine	No	Yes – limited	Yes	Yes	N/A	Yes	Yes	N/A	Yes	Yes – limited to contraception
Montana	No	Yes – limited	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes – limited to contraception unless additional credentialing is obtained
New Hampshire	No	Yes – limited	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes – limited to contraception unless additional credentialing is obtained
Oregon	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes – additional credentialing required
Utah	No	Yes - limited	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes – additional credentialing required
Vermont	No	Yes - limited	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes – additional credentialing required
Washington	No	Yes - limited	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes – gynecology examinations only

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	No	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; <u>and</u> complete approved internship, preceptorship or clinical program	NPLEX <u>and</u> 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	No
California	Graduate from a school that is accredited by the Council on Naturopathic Medical Education	NPLEX	Yes – 60 hours every two years, including 20 hours in pharmacotherapeutics.	Yes
Connecticut	Graduate from a school approved by the state board. Educational program must last at least 64 weeks	NPLEX	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	Competency-based examination approved by the board	Required for annual renewal	No

N/A – Not Available.

	Education Requirements	Examination Requirements	Mandatory Continuing Education	Professional Liability Insurance
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> a state examination on homeopathy	No	No
Kansas	Graduate from an approved school that offers a degree of doctor of naturopathy or naturopathic medicine and that requires a four-year, 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	No
Oregon	Two years liberal arts and sciences study, plus graduate from a 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

	Education Requirements	Examination Requirements	Mandatory Continuing Education	Professional Liability Insurance
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	No
Washington	Graduate from a school approved by the Secretary of Health that issues a doctorate degree and requires at least 200 post-graduate hours in the study of mechanotherapy	NPLEX <u>and</u> a state jurisprudence examination	Yes – 20 hours per year	No

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 its 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.

The first eight cases presented below were also reported in the Department of Regulatory Agencies' (DORA's) 2005 sunrise report. When appropriate, updated information is provided.

Case 1A: 17-Year Old Female in Wheatridge, Colorado Experienced Cardiac Arrest.¹¹

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.

¹¹ Bazi Kanani, "Naturopath arrested after 2 hospitalized," *9News.com*, March 31, 2004; Sue Lindsay, "Blood procedure prompts arrests," *Rocky Mountain News*, May 22, 2004; Sue Lindsay, "'Doctor' faces more charges," *Rocky Mountain News*, July 20, 2004.

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.

This case illustrates that naturopathic practitioners can harm the public.

Case 1B: Questionable Medicine: Criminal Charges Focus Spotlight on Alternative Healing, Wheatridge, Colorado.¹²

On several occasions in 2003, 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 patient's parents believe that their son was deprived of his last few months of life because of the treatment provided by this naturopathic medical doctor.

In 2006, this practitioner pleaded guilty to theft, perjury, illegal practice of medicine, third degree assault and criminally negligent homicide. The practitioner was sentenced to a total of 13 years in prison.¹³

This case illustrates that naturopathic practitioners can not only harm, but also kill, their patients.

¹² Bazi Kanani, "Naturopath arrested after 2 hospitalized," *9News.com*, March 31, 2004; Sue Lindsay, "Blood procedure prompts arrests," *Rocky Mountain News*, May 22, 2004; Sue Lindsay, "Questionable medicine," *Rocky Mountain News*, September 25, 2004; Sue Lindsay, "Manslaughter count added," *Rocky Mountain News*, February 8, 2005.

¹³ Jefferson County Press Release, March 26, 2006. Downloaded on December 6, 2007, from http://co.jefferson.co.us/news/news_item_T3_R171.htm

Case 2: Naturopath Guilty in Diabetic's Death.¹⁴

An eight-year old female in Asheville, North Carolina who was an insulin-dependent diabetic, was the patient of an unlicensed naturopath. The naturopath's credentials 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.

This case illustrates that naturopathic practitioners can not only harm, but also kill, their patients.

Case 3: Adult Female Treated for Breast Cancer.¹⁵

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 Centers 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.

The naturopathic practitioner at CTCA that reported this case reported in his letter that he had seen other patients with large weeping lesions that became infected and necrotic because treatment was delayed on the advice of unlicensed naturopathic doctors in other states who assured the patients that they were improving despite all evidence to the contrary.

This case illustrates that naturopathic practitioners can harm the public.

¹⁴ Tonya Maxwell, "Naturopath found guilty in diabetic girl's death, practicing medicine without license," *Asheville Citizen-Times*, April 16, 2002.

¹⁵ Letter to DORA from Dr. Paul Reilly, N.D., L.Ac, of the Cancer Treatment Center of America, Seattle, WA, dated June 26, 2004.

Case 4: Van Nuys “Faith Healer” Sentenced to Nine Years in State Prison.¹⁶

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.

This case illustrates that naturopathic practitioners can not only harm, but also kill, their patients.

Case 5: Utah Man Charged in Cancer Patient’s Death.¹⁷

A Canadian practitioner of alternative medicine who applied for a naturopathic license in Utah in 1997, but was denied because he lacked the necessary qualifications, periodically visited Utah to see patients. 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. In September 2006, the practitioner pleaded no contest to two counts of attempted unlawful conduct and was sentenced to 24 months probation, 160 hours of community service and ordered to pay a fine of \$740.

This case illustrates that naturopathic practitioners can harm the public.

¹⁶ Ryan Oliver, “Healers’ arrested after man’s death,” *Los Angeles Times*, October 30, 2002, Los Angeles County District Attorney’s Office Release. Downloaded on February 9, 2004, from <http://da.co.la.ca.us/mr/020904b.htm>

¹⁷ “Utah Man Charged in Cancer Patient’s Death,” Associated Press, November 21, 2004; Amy Choate, “Man charged in Utah County in breast cancer death,” *Deseret Morning News*, November 21, 2004; *In the Fourth District Court of Utah County, State of Utah*, November 15, 2004, Case No. 041404455.

Case 6: Colorado Woman with Thyroid Condition Became Dangerously Ill After Following Advice of a Naturopath.¹⁸

A 47-year old woman visited a naturopathic practitioner 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 practitioner 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.

This case illustrates that naturopathic practitioners can harm the public.

¹⁸ Letter from patient in Durango, August 5, 2004.

Case 7: Federal Agents Raid “Natural Healing” Office in Rhode Island.¹⁹

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 asserted 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. In May 2006, the practitioner was found guilty of 18 counts of wire fraud and three counts of money laundering for frightening healthy people into thinking they were ill, performing incorrect and unnecessary medical tests and selling patients \$1.3 million worth of treatment and products after providing incorrect diagnoses.

This case illustrates that naturopathic practitioners can harm the public.

¹⁹ Felice Freyer, “The state enters nearly 20 exhibits to bolster its claim that John E. Curran posed as a medical doctor to swindle patients,” *The Providence Journal*, June 18, 2005; Felice Freyer, “‘Natural healer’ charged with fraud,” *The Providence Journal*, September 17, 2005; “Man convicted of pretending to be a doctor, defrauding patients,” *The New York Times*, May 26, 2006.

Case 8A: Adult Female Patient Instructed to Cease Taking Thyroid Medicine.²⁰

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 underactive 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 Board of Medical Examiners and the naturopathic practitioner included the practitioner agreeing to: 1) not engage in the practice of medicine; 2) not perform any kind of surgical operation upon a human being, and 3) 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.

This case illustrates that naturopathic practitioners can harm the public.

²⁰ *In the Fourth District Court of El Paso County, State of Colorado, 2005, Case No. 2005CV2881.*

Case 8B: Adult Male Treated for Hemorrhoids.²¹

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 #8A for the final disposition).

The next case was provided by the Applicant in the current sunrise application.

Case 9: Adult Female Loses Baby.²²

In November 2006, an adult female visited a practitioner in Brighton, Colorado who presented as a naturopathic doctor. The patient reports that she informed the practitioner that she was two months pregnant. After a series of tests, the practitioner prescribed four different supplements, one of which contained juniper berries. The patient reports that she again told the practitioner of her pregnancy and asked whether the herbal supplements were safe. The practitioner reportedly assured the patient that the supplements were safe. The patient took the supplements for 12 days, and during her next OB/Gyn appointment, no fetal heartbeat could be detected and an ultrasound showed the fetus to be lifeless. According to at least one on-line source, juniper should be avoided during pregnancy, and among the documented adverse effects of this supplement are anti-implantation, abortifacient and emmenagogue effects.²³

This case illustrates that naturopathic practitioners can harm the public.

²¹ *In the Fourth District Court of El Paso County, State of Colorado*, 2005, Case No. 2005CV2881.

²² Personal statement written by the woman and submitted by the Applicant to DORA.

²³ Information relating to juniper berries was downloaded on November 19, 2007, from www.drugs.com/npp/juniper.html

In addition, information regarding six additional cases of harm caused by naturopathic practitioners who are licensed in other jurisdictions was presented to DORA. The following three cases represent those instances in which DORA was able to obtain sufficient information for presentation here.

Case 10: Practitioner Treated Patients with Deadly Therapy.²⁴

The practice of a Washington-licensed practitioner was restricted after it was found that he treated between 75 and 100 patients by telephone, online service, and by mail, with a thyroid treatment that had proven fatal in Florida seven years earlier.

Although no evidence of actual harm caused by the Washington practitioner is alleged in this case, the fact that someone had previously died from the same treatment is illustrative of the fact that naturopathic practitioners are in a position to cause harm.

Case 11: Teen Died from Asthmatic Attack After Visiting Naturopathic Practitioner.²⁵

In July 2001, a 16-year old asthmatic girl had difficulty breathing, so her mother called their naturopathic practitioner. While the practitioner claims to have directed the mother to take the girl to the hospital, the mother disputes this claim. Regardless, the mother took the girl to the practitioner's office where she received acupuncture treatment, a shot of B-12 and a tincture. No basic medical tests were performed. The girl died later that evening. Although the civil case brought by the girl's family settled, the Arizona Naturopathic Physicians Board of Medical Examiners dismissed the case, after, apparently, only looking at the practitioner's information.

This case illustrates that consumers with potentially fatal conditions seek care from naturopathic practitioners. As a result, it is reasonable to conclude that some demonstration of competency is justified.

²⁴ "‘Wilson’s Syndrome:’ a bogus diagnosis," *C-Health*, April 12, 2001. Downloaded on December 4, 2007, from http://chealth.canoe.ca/channel_health_news_details.asp?channel_id=155&news_channel_id=155&news_id=2889

²⁵ Nina Shapiro, "Death by Natural Causes," *Seattle Weekly*, June 8, 2005. Downloaded on December 4, 2007 from <http://www.seattleweekly.com/2005-06-08/news/death-by-natural-causes.php>

Case 12: Oregon Woman Died From Chelation Therapy.²⁶

In 2003, an Oregon-licensed naturopathic practitioner informed an adult woman that she had dangerously high levels of mercury, lead, cadmium and nickel, which were causing the aches and pains from which the woman had long suffered and from which traditional medicine had been unable to provide relief or explanation. On August 13, 2003, the woman underwent chelation therapy – a process whereby amino acids are administered intravenously to remove metals from the blood – by the naturopathic practitioner. However, chelation also removes metals that the body needs, such as calcium. The woman passed out during the therapy and died later that day at a hospital from cardiac arrhythmia due to low calcium resulting from the chelation therapy.

Although the practitioner settled the civil suit, the Oregon Naturopathic Board of Examiners (Oregon Board) found the practitioner:

- Had negligently caused the woman's death;
- Had prescribed medicine that such practitioners are not allowed to prescribe; and
- Had prescribed dangerously excessive amounts of acetaminophen with hydrocodone.

The Oregon Board imposed the following sanctions on the practitioner:

- Fine of \$8,250;
- Complete education on chelation therapy;
- No intravenous therapy for three years, including chelation therapy;
- No prescribing opiates for one year;
- Continuing education on approved substances; and
- Keep prescription records in triplicate.

This case illustrates the dangers inherent in some naturopathic practices, such as chelation. In this case, a patient died as a direct result of that treatment.

²⁶ James Pitkin, "Natural Disaster," *Willamette Week Online*. Downloaded on December 4, 2007, from <http://wweek.com/popup/print.php?index=9039>

Case 13: Adult Male Left Disabled From Too Much Prednisone.²⁷

A Florida-licensed practitioner prescribed four times the usual dose of prednisone, a steroid, for three years to an adult male. When the drug failed to help, the practitioner raised the dose. It was only when the patient sprained an ankle and visited a medical doctor that the patient learned that the steroids had caused severe damage to his hormonal and gastrointestinal systems, causing severe muscle, bone and eye damage. The patient was left disabled and in constant pain.

This case illustrates how naturopathic practitioners can harm the public.

Furthermore, the Arizona Naturopathic Board of Medicine (Arizona Board) posts its disciplinary actions on its website. That website indicates that the Arizona Board took at least 30 disciplinary actions against 26 practitioners between December 2000 and July 2006, several of which are discussed in the case studies above. Notably, only three of the 30 disciplinary actions were based on failure to satisfy continuing education requirements, meaning that 27 of the cases pertained to more substantive issues, which either did or could have resulted in harm to the public.

Finally, as part of this sunrise review, DORA contacted the Colorado Board of Medical Examiners, the Colorado Board of Chiropractic Examiners, the Colorado Office of Acupuncture Licensure and the Colorado Office of Physical Therapy Licensure to determine whether any complaints regarding naturopathic practitioners had been filed with those state bodies. Only the Board of Medical Examiners had any record of such complaints being filed, and the total was two.

In the end, the 13 cases presented here, plus the 30 cases of discipline imposed by the Arizona board, clearly indicate that naturopathic practitioners can cause harm to the public.

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.

Without question, many of the cases of harm reported in this sunrise report involved not only negligent practice by the relevant practitioners, but many also involved criminal conduct.

²⁷ Jan Goodwin, "Doctors of Nature – or Nonsense?" *Good Housekeeping*, Vol. 227, September 1998, p. 98.

Although regulation is an inherently weak response to criminal conduct, the fact that negligent practice is also involved in many of these cases supports the case for regulation.

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.

In short, the second sunrise criterion asks whether competency is an issue and whether state interference in the marketplace will serve to address that issue. This review concludes that competency is an issue with respect to most of the documented cases of harm. Since the public is ill equipped to determine the credentials and qualifications of naturopathic practitioners, some level of regulation is justified. Therefore, the second sunrise criterion is satisfied.

Additionally, given the wide spectrum of naturopathic practice, the public can easily become confused. 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. 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*,²⁸ 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.

²⁸ Holly J. Hough, *et al.*, *Profile of a Profession: Naturopathic Practice*. Center for the Health Professions, University of California, San Francisco, 2001, p. 3.

In addition to the plethora of titles, educational programs and types of practice 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 DORA, functions in cooperation with DORA. This is untrue.

All of this supports the Applicant's assertion that regulation is necessary to protect the public.

Alternatives to Regulation

The third sunrise criterion asks:

Whether the public can be adequately protected by other means in a more cost-effective 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 provides 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.

One alternative to the creation of a licensing program would be more stringent enforcement 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.²⁹ The CPA states that a person engages in deceptive trade practices when he or she claims, 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 seem to 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, doctors 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 provisions of the CPA. 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.

A final, and somewhat related, alternative would be the creation of a title protection scheme under the CPA. Under such a system, only those practitioners who possess certain, statutorily defined credentials would be permitted to utilize certain, statutorily enumerated titles.

²⁹ § 6-1-707(1)(a), C.R.S.

However, title protection schemes offer only minimal consumer protection and, given the breadth of Complementary Alternative Medicine (CAM) and naturopathic practice, the credentials and titles would, necessarily, be overly broad so as to be comprehensive.

Conclusion

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. In general, the goals of a regulatory program are: 1) protect the public from the dangers of unskilled practitioners and unsound treatment or advice; and 2) protect the public from reliance on unskilled practitioners, as well as directing them to proper medical care.³⁰

There are several 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 CPA; and the use of naturopathic care and CAM continues to be utilized by Colorado consumers; and the examples of harm discussed in this report may have been caused by negligent or incompetent practice. The potential regulation of any health profession has numerous implications for consumers, providers, and society as a whole.

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, [Human Immunodeficiency Virus] infection, or [Acquired Immune Deficiency Syndrome], arthritis, chronic pain, sinusitis, migraines) for which Western medicine can usually offer only symptomatic relief or palliation, not definitive treatment. [CAM is] often used in combination with the appropriate conventional approaches, as a way of enhancing and complementing them. Sometimes [CAM is] used instead of conventional therapies when the latter have proved ineffective or have produced deleterious side effects.³¹

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.

³⁰ 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.

³¹ J.S. Gordon, M.D. “Alternative Medicine and the Family Physician.” *American Family Physician*. 54, 7 (1996):2205-2212.

Not everyone agrees that 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. 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.

Importantly, the sunrise criteria do not require a finding that the occupation or profession for which regulation is sought prove that such practice is effective. Rather, the focus of the sunrise criteria is public harm. Without opining on whether CAM is effective, this review finds that absent regulation of at least some naturopathic practitioners, the public is at risk of harm. Therefore regulation is justified.

To be sure, there is considerable opposition to regulation, and this opposition comes from both the established medical community as well as the naturopathic community itself.

The naturopathic community encompasses a wide spectrum of practitioners, depending upon how one defines the practice. A broad definition could include a person stocking vitamins at a store, those purportedly represented by the Applicant, and everyone in between – from faith healers and herbalists, to nutritional consultants and those who sell supplements.

For the most part, the cases of harm reported in this sunrise report were perpetrated either by licensees in other states, or those engaging in similar scopes of practice. These are the practitioners most closely aligned, in terms of training and holding out to the public, as the Applicant.

As a result, it is reasonable to conclude that any legislation purporting to regulate naturopathic practitioners include a scope of practice that clearly delineates those practices that pose a risk to the public, thereby requiring regulation, and those that do not, thereby requiring no regulation.

Practices requiring regulation could include:

- Diagnosing and treating;
- Ordering and interpreting tests;
- Prescribing appropriate, natural remedies;
- Performing minor office procedures;
- Puncturing the skin; and
- Giving injections.

Additionally, since this review concludes that incompetent practice can harm the public, assurances of competency are appropriate. These encompass education and examinations.

Training and education are important issues in the naturopathic community. Not all safe, competent naturopathic practitioners have graduated from a school accredited by the Council on Naturopathic Medical Education, as is advocated by the Applicant. Regulation should be crafted to permit the regulatory authority the ability to determine which schools and programs are acceptable for practitioners in Colorado.

Which examination to use, too, could prove controversial. The Naturopathic Physicians Licensing Examinations are the most widely used examinations in the United States and Canada for this profession, yet they may not be the best suited for use in Colorado. Therefore, the regulatory authority should have the ability to select the competency examination to be used or, absent a commercially available examination, to create its own.

Finally, a Type 1 board should be created such that consumer protection is its primary mission. This could be accomplished by mandating that the board comprise licensed medical doctors, regulated naturopathic practitioners and public members. It may not be unreasonable for licensed medical doctors and the public members to comprise the majority of board members, to better ensure that the public interest remains paramount.

Alternatively, regulatory authority could be vested in the Colorado Board of Medical Examiners, under which an advisory committee could be created.

Finally, a title must be selected for the regulated practitioners of naturopathy. Many opposed to regulation also oppose the Applicant's use of the term "doctor of naturopathy" and its numerous derivatives, claiming that they, too, hold such degrees, yet do not engage in the same level of practice as do members of the Applicant, thereby possibly exempting them from any regulatory scheme.

While there may be some legitimacy to this line of reasoning, a more compelling argument lies in the idea of protecting a title that is also a degree. While this is done in some professions, it is generally inadvisable because in doing so, those who legitimately hold such degrees, yet are not authorized to practice, cannot, legally, claim to hold the degree.

Still other opponents of regulation oppose the use of the title “physician.” These opponents assert that this term is protected for use by licensed medical doctors only and that it serves to provide the public some distinction between practitioners. This argument, too, is reasonable.

Therefore, selecting the proper title to protect for the regulated naturopathic community will be challenging, but must be done in order to protect the public from even greater confusion.

In the end, 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, regulatory programs 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.

A report from the Pew Commission³² 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.

³² Christine M. Gagnola and Elizabeth Stone, MD, *Considering the Future of Health Care Workforce Regulation*, Pew Health Professions Commission, Center for the Health Professions, University of California, San Francisco, 1997.

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 at the hands of multiple practitioners, and the Applicant has established that the potential for future harm, as found across the nation, exists in Colorado.

Since this review concludes that harm can be caused by naturopathic practitioners engaging in certain types of practice, a licensing scheme, by any label, should be implemented, since it would offer the public the greatest level of regulatory protection. Only those individuals who have fulfilled the requirements for licensure should be allowed to engage in the scope of practice for naturopathic physicians, thus ensuring a minimum level of competency for those tasks deemed most risky.

Recommendation: Regulate those naturopathic practitioners whose practices/activities pose a risk of harming the public and require that competency be demonstrated to engage in regulated practice.