



**COLORADO**

**Department of  
Regulatory Agencies**

Colorado Office of Policy, Research &  
Regulatory Reform

## **2016 Sunset Review: Naturopathic Doctor Act**

*October 14, 2016*





**COLORADO**

**Department of  
Regulatory Agencies**

Executive Director's Office

October 14, 2016

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:

This year, Colorado's sunset review process celebrates its 40<sup>th</sup> anniversary with the publication of the 2016 sunset reports. The Colorado General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Since that time, Colorado's sunset process has gained national recognition and is routinely highlighted as a best practice as governments seek to streamline regulation and increase efficiencies.

The Colorado Office of Policy, Research and Regulatory Reform (COPRRR), located within my office, is responsible for fulfilling these statutory mandates. To emphasize the statewide nature and impact of this endeavor, COPRRR recently launched a series of initiatives aimed at encouraging greater public participation in the regulatory reform process, including publication of a new "Citizen's Guide to Rulemaking" (available online at [www.dora.colorado.gov/opr](http://www.dora.colorado.gov/opr)).

Section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), directs the Department of Regulatory Agencies (DORA) to:

- Conduct an analysis of the performance of each division, board or agency or each function scheduled for termination; and
- Submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination.

Accordingly, COPRRR has completed the evaluation of the Naturopathic Doctor Act. I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2017 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Article 37.3 of Title 12, C.R.S. The report also discusses the effectiveness of the Director of the Division of Professions and Occupations and staff in carrying out the intent of the statutes and makes recommendations for statutory changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Joe Neguse  
Executive Director





# COLORADO

## Department of Regulatory Agencies

Colorado Office of Policy, Research &  
Regulatory Reform

### 2016 Sunset Review Naturopathic Doctor Act

#### SUMMARY

##### ***What Is Regulated?***

Naturopathic doctors are health-care providers who diagnose and treat acute and chronic conditions with an emphasis on prevention. Naturopathic doctors rely on a variety of treatment methods including nutrition, lifestyle counseling, herbal medicine, homeopathy, body work and hydrotherapy. Naturopathic doctors are also trained to repair superficial wounds, remove foreign bodies, cysts and other superficial masses.

##### ***Why Is It Regulated?***

The laws that govern naturopathic doctors protect consumers by ensuring that only qualified naturopathic doctors practice in Colorado.

##### ***Who Is Regulated?***

Colorado had 137 registered naturopathic doctors in fiscal year 15-16.

##### ***How Is It Regulated?***

Naturopathic doctors must register with the Director of the Division of Professions and Occupations (Division) in the Department of Regulatory Agencies. Applicants must have a doctor of naturopathic medicine degree from an approved college and successfully pass a national examination.

##### ***What Does It Cost?***

In fiscal year 15-16, the total expenditures to oversee this program were approximately \$69,000, and there were 0.60 full-time equivalent employees associated with the program.

##### ***What Disciplinary Activity Is There?***

Between fiscal years 13-14 and 15-16, four cease and desist orders were issued for unregistered practice.

## KEY RECOMMENDATIONS

### ***Continue the regulation of naturopathic doctors for five years, until 2022.***

The laws that govern naturopathic doctors ensure competent and qualified practitioners. Naturopathic doctors diagnose and treat disease, so the potential for harm is considerable. If a naturopathic doctor misses a diagnosis, provides improper treatment or fails to refer to another health-care provider, a patient could delay or forgo necessary treatment, which could have dire results. It is, therefore, in the public interest for the State of Colorado to regulate naturopathic doctors.

### ***Require naturopathic doctors to report abuse or neglect of a child and anyone who is elderly or intellectually or developmentally disabled.***

Mandatory reporting of abuse and neglect of people who are vulnerable to abuse and neglect is necessary to protect the health, safety and welfare of the public. Professionals who are in close contact with children or people who are elderly or intellectually or developmentally disabled are likely to identify signs of abuse or neglect when others may be unaware of it. Therefore, it is in the public interest to include naturopathic doctors among those practitioners who are required to report cases of abuse and neglect to the appropriate authorities.

## METHODOLOGY

As part of this review, Colorado Office of Policy, Research and Regulatory Reform staff attended meetings of the Naturopathic Advisory Committee (Advisory Committee), interviewed Division staff and Advisory Committee members, reviewed records, interviewed officials with state and national professional associations, interviewed other stakeholders, interviewed regulators from other states, interviewed officials from naturopathic schools, surveyed registered naturopathic doctors, reviewed Colorado statutes and rules, and reviewed the laws of other states.

## MAJOR CONTACTS MADE DURING THIS REVIEW

Arizona Naturopathic Physicians Medical Board  
Association of Accredited Naturopathic Medical Colleges  
Bastyr University  
Coalition for Natural Health  
Colorado Association of Naturopathic Doctors  
Colorado Citizens for Science in Medicine  
Colorado Department of Law  
Colorado Division of Professions and Occupations

Colorado Medical Society  
Colorado Pharmacists Society  
Colorado Society of Osteopathic Medicine  
Montana Alternative Healthcare Board  
National College of Natural Medicine  
North American Board of Naturopathic Examiners  
Oregon Board of Naturopathic Medicine  
Southwest College of Naturopathic Medicine  
Washington State Department of Health

### **What is a Sunset Review?**

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are prepared by:  
Colorado Department of Regulatory Agencies  
Colorado Office of Policy, Research and Regulatory Reform  
1560 Broadway, Suite 1550, Denver, CO 80202  
[dora.www.colorado.gov/opr](http://dora.www.colorado.gov/opr)



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# Background

## Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria<sup>1</sup> and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

- Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

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<sup>1</sup> Criteria may be found at § 24-34-104, C.R.S.

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- Whether the agency through its licensing or certification process imposes any disqualifications on applicants based on past criminal history and, if so, whether the disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subparagraph (i) of paragraph (a) of subsection (8) of this section shall include data on the number of licenses or certifications that were denied, revoked, or suspended based on a disqualification and the basis for the disqualification; and
  - Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

## Types of Regulation

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

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

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.

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## Certification

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

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.

## Title Protection

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.



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## Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

## **Sunset Process**

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review on COPRRR's website at: [dora.colorado.gov/opr](http://dora.colorado.gov/opr).

The functions of the Director of the Division of Professions and Occupations (Director and Division, respectively) as enumerated in Article 37.3 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2017, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR to conduct an analysis and evaluation of the registration of naturopathic doctors pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed program to regulate naturopathic doctors should be continued and to evaluate the performance of the Director. During this review, the Director must demonstrate that the program serves the public interest. COPRRR's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

## **Methodology**

As part of this review, COPRRR staff attended meetings of the Naturopathic Advisory Committee (Advisory Committee), interviewed Division staff and Advisory Committee members, reviewed records, interviewed officials with state and national professional associations, interviewed other stakeholders, interviewed regulators from other states, interviewed officials from naturopathic schools, surveyed registered naturopathic doctors, reviewed Colorado statutes and rules, and reviewed the laws of other states.

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## Profile of the Profession

Naturopathic medicine is a holistic system of health care based on six principles:<sup>2</sup>

- Support the healing power of nature by identifying and removing obstacles to health and recovery;
- Treat the cause of disease, rather than merely eliminating or suppressing symptoms;
- Apply the least possible force necessary to diagnose illness and treat the patient;
- Educate the patient and emphasize self-responsibility in health;
- Treat the whole person, taking into account physical, mental, emotional, genetic, social and other factors, including encouraging spiritual development; and
- Emphasize the prevention of disease.

Naturopathic doctors treat acute and chronic conditions, but the emphasis of naturopathy is to prevent disease.<sup>3</sup> Most naturopathic doctors work in office-based, private practice settings.<sup>4</sup>

Naturopathic doctors rely on a variety of treatment methods including nutrition, herbal medicine, homeopathy, body work and hydrotherapy.<sup>5</sup> They are also trained to repair superficial wounds and remove foreign bodies, cysts and other superficial masses.<sup>6</sup> When appropriate, naturopathic doctors refer patients to other health-care providers.<sup>7</sup>

In addition to naturopathic doctors, other practitioners may also use naturopathy in their practice.<sup>8</sup>

Traditional naturopaths or lay naturopaths are often confused with naturopathic doctors. While there are similarities in their practices, they are very different in training and scope of practice. Traditional naturopaths use exercise and other noninvasive treatments to improve health. Unlike naturopathic doctors, traditional naturopaths do not use injections or perform minor office procedures.

Myriad other natural health practitioners use naturopathic treatments, such as herbalists, Ayurvedic practitioners, holistic health consultants, classical homeopaths, healing arts practitioners and natural health specialists.

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<sup>2</sup> American Association of Naturopathic Physicians. *Definition of Naturopathic Medicine*. Retrieved on October 23, 2015, from <http://www.naturopathic.org/content.asp?pl=16&sl=59&contentid=59>

<sup>3</sup> University of Maryland Medical Center. *Naturopathy*. Retrieved on October 23, 2015, from <http://www.umm.edu/altmed/articles/naturopathy-000356.htm>

<sup>4</sup> Bastyr University. *About Naturopathic Medicine: The Basics*. Retrieved on October 23, 2015, from <http://www.bastyr.edu/academics/areas-study/study-naturopathic-medicine/about-naturopathic-medicine>

<sup>5</sup> University of Maryland Medical Center. *Naturopathy*. Retrieved on October 23, 2015, from <http://www.umm.edu/altmed/articles/naturopathy-000356.htm> See: Oregon Board of Naturopathic Medicine.

*Naturopathy*. Retrieved on October 23, 2015, from <http://www.oregon.gov/obnm/Pages/Aboutnaturopathy.aspx>

<sup>6</sup> Oregon Board of Naturopathic Medicine. *Naturopathy*. Retrieved on October 23, 2015, from <http://www.oregon.gov/obnm/Pages/Aboutnaturopathy.aspx>

<sup>7</sup> National Institutes of Health, National Center for Complementary and Integrative Health. *Naturopathy*. Retrieved on October 23, 2015, from <http://nccam.nih.gov/health/naturopathy/naturopathyintro.htm>

<sup>8</sup> National Institutes of Health, National Center for Complementary and Integrative Health. *Naturopathy*. Retrieved on October 23, 2015, from <http://nccam.nih.gov/health/naturopathy/naturopathyintro.htm>

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The content and length of educational programs for other natural health practitioners, including traditional naturopaths, is inconsistent. Practitioners may be self-taught or they may obtain degrees or certificates through online, correspondence or traditional schools. Some schools may provide on-site clinical training; many do not.

Other health-care providers—such as physicians, chiropractors, dentists and nurses—may also have training in naturopathy and employ naturopathic treatment in their practice.<sup>9</sup>

The focus of this report is the regulation of naturopathic doctors, not other practitioners who may use naturopathy in their practice.

Naturopathic doctors earn doctorate degrees, in programs accredited by the Council on Naturopathic Medical Education (CNME), an organization approved by the U.S. Department of Education.<sup>10</sup> They must complete four years of education in naturopathic medicine, which includes clinical training in outpatient settings under close supervision by licensed professionals.<sup>11</sup>

There are six CNME-accredited programs in the United States:<sup>12</sup>

- Bastyr University in Washington
- Bastyr University in California
- National College of Natural Medicine in Oregon
- National University of Health Sciences in Illinois
- Southwest College of Naturopathic Medicine in Arizona
- University of Bridgeport - College of Naturopathic Medicine in Connecticut

The prerequisites for entry to a naturopathic school include a bachelor's degree and standard premedical courses. The programs consist of courses in the basic sciences, naturopathic therapies and techniques, diagnostic techniques and tests, specialty courses, clinical sciences and clinical training. Graduates of these programs obtain either a Naturopathic Doctor (ND) or a Naturopathic Medical Doctor (NMD) degree. In order to qualify for licensure, naturopathic doctors are required to pass the Naturopathic Physicians Licensing Examination (NPLEX).<sup>13</sup>

Currently, 17 states including Colorado, the District of Columbia, and two U.S. jurisdictions regulate naturopathic doctors.<sup>14</sup>

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<sup>9</sup> National Institutes of Health, National Center for Complementary and Integrative Health. *Naturopathy*. Retrieved on October 23, 2015, from <http://nccam.nih.gov/health/naturopathy/naturopathyintro.htm>

<sup>10</sup> Council on Naturopathic Medicine. About the Council on Naturopathic Medicine. Retrieved on August 30, 2016, from <http://www.cnme.org/index.html>

<sup>11</sup> National Institutes of Health, National Center for Complementary and Integrative Health. *Naturopathy*. Retrieved on October 23, 2015, from <http://nccam.nih.gov/health/naturopathy/naturopathyintro.htm>

<sup>12</sup> North American Board of Naturopathic Examiners. Approved Naturopathic Medical Programs. Retrieved on October 27, 2015, from <https://www.nabne.org/home/approved-naturopathic-medical-education-programs/>

<sup>13</sup> National Institutes of Health, National Center for Complementary and Integrative Health. *Naturopathy*. Retrieved on October 23, 2015, from <http://nccam.nih.gov/health/naturopathy/naturopathyintro.htm>

<sup>14</sup> American Association of Naturopathic Physicians. *Licensed States and Licensing Authorities*. Retrieved on October 23, 2015, from <http://www.naturopathic.org/content.asp?contentid=57>

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## Legal Framework

### History of Regulation

In Colorado, naturopathic doctors sought regulation as early as 1993. The Colorado Department of Regulatory Agencies (DORA) recommended regulating naturopathic doctors in a sunrise review released in 1998, and again in 2005 and 2008.

DORA declined to conduct sunrise reviews in 2009 and 2011 since the sunrise applications that were submitted did not provide any additional information that would warrant a change in the recommendation to regulate naturopathic doctors.

In 2013, the General Assembly enacted the Naturopathic Doctor Act (Act), which established a program to regulate naturopathic doctors. Consequently, anyone seeking to practice as a naturopathic doctor in Colorado must meet the qualifications defined in the Act and register with the Director of the Division of Professions and Occupations (Director and Division, respectively).

In 2015, two bills passed that amended the Act. House Bill 1075 expanded the scope of practice to allow qualified naturopathic doctors to treat children under the age of two, provided certain conditions are met. House Bill 1352 expanded the list of medications that naturopathic doctors are authorized to obtain and administer.

### Legal Summary

The practice of naturopathic medicine is governed by the Act, which is located in Article 37.3 of Title 12, Colorado Revised Statutes (C.R.S.).

As of June 1, 2014, no one may practice naturopathic medicine without registering with the state,<sup>15</sup> and only registered naturopathic doctors may hold themselves out as naturopathic doctors or use the titles “naturopathic doctor,” “doctor of naturopathy” or the initials “N.D.”<sup>16</sup>

Anyone who practices or offers to practice as a naturopathic doctor without an active registration commits a Class 2 misdemeanor,<sup>17</sup> punishable by 3 to 12 months imprisonment or a fine of between \$250 and \$1,000, or both.<sup>18</sup>

Naturopathic doctors are prohibited from using the titles “physician,” “naturopathic medical doctor” or the initials “N.M.D.”<sup>19</sup>

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<sup>15</sup> § 12-37.3-106(1), C.R.S.

<sup>16</sup> § 12-37.3-110(1), C.R.S.

<sup>17</sup> § 12-37.3-113, C.R.S.

<sup>18</sup> § 18-1.3-501(1)(a), C.R.S.

<sup>19</sup> § 12-37.3-110(3), C.R.S.

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The practice of naturopathic medicine includes education, dietary and nutritional advice, and the promotion of a healthy lifestyle provided by a registered practitioner in order to prevent and treat human injury, conditions and disease.<sup>20</sup> It also includes physical examination and ordering clinical, laboratory or radiological diagnostic procedures for the purpose of diagnosing and evaluating injuries, conditions and diseases of the human body.<sup>21</sup>

Additionally, the scope of practice includes the use of:<sup>22</sup>

- Medicines in the naturopathic formulary,
- Epinephrine to treat anaphylaxis,
- Barrier contraceptives,
- Oxygen for emergency use only,
- Vitamins B6 and B12,
- Substances regulated by the Federal Food and Drug Administration that do not require a prescription in order to be dispensed, and
- Vaccines for patients who are 18 or older.

Naturopathic doctors may also conduct minor office procedures.<sup>23</sup>

A naturopathic doctor may only treat a child who is under the age of eight if certain conditions are met. The naturopathic doctor must:<sup>24</sup>

- Recommend that the parent or guardian follow the immunization schedule recommended by the federal Centers for Disease Control and Prevention and provide the parent or guardian a copy of the most recent immunization schedule;
- Develop a written collaborative agreement with a licensed pediatrician or family physician;
- Complete three hours a year of education or practicum training related to pediatrics, in order to treat a child who is two or older; and
- Complete five hours a year of education or practicum training related to pediatrics that includes subject matter related to recognizing a sick infant and when to refer an infant for more intensive care, in order to treat a child who is under the age of two.

In order to treat a child under the age of eight, a naturopathic doctor must also obtain from a parent or legal guardian a signed informed consent and disclosure form that:

- Discloses that the naturopathic doctor is registered as a naturopathic doctor and is not a licensed physician,

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<sup>20</sup> § 12-37.3-105(1), C.R.S.

<sup>21</sup> § 12-37.3-105(1)(b), C.R.S.

<sup>22</sup> § 12-37.3-105(1)(c), C.R.S.

<sup>23</sup> § 12-37.3-105(1)(d), C.R.S.

<sup>24</sup> §§ 12-37.3-105(2)(e) and 12-37.5-105(2)(f), C.R.S.

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- Recommends that the child have a relationship with a licensed pediatric health-care provider, and
  - Requests, from the parent or legal guardian, permission to develop and maintain a collaborative relationship with the licensed pediatric health-care provider.

A naturopathic doctor may not engage in the practice of medicine, perform surgery or engage in any other form of healing.<sup>25</sup>

Specifically, a naturopathic doctor is prohibited from:<sup>26</sup>

- Prescribing, dispensing or administering controlled substances or devices,
- Using anesthetics other than topical, or
- Administering ionizing radioactive substances for therapeutic purposes.

The Act does not carve out for naturopathic doctors an exclusive privilege for the use of therapies such as nutritional supplements, herbs, foods, homeopathic remedies and physical forces such as heat, cold, water, touch and light.<sup>27</sup>

However, the Act prohibits a person who practices natural health care who is not a registered naturopathic doctor or a licensed health-care provider from:<sup>28</sup>

- Diagnosing injuries or diseases,
- Prescribing medicines in the naturopathic formulary,
- Prescribing prescription drugs or controlled substances, or
- Performing minor office procedures authorized under the Act.

## The Director

The Director oversees the registration of naturopathic doctors and may adopt rules to implement the Act.<sup>29</sup>

The Director is also granted the authority to:<sup>30</sup>

- Deny, revoke or suspend a registration,
- Issue a letter of admonition, and
- Place a registrant on probation.

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<sup>25</sup> § 12-37.3-105(1)(g), C.R.S.

<sup>26</sup> § 12-37.3-105(2), C.R.S.

<sup>27</sup> § 12-37.3-105(6), C.R.S.

<sup>28</sup> § 12-37.3-105(4)(b), C.R.S.

<sup>29</sup> § 12-37.3-104(1)(a), C.R.S.

<sup>30</sup> § 12-37.3-112(1), C.R.S.

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## The Naturopathic Medicine Advisory Committee

The Naturopathic Medicine Advisory Committee (Advisory Committee) was created to advise the Director concerning the regulation of naturopathic doctors and the implementation of the Act.<sup>31</sup>

The Advisory Committee consists of nine members appointed by the Director:<sup>32</sup>

- Three naturopathic doctors,
- Three medical or osteopathic doctors,
- One pharmacist, and
- Two public members who are preferably consumers of naturopathic medicine.

The members may not serve more than two consecutive four-year terms.<sup>33</sup> The Director is authorized to remove any member for misconduct, incompetence or neglect of duty.<sup>34</sup>

### Registration

In order to register as a naturopathic doctor, an applicant must:<sup>35</sup>

- Be at least 21 years of age,
- Have a baccalaureate degree from an accredited college or equivalent experience,
- Have a doctor of naturopathic medicine degree from an approved college,
- Have successfully passed an examination approved by the Director or administered by the North American Board of Naturopathic Examiners, and
- Be in good standing if licensed in another state or previously registered in Colorado.

The Director may register a naturopathic doctor by endorsement as long as the applicant has a license, certificate or registration as a naturopathic doctor in good standing in another state and can present evidence of having credentials and qualifications that are substantially equivalent to those required by Colorado.<sup>36</sup>

The Director also has the authority to determine any necessary qualifications in the case of an application by an individual who has not successfully passed the required education and examination and who is not currently licensed, certified or registered as a naturopathic doctor in another jurisdiction.<sup>37</sup>

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<sup>31</sup> § 12-37.3-103(1)(a), C.R.S.

<sup>32</sup> § 12-37.3-103(1)(b)(I), C.R.S.

<sup>33</sup> § 12-37.3-103(1)(c)(I), C.R.S.

<sup>34</sup> § 12-37.3-103(1)(d), C.R.S.

<sup>35</sup> § 12-37.3-106(2), C.R.S.

<sup>36</sup> § 12-37.3-106(3), C.R.S.

<sup>37</sup> § 12-37.3-106(4), C.R.S.

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## Grounds for Discipline

The grounds for discipline include:<sup>38</sup>

- Violating, or aiding or abetting another in the violation of, the Act or rules;
- Violating a valid order of the Director;
- Engaging in an act or omission that does not meet generally accepted standards of practice of naturopathic medicine or of safe care for patients;
- Habitual or excessive use or abuse of alcohol, a habit-forming drug or a controlled substance;
- Failing to refer a patient to an appropriate health-care provider when the services required by the patient are beyond the naturopathic doctor's level of competence or scope of practice;
- Falsifying, repeatedly failing to make essential entries in or repeatedly making incorrect essential entries in patient records;
- Conviction of a felony, an offense of moral turpitude or a crime that would constitute a violation of the Act;
- Engaging in a sexual act with a patient during the course of patient care or within six months immediately following the written termination of the professional relationship with the patient;
- Committing abuse of health insurance;
- Failing to notify the Director of a physical or mental illness or condition that affects the naturopathic doctor's ability to treat patients with reasonable skill and safety or that may endanger the health or safety of persons under his or her care;
- Failing to act within the limitations created by a physical or mental illness or condition that renders the naturopathic doctor unable to practice naturopathic medicine with reasonable skill and safety or that may endanger the health or safety of persons under his or her care;
- Failing to comply with the limitations agreed to under a confidential agreement;
- Refusing to submit to a physical or mental examination ordered by the Director;
- Failing to timely respond to a complaint filed against the naturopathic doctor; and
- Failing to obtain and continually maintain professional liability insurance.

Any person whose registration is revoked or surrendered is ineligible to apply for a registration under this article for at least two years.<sup>39</sup>

The Director is also provided the authority to fine a naturopathic doctor who violates any of the grounds for discipline. Any fines collected pursuant to the Act are directed to the General Fund.<sup>40</sup>

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<sup>38</sup> § 12-37.3-112(1), C.R.S.

<sup>39</sup> § 12-37.3-112(3), C.R.S.

<sup>40</sup> § 12-37.3-112(2), C.R.S.



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## Professional Competency

Naturopathic doctors must maintain continued professional competency in order to renew or reinstate a registration.<sup>41</sup>

At a minimum, a continued professional competency program established by the Director must include:<sup>42</sup>

- A self-assessment of professional knowledge and skills;
- Development, execution and documentation of a learning plan based on the assessment; and
- Periodic demonstration of knowledge and skills through documentation of activities necessary to ensure continuing competency in the profession.

Naturopathic doctors must participate in the Healthcare Professions Profile Program and disclose any information required by the Director pursuant to the Michael Skolnik Medical Transparency Act of 2010.<sup>43</sup>

A naturopathic doctor is required to disclose certain information to any patient, such as how to file a complaint.<sup>44</sup> The naturopathic doctor must obtain written acknowledgement that the patient received the required disclosures and maintain the acknowledgement for seven years after providing services to the patient.<sup>45</sup>

A naturopathic doctor is also required to develop a written plan to ensure the security of patient records<sup>46</sup> and inform patients in writing how to access patient records in case the practitioner dies, retires or otherwise ceases to provide care to patients.<sup>47</sup>

Any naturopathic doctor who treats a patient for cancer must recommend that the patient consult with a licensed physician specializing in oncology and document the recommendation in writing.<sup>48</sup>

Naturopathic doctors must maintain professional liability insurance in the amount of at least \$1 million.<sup>49</sup>

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<sup>41</sup> §§ 12-37.3-108(1)(a) and 12-37.3-108(1)(d)(I), C.R.S.

<sup>42</sup> § 12-37.3-108(1)(b), C.R.S.

<sup>43</sup> § 12-37.3-109, C.R.S.

<sup>44</sup> § 12-37.3-111(1), C.R.S.

<sup>45</sup> § 12-37.3-111(2), C.R.S.

<sup>46</sup> § 12-37.3-115(1), C.R.S.

<sup>47</sup> § 12-37.3-115(3), C.R.S.

<sup>48</sup> § 12-37.3-111(3), C.R.S.

<sup>49</sup> § 12-37.3-114(1), C.R.S.

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## Program Description and Administration

The Director of the Division of Professions and Occupations (Director and Division, respectively) within the Colorado Department of Regulatory Agencies (DORA) is vested with the authority to regulate naturopathic doctors. The Director is responsible for registration, rulemaking, policymaking and, when appropriate, imposing discipline on practitioners.

The Naturopathic Advisory Committee (Advisory Committee), which meets quarterly, assists the Director in regulating the profession. The Advisory Committee is appointed by the Director and consists of nine members including:

- Three naturopathic doctors,
- Three doctors of medicine or osteopathy,
- One pharmacist, and
- Two public members.

The regulatory program officially began operating in August 2013. Applications were available in April 2014, and the first registrations were issued in May 2014.

Table 1 illustrates the expenditures and staff associated with the program.

**Table 1**  
**Program Fiscal Information**

| Fiscal Year | Total Program Expenditures | FTE  |
|-------------|----------------------------|------|
| 13-14       | \$90,956                   | 0.80 |
| 14-15       | \$80,699                   | 0.60 |
| 15-16       | \$69,266                   | 0.60 |

The full-time equivalent (FTE) employees reported in Table 1 do not include employees in the centralized offices of the Division, who provide licensing, administrative, technical and investigative support to the Division. However, the cost of those employees is reflected in the Total Program Expenditures.

The expenditures and FTE employees were initially higher based on the anticipated cost of implementing a new program.

In fiscal year 14-15, 0.60 FTE were dedicated to the program:

- A Program Director (0.10 FTE, Program Management II), who manages the day-to-day operations related to the program;
- A Program Manager (0.05 FTE, Technician IV), who responds to inquiries from the public and monitors licensees under disciplinary action; and
- An Administrative Assistant III (0.45 FTE), who provides administrative support to the Office.

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As of June 1, 2014, anyone who practices naturopathic medicine or holds themselves out as a naturopathic doctor must be registered with the Director. Naturopathic Doctors must renew their registration annually on or before July 1. Since registration had only been in place for a few months, the Director did not charge a renewal fee in fiscal year 14-15.

Table 2 provides the registration fees for naturopathic doctors.

**Table 2  
Registration Fees**

| <b>Fiscal Year</b> | <b>Original</b> | <b>Endorsement</b> | <b>Renewal</b> | <b>Reinstatement</b> |
|--------------------|-----------------|--------------------|----------------|----------------------|
| 13-14              | \$975           | \$975              | NA             | NA                   |
| 14-15              | \$975           | \$975              | \$950          | \$965                |
| 15-16              | \$975           | \$975              | \$950          | \$950                |

The fees for this program are fairly high in comparison with other health-care practitioners because the cost of regulation is borne by the regulated community and there are relatively few naturopathic doctors registered with the program.

Although the expenditures and FTE were reduced in fiscal year 14-15, the registration fees were not reduced in the following year since the registration fees in fiscal year 13-14 were only collected for two months before another fiscal year began. Further, the Division overestimated the number of naturopathic doctors that would register with the program when it began, so in fiscal year 15-16, the fees were established to cover the cost of the program, which included a deficit from the previous fiscal year.

## **Registration**

In order to register with the Director, a naturopathic doctor must complete an online application and pay the fee.

Applicants are qualified to register if they have completed a four-year, graduate-level program accredited by the Council on Naturopathic Medical Education (CNME), approved by the U.S. Department of Education. Applicants are also required to pass the Naturopathic Physicians Licensing Examination (NPLEX).

Table 3 shows the number of naturopathic doctors who registered with the Director over a three-year period.

**Table 3  
Registered Naturopathic Doctors**

| Fiscal Year | Original | Endorsement | Renewal | Reinstatement | Total* |
|-------------|----------|-------------|---------|---------------|--------|
| 13-14       | 11       | 56          | NA      | NA            | 67     |
| 14-15       | 15       | 19          | 65      | 0             | 99     |
| 15-16       | 16       | 21          | 99      | 1             | 137    |

\*As of June 30 of each fiscal year.

The increase in registrations from fiscal year 13-14 may be due to a number of factors. First, registration of naturopathic doctors in fiscal year 13-14 only represents two months of registration activity, and it is likely that many naturopathic doctors in the state were initially unaware of the registration requirement. Additionally, the practice act does not prohibit other natural health practitioners from practicing in Colorado, and some qualified individuals may have initially opted to forgo registration and not represent themselves as naturopathic doctors or practice to the full scope of practice.

In the 2012 Sunrise Application, the applicant estimated the number of naturopathic doctors practicing in Colorado to be 130.<sup>50</sup> As of the end of fiscal year 15-16, the total number of actively licensed naturopathic doctors surpassed the estimate.

A registrant must complete the continuing professional competency requirements established by the Director in order to renew registration. Continuing professional competency differs from traditional continuing education because it requires professionals to assess their work and identify areas of growth in order to maintain competency and stay current with the profession.

In order to comply with the continuing professional competency requirements, a registrant must annually:<sup>51</sup>

- Complete a self-assessment,
- Create a learning plan based on the self-assessment, and
- Complete 25 hours of professional development activities.

Professional development activities may include:<sup>52</sup>

- Coursework,
- Group study,
- Independent learning,
- Mentoring,
- Presenting,

<sup>50</sup> Sunrise Review Application: Proposal for the Regulation of Naturopathic Doctors Who Practice Naturopathic Medicine. *Colorado Association of Naturopathic Doctors*. November 30, 2012. Page 4.

<sup>51</sup> Colorado Department of Regulatory Agencies. *Office of Naturopathic Doctor Registration*. Retrieved on August 5, 2016, from [https://www.colorado.gov/pacific/dora/Naturopathy\\_CPC\\_FAQ](https://www.colorado.gov/pacific/dora/Naturopathy_CPC_FAQ)

<sup>52</sup> Colorado Department of Regulatory Agencies. *Office of Naturopathic Doctor Registration*. Retrieved on August 5, 2016, from [https://www.colorado.gov/pacific/dora/Naturopathy\\_CPC\\_FAQ](https://www.colorado.gov/pacific/dora/Naturopathy_CPC_FAQ)

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- Publishing, and
  - Volunteer service.

At least 13 hours of professional development must be obtained through coursework.<sup>53</sup>

## Examinations

The North American Board of Naturopathic Examiners (NABNE) develops and administers the NPLEX examinations.<sup>54</sup>

The NPLEX consists of two examinations:<sup>55</sup>

- Part I - Biomedical Science Examination (Part I), and
- Part II - Clinical Electives Examination (Part II).

Both Part I and Part II are multiple choice examinations that consist of clinical summaries followed by questions related to each case.<sup>56</sup>

In Part I, the clinical summaries are fairly brief and the responses relate to the biomedical basis for the patient's condition and do not require diagnosis of the condition or treatment options. The examination lasts five hours, and it is divided into two sessions administered in the morning and the afternoon.<sup>57</sup>

Part I is composed of 200 items covering:<sup>58</sup>

- Anatomy,
- Physiology,
- Biochemistry and genetics,
- Microbiology and immunology, and
- Pathology.

In order to take Part I, an individual must be a student at a CNME-approved naturopathic school who has completed the biomedical science coursework or has graduated from a CNME-approved school in the previous five years.<sup>59</sup>

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<sup>53</sup> Colorado Department of Regulatory Agencies. *Office of Naturopathic Doctor Registration*. Retrieved on August 5, 2016, from [https://www.colorado.gov/pacific/dora/Naturopathy\\_CPC\\_FAQ](https://www.colorado.gov/pacific/dora/Naturopathy_CPC_FAQ)

<sup>54</sup> North American Board of Naturopathic Examiners. *About Us*. Retrieved on April 8, 2016, from <https://www.nabne.org/home/about/>

<sup>55</sup> North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved on April 12, 2016, from <https://www.nabne.org/home/exam-overview/>

<sup>56</sup> North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved on April 12, 2016, from <https://www.nabne.org/home/exam-overview/>

<sup>57</sup> North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved on April 12, 2016, from <https://www.nabne.org/home/exam-overview/>

<sup>58</sup> North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved on April 12, 2016, from <https://www.nabne.org/home/exam-overview/>

<sup>59</sup> North American Board of Naturopathic Examiners. *Eligibility to Take the NPLEX Part I - Biomedical Science Examination*. Retrieved on April 12, 2016, from <https://www.nabne.org/home/nplex-part-i-biomedical-science-examination/>

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Part II is composed of 400 items based on 80 cases covering:<sup>60</sup>

- Physical, clinical and lab diagnosis;
- Botanical medicine and homeopathy;
- Nutrition, physical medicine, health psychology and research; and
- Emergency medicine, medical procedures, public health and pharmacology.

In Part II, an examinee may be required to provide a differential diagnosis for a single case, to select appropriate lab tests, to prescribe therapies to address a patient's condition and to respond to acute care emergencies. The examination lasts 10 hours and 30 minutes, and it is divided into three sessions administered over a three-day period.<sup>61</sup>

In order to take Part II, an individual must have graduated from a CNME-approved naturopathic school in the previous five years, or passed Part I in the last 10 years.<sup>62</sup>

In August 2016, the NPLEX was administered at six testing sites:<sup>63</sup>

- Bridgeport, Connecticut
- Glen Ellyn, Illinois
- Phoenix, Arizona
- San Diego, California
- Portland, Oregon
- Bothell, Washington

The fees for the NPLEX are:

- \$475 for Part I - Biomedical Science
- \$750 for Part II - Core Clinical Science
- \$100 for Part II - Clinical Elective Acupuncture
- \$100 for Part II - Clinical Elective Minor Surgery

Table 4 shows the total number of first-time test takers and pass rates for the NPLEX over a five-year period.

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<sup>60</sup> North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved on April 12, 2016, from <https://www.nabne.org/home/exam-overview/>

<sup>61</sup> North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved on April 12, 2016, from <https://www.nabne.org/home/exam-overview/>

<sup>62</sup> North American Board of Naturopathic Examiners. *Eligibility to Take the NPLEX Part II - Core Clinical Sciences Examination*. Retrieved on April 12, 2016, from <https://www.nabne.org/home/nplex-part-ii-core-clinical-science-examination/>

<sup>63</sup> North American Board of Naturopathic Examiners. *Test Sites*. Retrieved on August 29, 2016, from <https://www.nabne.org/home/test-sites/>

**Table 4**  
**Number of First-Time Test Takers and**  
**Pass Rates for the NPLEX**

| Category              | 2011 | 2012 | 2013 | 2014 | 2015 |
|-----------------------|------|------|------|------|------|
| Part I - Test Takers  | 453  | 514  | 472  | 520  | 516  |
| Part I - Pass Rates   | 78%  | 81%  | 76%  | 74%  | 79%  |
| Part II - Test Takers | 402  | 433  | 432  | 460  | 476  |
| Part II - Pass Rates  | 88%  | 84%  | 85%  | 82%  | 83%  |

The total number of first-time test takers increased gradually over the five-year period. On average approximately 495 naturopathic students took Part I of the NPLEX each year, and about 78 percent of the examinees passed the examination on the first attempt. Approximately 440 graduates of naturopathic schools took Part II of the NPLEX each year, and the average pass rate was 85 percent.

### Complaints/Disciplinary Actions

Table 5 demonstrates the number and type of complaints received by the Director over a three-year period.

**Table 5**  
**Complaints**

| Nature of Complaints                  | FY 13-14 | FY 14-15  | FY 15-16 |
|---------------------------------------|----------|-----------|----------|
| Felony Conviction                     | 0        | 1         | 1        |
| Substandard Practice                  | 0        | 2         | 1        |
| Unregistered Practice                 | 1        | 12        | 0        |
| Failure to Report Disciplinary Action | 0        | 1         | 0        |
| Failure to Update HPPP                | 0        | 1         | 3        |
| <b>Total</b>                          | <b>1</b> | <b>17</b> | <b>5</b> |

Much of the complaint activity in the first three years of registration concerned individuals who were practicing naturopathic medicine or representing themselves as naturopathic doctors without being registered.

One complaint regarding registered naturopathic doctors was related to the practice of naturopathic medicine. The complaint concerned a malpractice settlement agreement that was nearly 15 years old, and no disciplinary action related to the settlement was taken against the applicant in the state where the applicant was previously licensed. The applicant was granted a registration.

No other complaints against registered naturopathic doctors were related to the practice of naturopathic medicine.

Another complaint opened by the Director was based on an applicant’s disclosure of a felony conviction of cruelty to animals. The conviction was subsequently dismissed. The applicant had been licensed in another state since 1996, and with no other problems on the applicant’s record, the Director approved the application.

Table 6 illustrates the disciplinary activity over a three-year period.

**Table 6  
Final Agency Actions**

| Nature of Complaints                            | FY 13-14 | FY 14-15 | FY 15-16 |
|---|----------|----------|----------|
| Revocations                                     | 0        | 0        | 0        |
| Denials   | 0        | 0        | 0        |
| Suspensions                                     | 0        | 0        | 0        |
| Stipulations                                    | 0        | 0        | 0        |
| Letters of Admonition                           | 0        | 0        | 0        |
| Cease & Desist Orders, Citations or Injunctions | 0        | 0        | 4        |
| <b>Total Disciplinary Actions</b>               | <b>0</b> | <b>0</b> | <b>4</b> |
| Dismissals                                      | 0        | 2        | 5        |
| Letters of Concern                              | 0        | 1        | 0        |
| <b>Total Dismissals</b>                         | <b>0</b> | <b>3</b> | <b>5</b> |

Over the life of the program, the majority of complaints have concerned unregistered practice. During the first two years, the Director was primarily concerned with bringing people into compliance rather than taking enforcement actions, and the individuals who were practicing without a registration were simply sent letters informing them that they would no longer be able to practice or represent themselves as naturopathic doctors without registration.

However, in fiscal year 15-16, the Director began issuing cease and desist orders against providers who were practicing without registration.



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Although the Director has the ability to fine a naturopathic doctor as much as \$5,000, no fines have been issued since the program began in 2014.

## **Collaborative Agreements – Children Under Two**

In order to treat children under the age of two, the Act places several requirements on naturopathic doctors. One of these requirements is to develop a written collaborative agreement with a licensed physician specializing in pediatrics or family medicine.<sup>64</sup>

According to Director rules, the collaborative agreements must:<sup>65</sup>

- Be signed by both parties,
- Contain responsibilities and duties of each party,
- Contain the process for the Naturopathic Doctor to consult with the licensed physician,
- Contain the process for the Naturopathic Doctor to refer a patient to a licensed physician, and
- Be kept on file for seven years.

Section 12-37.3-119(2)(a), Colorado Revised Statutes (C.R.S.), requires the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) to review the written collaborative agreements kept on file by naturopathic doctors and to include a summary of the agreements in this sunset report.

Sixteen naturopathic doctors reported treating children under the age of two, and all but one of the collaborative agreements were compliant with Director rules. Most of the naturopathic doctors reported treating fewer than 10 children under the age of two. At the time of writing this report, the Director was working with the remaining naturopathic doctor to bring him or her into compliance or, if necessary, take action for noncompliance.

Section 12-37.3-119(2)(a), C.R.S., also requires COPRRR to gather and report the following:

- The number of children under two treated by naturopathic doctors,
- The conditions for which naturopathic doctors treated children under two, and
- The number and the description of any adverse events connected to treating children under two.

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<sup>64</sup> § 12-37.3-105(2)(e)(III)(A), C.R.S.

<sup>65</sup> 4 CCR 749-1 § 16(A)(3)(a), Naturopathic Doctors Registration Rules.

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Sixteen registered naturopathic doctors reported treating approximately 152 children under the age of two with no adverse events. The most common conditions naturopathic doctors reported treating included:

- Allergies,
- Eczema, and
- Digestive issues.

Only five naturopathic doctors reported seeing 10 or more children under the age of two during the previous year. The complete responses are reported in Appendix A.

### **Collateral Consequences – Criminal Convictions**

Section 24-34-104(6)(b)(IX), C.R.S., requires COPRRR to determine whether the agency under review, through its licensing processes, imposes any disqualifications on applicants or registrants based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

The Director has the authority, in section 12-37.3-112(1)(h), C.R.S., to deny, revoke or suspend a registration if the registrant is convicted of a felony, an offense of moral turpitude, or a crime that would constitute a violation of the Act, or if a court accepts a plea of guilty or nolo contendere to a felony, or if the court imposes a deferred sentence or judgment. During the three fiscal years reported here, the Director did not deny, revoke or suspend the registration of any naturopathic doctors based on past criminal history.

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## Analysis and Recommendations

### Recommendation 1 – Continue the regulation of naturopathic doctors for five years, until 2022.

Naturopathic medicine is a holistic system of health care based on six principles:<sup>66</sup>

- Support, facilitate and augment the healing power of nature by identifying and removing obstacles to health and recovery;
- Treat the cause of disease, rather than merely eliminating or suppressing symptoms;
- Apply the least possible force or intervention necessary to diagnose illness and treat the patient;
- Educate the patient and emphasize self-responsibility in health;
- Treat the whole person, taking into account physical, mental, emotional, genetic, social and other factors, including spiritual health; and
- Emphasize the prevention of disease.

Naturopathic doctors treat acute and chronic conditions, but the emphasis of naturopathy is to prevent disease.<sup>67</sup> Most naturopathic doctors work in office-based, private practice settings.<sup>68</sup>

Naturopathic doctors rely on a variety of treatment methods including nutrition, lifestyle counseling, herbal medicine, homeopathy, body work and hydrotherapy.<sup>69</sup> Naturopathic doctors are also trained to repair superficial wounds and to remove foreign bodies, cysts and other superficial masses.<sup>70</sup>

Sunset reviews are guided by statutory criteria found in section 24-34-104, Colorado Revised Statutes (C.R.S.), and the first criterion asks whether regulation is necessary to protect the health, safety and welfare of the public.

In 2013, the General Assembly enacted the Naturopathic Doctor Act (Act), which established a program to regulate naturopathic doctors. Anyone seeking to practice as a naturopathic doctor in Colorado must meet the qualifications established in the Act and register with the Director of the Division of Professions and Occupations (Director and Division, respectively).

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<sup>66</sup> American Association of Naturopathic Physicians. *Definition of Naturopathic Medicine*. Retrieved on October 23, 2015, from <http://www.naturopathic.org/content.asp?pl=16&sl=59&contentid=59>

<sup>67</sup> University of Maryland Medical Center. *Naturopathy*. Retrieved on October 23, 2015, from <http://www.umm.edu/altmed/articles/naturopathy-000356.htm>

<sup>68</sup> Bastyr University. *About Naturopathic Medicine: The Basics*. Retrieved on October 23, 2015, from <http://www.bastyr.edu/academics/areas-study/study-naturopathic-medicine/about-naturopathic-medicine>

<sup>69</sup> University of Maryland Medical Center. *Naturopathy*. Retrieved on October 23, 2015, from <http://www.umm.edu/altmed/articles/naturopathy-000356.htm> See: Oregon Board of Naturopathic Medicine.

*Naturopathy*. Retrieved on October 23, 2015, from <http://www.oregon.gov/obnm/Pages/Aboutnaturopathy.aspx>

<sup>70</sup> Oregon Board of Naturopathic Medicine. *Naturopathy*. Retrieved on October 23, 2015, from <http://www.oregon.gov/obnm/Pages/Aboutnaturopathy.aspx>

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Some critics of naturopathic doctors believe that naturopathic medicine and other forms of alternative care should be prohibited because if they were effective they would be incorporated into the practice of medicine, and only medical doctors should be allowed to practice medicine.

However, complementary and alternative health-care practices, such as acupuncture, massage therapy and clinical nutrition, have become more accepted within the conventional medical community, and some medical doctors do incorporate naturopathic treatment methods into their practice.

Moreover, sunset criteria do not require a finding that an occupation or profession is effective. Rather, the focus of the sunset criteria is public harm.

Traditional or lay naturopaths are critical of the Act because they can no longer refer to themselves as naturopathic doctors since they do not have the necessary qualifications.

While there is significant opposition to the regulation of naturopathic doctors, there are also compelling reasons to support it.

Naturopathic doctors in Colorado are authorized to:

- Diagnose and treat disease,
- Order and interpret tests,
- Prescribe naturopathic remedies,
- Perform minor office procedures, and
- Provide injections.

If a naturopathic doctor misses a diagnosis, fails to provide appropriate treatment or fails to refer to another health-care provider when necessary, a patient could delay or forgo proper treatment. This could result in serious injury or even death.

Therefore, the potential for harm is significant.

The laws that govern naturopathic doctors in Colorado are located in Article 37.3 of Title 12, C.R.S., and the Director is vested with the authority to enforce the Act.

The Director protects the public by ensuring that naturopathic doctors are qualified to practice.

A naturopathic doctor must have a doctorate degree from a school accredited by the CNME, which is approved by the U.S. Department of Education. In order to graduate, a student must complete four years of education in naturopathic medicine, which includes clinical training in an outpatient settings under close supervision by licensed professionals. A naturopathic doctor is also required to have passed an examination administered by the North American Board of Naturopathic Examiners.

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These qualifications are necessary to ensure the minimum level of competence.

The Director also protects the public by denying, revoking or suspending the registration of a naturopathic doctor who harms patients or is at risk of harming patients. The Director may also issue a letter of admonition or place a naturopathic doctor on probation.

The Naturopathic Medicine Advisory Committee (Advisory Committee) protects the public by advising the Director regarding the practice of naturopathic medicine.

The Advisory Committee consists of nine members:

- Three naturopathic doctors,
- Three medical or osteopathic doctors,
- One pharmacist, and
- Two public members who are preferably consumers of naturopathic medicine.

The Advisory Committee meets quarterly to discuss complaints and rules in which the Director may benefit from the expertise provided by the members.

One important consumer protection provision in the Act is the requirement for naturopathic doctors to maintain professional liability insurance. Prior to registration, patients who were harmed by naturopathic doctors due to substandard practice may not have been able to obtain compensation without a lengthy and costly lawsuit.

The registration program is only two years old, and the Director has received few complaints against naturopathic doctors. A member of the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) reviewed these complaints and found that the majority of complaints are related to unregistered practice. The Division thoroughly investigated each complaint received by the Director, and the Director was fair in screening applicants and taking enforcement actions. Since the Act was new, during the first year, the Director attempted to bring individuals into compliance rather than take punitive action.

At this time, there is little evidence of harm to the public from naturopathic medicine in Colorado. However, it would be premature to repeal regulation based on a lack of harm to the public since there are only two years of data to consider.

Moreover, naturopathic doctors diagnose and treat disease, so the potential for harm is considerable. Regulation is necessary to ensure competent and qualified professionals.

For these reasons, the registration of naturopathic doctors should be continued.

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Over the three-year period which represents the life of the program, the majority of complaints against naturopathic doctors concerned unregistered practice. Since few of the complaints required the expertise of naturopathic doctors or other health-care practitioners, the Director-model program with an advisory committee is appropriate at this time and should be continued.

As authorized in section 24-34-104, C.R.S., the General Assembly may continue this program for any period between 1 and 15 years.

As this report recommends a significant change to the scope of practice, a five-year continuation would be appropriate in order to monitor this change.

Therefore, the General Assembly should continue the regulation of naturopathic doctors for five years, until 2022.

**Recommendation 2 – Require insurance carriers to report to the Director any malpractice settlements or judgments against naturopathic doctors.**

Currently, the grounds for discipline include failure to report malpractice settlements or judgments. Since this information is self-reported, it is not necessarily reliable.

For this reason, insurance companies are required to report malpractice settlements and judgments to the appropriate regulatory authority if they write professional liability insurance for practitioners such as:

- Physicians,
- Optometrists,
- Podiatrists, and
- Physical therapists.

As health-care providers, naturopathic doctors should also be included in this law. It is extremely important for the regulatory authority to have knowledge of malpractice settlements and judgments because the information provided by an insurance company could help protect the public in case a naturopathic doctor is unsafe to practice.

While naturopathic doctors themselves are required to report malpractice judgments and settlements in their practice act,<sup>71</sup> this would ensure that they do.

Therefore, the General Assembly should require insurance companies who underwrite professional liability insurance for naturopathic doctors to report any malpractice settlements or judgments to the Director.

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<sup>71</sup> § 12-37.3-112(1)(n), C.R.S.

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### **Recommendation 3 – Require naturopathic doctors to report child abuse or neglect.**

All states, the District of Columbia, and other U.S. jurisdictions have statutes that identify people required to report child abuse and neglect. Professionals who are likely to have contact with children, such as teachers, social workers and health-care practitioners, are typically mandatory reporters.<sup>72</sup>

Abuse and neglect have long-term effects on children including:<sup>73</sup>

- Improper brain development;
- Impaired learning ability and social and emotional skills;
- Lower language development;
- Blindness and cerebral palsy from head trauma;
- Increased risk of heart, lung and liver diseases, obesity, cancer, high blood pressure and cholesterol;
- Anxiety; and
- Smoking, alcoholism and drug abuse.

Section 19-3-304, C.R.S., requires doctors and other practitioners to report to the appropriate authorities if they have reasonable cause to suspect or have knowledge that a child is being subjected to abuse or neglect. The list of professionals that are considered mandatory reporters under Colorado law is long and includes most other health-care practitioners. It is unclear why naturopathic doctors were not included among mandatory reporters when the Act was drafted, but it was likely a simple oversight.

As health-care providers, naturopathic doctors have the same professional responsibility as other health-care professionals to report abuse or neglect of children when they suspect or have evidence of it.

Moreover, mandatory reporting of child abuse and neglect is necessary to protect the health, safety and welfare of the child. Professionals who are in close contact with children are likely to identify signs of abuse or neglect when others may be unaware of it, and it is in the public interest for them to report cases to the appropriate authorities.

Therefore, the General Assembly should include naturopathic doctors in section 19-3-304, C.R.S., among other practitioners who are required to report child abuse or neglect.

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<sup>72</sup> Child Welfare Information Gateway, U.S. Department of Health and Human Services. *Mandatory Reporters of Abuse and Neglect*. Retrieved on July 5, 2016, from <https://www.childwelfare.gov/pubPDFs/manda.pdf>

<sup>73</sup> Centers for Disease Control and Prevention. *Child Abuse and Neglect: Consequences*. Retrieved on July 5, 2016, from <http://www.cdc.gov/violenceprevention/childmaltreatment/consequences.html>

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**Recommendation 4 – Require naturopathic doctors to report abuse or exploitation of anyone who is elderly or intellectually or developmentally disabled.**

Section 18-6.5-108(1)(a), C.R.S., requires suspected abuse or exploitation of at-risk elders or at-risk persons with intellectual or developmental disabilities to be reported to the authorities within 24 hours of making the observation or discovery.

Practitioners who are required to report include:

- Physicians,
- Physician assistants,
- Osteopaths,
- Physicians in training,
- Podiatrists,
- Physical therapists,
- Medical examiners and coroners,
- Nurses,
- Emergency medical service providers,
- Chiropractors,
- Dentists, and
- Pharmacists.

To willfully violate this law is a Class 3 misdemeanor.

Naturopathic doctors were not included in this law, but they should be mandatory reporters. Just like other health-care providers, naturopathic doctors may observe signs of abuse or neglect on an elderly or at-risk adult in their practice, and it should be reported. It is unclear why naturopathic doctors were not included among mandatory reporters when the Act was drafted. It was likely a simple oversight.

As health-care practitioners, naturopathic doctors have a professional responsibility to report abuse or neglect of elderly, intellectually disabled or developmentally disabled individuals when they suspect or have evidence of it.

Moreover, mandatory reporting of at-risk individuals is necessary to protect the health, safety and welfare of the individuals who are especially vulnerable to abuse or neglect. Professionals who are in close contact with at-risk people are likely to identify signs of abuse or neglect when others may be unaware of it, and it is in the public interest for them to report cases to the appropriate authorities.

Therefore, the General Assembly should include naturopathic doctors in section 18-6.5-108(1)(a), C.R.S., among the practitioners who are required to report abuse or exploitation of at-risk elderly, intellectually disabled or developmentally disabled individuals.



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## **Recommendation 5 – Clarify that the naturopathic formulary includes specified prescription medications and devices.**

The naturopathic formulary in section 12-37.3-102(11), C.R.S., states:

“Naturopathic formulary” means the list of nonprescription classes of medicines determined by the Director that naturopathic doctors use in the practice of naturopathic medicine.

However, a different part of the Act, section 12-37.3-105(1)(c), C.R.S., allows naturopathic doctors to use:

- Epinephrine to treat anaphylaxis,
- Barrier contraceptives,
- Oxygen for emergency use only,
- Vitamins B6 and B12, and
- Vaccines for patients who are 18 or older.

All of these items require prescriptive authority. This inconsistency should be addressed by clarifying that the naturopathic formulary includes any prescription substances and devices specified in the Act.

Therefore, the General Assembly should amend 12-37.3-102(11), C.R.S., to clarify that the formulary does include prescription substances and devices when authorized by the Act.

## **Recommendation 6 – Amend the name of the homeopathic pharmacopoeia.**

Homeopathic preparations are defined in the Act as, “medicines prepared according to the most current version of the homeopathic pharmacopoeia of the United States, revised services.”<sup>74</sup>

However, the official name is: The Homeopathic Pharmacopoeia of the United States. In 1988, the first version was published under the name, “Homeopathic Pharmacopoeia Revision Service.”<sup>75</sup> The error in the name is slight, but it should read “revision service” not “revised services.”

The General Assembly should amend the name of the homeopathic pharmacopoeia so that it is accurate.

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<sup>74</sup> § 12-37.3-102(7), C.R.S.

<sup>75</sup> The Homeopathic Pharmacopoeia of the United States. *Regulations*. Retrieved on August 5, 2016, from <http://www.hpus.com/regulations.php>

## Appendix A - Collaborative Agreements - Children Under Two

Section 12-37.3-119, C.R.S., requires the Colorado Office of Policy, Research and Regulatory Reform to gather and report the following:

- The number of children under two treated by naturopathic doctors,
- The conditions for which naturopathic doctors treated children under two, and
- The number and the description of any adverse events connected to treating children under two.

The responses from the 16 naturopathic doctors that reported treating children under two are provided in the table below.

| Number of Children Under Two Treated | Conditions Treated  | Number of Adverse Events |
|--------------------------------------|---|--------------------------|
| 5                                    | Eczema, constipation  | 0                        |
| 1                                    | Colic   | 0                        |
| 6                                    | Digestive Complaints, insomnia, URI, rashes   | 0                        |
| 2                                    | Nutrition questions, eczema   | 0                        |
| 2                                    | Well-child check, rash, boil  | 0                        |
| 3                                    | Not reported  | Not reported             |
| 4                                    | Constipation, eczema  | 0                        |
| 2                                    | Eczema, nasal congestion  | 0                        |
| 16                                   | Well-child, vaccination, eczema, fused labia, constipation, diarrhea, vomiting, reflux  | 0                        |
| 32                                   | Eczema, colitis, failure to thrive, reflux, chronic ear infections, sleep disorders, general wellness, sensory processing disorder                            | 0                        |
| 14                                   | Dermatitis, recurrent upper respiratory infections, otitis media, constipation, colic, sleep disturbance, diarrhea, bronchitis, acid reflux, nasal congestion | 0                        |
| 4                                    | Reflux, eczema  | 0                        |
| 5                                    | Growth and development, ear, infections, allergies-seasonal and food, eczema, viral infections  | 0                        |
| 12                                   | Well-child, rash, upper respiratory, blood in stool, fever, chronic diarrhea, eczema, congestions, developmental delay  | 0                        |
| 4                                    | Otitis, PE  | 0                        |
| 40                                   | Food sensitivities, environmental allergies, sinusitis, otitis media, upper respiratory infection-viral and bacterial, sleep disorder, anxiety disorder       | 0                        |

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## Appendix B - Survey of Naturopathic Doctors

The Colorado Office of Policy, Research and Regulatory Reform emailed the following survey on June 20, 2016 to 118 registered naturopathic doctors and received 60 responses, which is a response rate of 51 percent.

*Which of the following best describes the level of customer service provided by the Division of Professions and Occupations when you first registered as a naturopathic doctor?*

|                   |       |
|-------------------|-------|
| Excellent         | 23.3% |
| Very Good         | 41.7% |
| Satisfactory      | 21.7% |
| Needs Improvement | 11.7% |
| Poor              | 1.7%  |

*Which of the following best describes the level of customer service provided by the Division of Professions and Occupations when you renewed your registration?*

|                                |       |
|--------------------------------|-------|
| Excellent                      | 31.7% |
| Very Good                      | 31.7% |
| Satisfactory                   | 13.3% |
| Needs Improvement              | 5%    |
| Poor                           | 0%    |
| I have yet to renew my license | 18.3% |

*Which of the following would you use in your practice if you were provided the authority to prescribe or administer?*

|   |       |
|---|-------|
| Antibiotics                                       | 82.8% |
| Antivirals  | 48.3% |
| Antifungals                                       | 67.2% |
| Hormones  | 87.9% |
| Intravenous nutrients (in addition to B6 and B12) | 75.9% |
| None of the above                                 | 1.7%  |

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*How important would your ability to prescribe antibiotics be to your practice if you were provided the authority?*

|                      |       |
|----------------------|-------|
| Very important       | 35%   |
| Important            | 28.3% |
| Somewhat important   | 23.3% |
| Not very important   | 10%   |
| Not at all important | 3.3%  |

*How important would your ability to prescribe antivirals be to your practice if you were provided the authority?*

|                      |       |
|----------------------|-------|
| Very important       | 11.7% |
| Important            | 18.3% |
| Somewhat important   | 36.7% |
| Not very important   | 25%   |
| Not at all important | 8.3%  |

*How important would your ability to prescribe antifungals be to your practice if you were provided the authority?*

|                      |       |
|----------------------|-------|
| Very important       | 18.3% |
| Important            | 28.3% |
| Somewhat important   | 35%   |
| Not very important   | 15%   |
| Not at all important | 3.3%  |

*How important would your ability to prescribe hormones be to your practice if you were provided the authority?*

|                      |       |
|----------------------|-------|
| Very important       | 61.7% |
| Important            | 13.3% |
| Somewhat important   | 21.7% |
| Not very important   | 1.7%  |
| Not at all important | 1.7%  |

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*How important would your ability to administer nutrients (in addition to vitamin B6 and B12) intravenously be to your practice if you were provided the authority?*

|                      |       |
|----------------------|-------|
| Very important       | 50%   |
| Important            | 23.3% |
| Somewhat important   | 10%   |
| Not very important   | 13.3% |
| Not at all important | 3.3%  |