

COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2019 Sunset Review

Naturopathic Doctor Act





Executive Director's Office

October 15, 2019

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

Dear Members of the General Assembly:

The Colorado 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.

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

The Colorado Office of Policy, Research and Regulatory Reform (COPRRR), located within my office, is responsible for fulfilling these statutory mandates. 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 2020 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 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,

Patty Salazar Executive Director





COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2019 Sunset Review Naturopathic Doctor Act

SUMMARY

What is regulated?

Naturopathic doctors (NDs) are health-care providers who diagnose, prevent and treat acute and chronic illness to restore and establish optimal health by supporting a person's inherent self-healing process.

Why is it regulated?

The Naturopathic Doctor Act (Act), which is administered by the Director of the Division of Professions and Occupation (Director), protects consumers by ensuring that only qualified NDs practice in Colorado.

Who is regulated?

In fiscal year 17-18, the Director registered 132 NDs.

How is it regulated?

NDs are required to secure a registration from the Director. Applicants must have a doctor of naturopathic medicine degree from an approved college and pass a national examination.

What does it cost?

In fiscal year 17-18, the total expenditures to oversee the program were \$88,554, and there were 0.75 full-time equivalent employees associated with the program.

What disciplinary activity is there?

In fiscal years 13-14 through 17-18, the Director issued nine cease and deist orders and letters of admonition to NDs.

KEY RECOMMENDATIONS

Continue the Act for nine years, until 2029.

Since the Act was implemented in 2014, there have been very few complaints, and even fewer disciplinary actions imposed on registered NDs. Due to the lack of harm to consumers identified during this sunset review, the central question is whether the State of Colorado should continue to require NDs to become registered prior to practicing.

It could be argued that the implementation of the registration program in Colorado has ensured only competent, qualified practitioners have been providing services to consumers, which at least partially explains the low number of complaints and disciplinary actions.

As such, the General Assembly should continue the Act for nine years, until 2029. A seven-year continuation is reasonable because the analysis of the regulatory program did not identify systemic or structural issues where consumers were being harmed. Therefore, the current level of regulation, including the licensing requirements and those for continued competency, appear to be providing adequate consumer protection.

Repeal the Naturopathic Medicine Advisory Committee.

The Naturopathic Medicine Advisory Committee (Advisory Committee), which consists of nine members, was originally created to provide guidance and advice on the initial development of the rules and policies associated with the registration of NDs. Since the rules and policies have been implemented, the utilization of the Advisory Committee has diminished. In fact, five of the past 10 Advisory Committee meetings were cancelled due to the lack of tasks to accomplish. As such, the Advisory Committee is no longer necessary and should be repealed.

METHODOLOGY

As part of this review, Colorado Office of Policy, Research and Regulatory Reform staff interviewed Division staff, and officials with state and national professional associations, and reviewed Colorado statutes and rules, and the laws of other states.

MAJOR CONTACTS MADE DURING THIS REVIEW

Colorado Association of Naturopathic Doctors
Colorado Medical Society
North American Board of Naturopathic Examiners

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 www.dora.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 criteria¹ 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:

- I. 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;
- II. 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;
- III. 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;
- IV. Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- V. 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;
- VI. The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- VII. 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;
- VIII. Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

¹ Criteria may be found at § 24-34-104(6)(b), C.R.S.

- IX. Whether the agency through its licensing or certification process imposes any sanctions or disqualifications on applicants based on past criminal history and, if so, whether the sanctions or disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subsection (5)(a) of this section must include data on the number of licenses or certifications that the agency denied based on the applicant's criminal history, the number of conditional licenses or certifications issued based upon the applicant's criminal history, and the number of licenses or certifications revoked or suspended based on an individual's criminal conduct. For each set of data, the analysis must include the criminal offenses that led to the sanction or disqualification; and
- X. Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Sunset reports are organized so that a reader may consider these criteria while reading. While not all criteria are applicable to all sunset reviews, the various sections of a sunset report generally call attention to the relevant criteria. For example,

- In order to address the first criterion and determine whether a particular regulatory program is necessary to protect the public, it is necessary to understand the details of the profession or industry at issue. The Profile section of a sunset report typically describes the profession or industry at issue and addresses the current environment, which may include economic data, to aid in this analysis.
- To ascertain a second aspect of the first sunset criterion--whether conditions that led to initial regulation have changed--the History of Regulation section of a sunset report explores any relevant changes that have occurred over time in the regulatory environment. The remainder of the Legal Framework section addresses the third sunset criterion by summarizing the organic statute and rules of the program, as well as relevant federal, state and local laws to aid in the exploration of whether the program's operations are impeded or enhanced by existing statutes or rules.
- The Program Description section of a sunset report addresses several of the sunset criteria, including those inquiring whether the agency operates in the public interest and whether its operations are impeded or enhanced by existing statutes, rules, procedures and practices; whether the agency performs efficiently and effectively and whether the board, if applicable, represents the public interest.
- The Analysis and Recommendations section of a sunset report, while generally applying multiple criteria, is specifically designed in response to the tenth criterion, which asks whether administrative or statutory changes are necessary to improve agency operations to enhance the public interest.

These are but a few examples of how the various sections of a sunset report provide the information and, where appropriate, analysis required by the sunset criteria. Just as not all criteria are applicable to every sunset review, not all criteria are specifically highlighted as they are applied throughout a sunset review.

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.

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.

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: www.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.),² shall terminate on September 1, 2020, 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 Naturopathic Doctor Act pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed regulation should be continued and to evaluate the performance of 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.

² House Bill 19-1172 re-codified § 12-37.3-101, et seq., C.R.S., and moved them to § 12-250-101, et seq., C.R.S. In order to avoid confusion and erroneous citations and references, this sunset report consistently refers to the statutory provisions as if they remained in § 12-37.3-101, et seq., C.R.S.

Methodology

As part of this review, COPRRR staff interviewed Division staff and officials with state and national associations, regulators in other states, and reviewed Colorado statutes and rules, and the laws of other states.

Profile of the Profession

In a sunset review, COPRRR is guided by the sunset criteria located in section 24-34-104(6)(b), C.R.S. The first criterion asks 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.

In order to understand the need for regulation, it is first necessary to understand what the profession does, where they work, who they serve and any necessary qualifications.

Currently, there are 132 naturopathic doctors in Colorado.

According to the American Association of Naturopathic Physicians,

Naturopathic medicine is a distinct primary health care profession, emphasizing prevention, treatment, and optimal health through the use of therapeutic methods and substances that encourage individuals' inherent self-healing process.³

The practice of naturopathic medicine is based on the following six principles:4

- The healing power of nature Naturopathic medicine recognizes the self-healing process in people that is ordered and intelligent, [and it attempts] to identify and remove obstacles to healing and recovery, [as well as facilitating and augmenting the] inherent self-healing process.
- Identify and treat the causes [Naturopathic doctors (NDs) attempt] to identify and remove the underlying causes of illness rather than to merely eliminate or suppress symptoms.
- First do no harm Naturopathic doctors follow three guidelines to avoid harming patients:
 - Utilize methods and medicinal substances which minimize the risk of harmful side effects, using the least force necessary to diagnose and treat;

³ American Association of Naturopathic Physicians. *Definition of Naturopathic Medicine*. Retrieved July 1, 2019, from https://www.naturopathic.org/content.asp?contentid=59

⁴ American Association of Naturopathic Physicians. *Definition of Naturopathic Medicine*. Retrieved July 1, 2019, from https://www.naturopathic.org/content.asp?contentid=59

- o Avoid, when possible, the harmful suppression of symptoms; and
- Acknowledge, respect and work with individuals' self-healing process.
- **Doctor is teacher** Naturopathic doctors educate their patients and encourage self-responsibility for health. They also recognize and employ the therapeutic potential of the doctor-patient relationship.
- Treat the whole person [treatment includes] taking into account individual physical, mental, emotional genetic, environmental, social and other factors. Treating the whole person also includes spiritual health... and
- **Prevention** Naturopathic [doctors] emphasize the prevention of disease by assessing risk factors, heredity and susceptibility to disease...

NDs "diagnose, prevent, and treat acute and chronic illness to restore and establish optimal health by supporting a person's inherent self-healing process."⁵ Further, NDs work to "identify underlying causes of illness, and develop personalized treatment plans to address them."⁶

In order to practice as an ND in Colorado, a person is required to complete a four-year, graduate-level program at a North American Naturopathic Medical School. These schools are accredited by the Council on Naturopathic Medical Education (CNME), which is an organization recognized for accreditation purposes by the U.S. Department of Education.⁷

Currently, there are six CNME-accredited naturopathic schools in the United States:8

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

⁵ American Association of Naturopathic Physicians. *What is a Naturopathic Doctor?* Retrieved July 9, 2019, from https://www.naturopathic.org/content.asp?contentid=60

⁶ American Association of Naturopathic Physicians. *What is a Naturopathic Doctor?* Retrieved July 9, 2019, from https://www.naturopathic.org/content.asp?contentid=60

⁷ National Center for Complementary and Integrative Health. *Naturopathy*. Retrieved July 9, 2019, from https://nccih.nih.gov/health/naturopathy

⁸ Council on Naturopathic Medical Education. *Accredited Naturopathic Schools*. Retrieved July 9, 2019, from https://cnme.org/accredited-programs/#schools

Legal Framework

History of Regulation

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by the sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The first sunset criterion questions 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.

One way that COPRRR addresses this is by examining why the program was established and how it has evolved over time.

COPRRR conducted several sunrise reviews to determine whether naturopathic doctors (NDs) should be regulated by the State of Colorado. Specifically, sunrise reviews were completed in 1993, 1998, 2005 and 2008. With the exception of the 1993 sunrise review, the remaining reviews recommended regulation of NDs.

NDs also submitted sunrise applications to DORA in 2009 and 2011, and DORA declined to conduct those reviews because the applications did not provide additional information that would warrant a change in the recommendation to regulate NDs.

In 2013, the General Assembly created the Naturopathic Doctor Act (Act), which provided regulatory oversight of the profession. Upon enactment of the Act, NDs would be required to meet minimum established requirements and register with the Director of the Division of Professions and Occupations (Director and Division, respectively).

COPRRR completed a sunset review of the Act in 2016. Salient recommendations in the 2016 sunset review included requiring NDs to report child abuse or neglect and requiring NDs to report abuse or exploitation of anyone who is elderly or intellectually or developmentally disabled.

Finally, effective October 1, 2019, the statutes governing NDs were moved from section 12-37.3-101, et seq., Colorado Revised Statutes (C.R.S.) into section 12-250-101, et seq., C.R.S. with the passage of House Bill 19-1172. Notwithstanding this recodification, in order to avoid confusion and erroneous citations and references, this sunset report consistently refers to statutory provisions as if they remained in section 12-37.3-101, et seq., C.R.S.

Legal Summary

The second and third sunset criteria question

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; and

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.

A summary of the current statutes and rules is necessary to understand whether regulation is set at the appropriate level and whether the current laws are impeding or enhancing the agency's ability to operate in the public interest.

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

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." 9

Naturopathic doctors are prohibited from using the titles "physician," "naturopathic medical doctor" or the initials "N.M.D." ¹⁰

Anyone who practices or offers to practice as an ND without an active registration commits a Class 2 misdemeanor, ¹¹ punishable by 3 to 12 months imprisonment, a fine of between \$250 and \$1,000, or both. ¹²

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.¹³ It also includes physical examinations and ordering clinical, laboratory or radiological diagnostic procedures for the purpose of diagnosing and evaluating injuries, conditions and diseases of the human body.¹⁴

⁹ § 12-37.3-110(1), C.R.S.

¹⁰ § 12-37.3-110(3), C.R.S.

¹¹ § 12-37.3-113, C.R.S.

¹² § 18-1.3-501(1)(a), C.R.S.

¹³ § 12-37.3-105(1)(a), C.R.S.

¹⁴ § 12-37.3-105(1)(b), C.R.S.

Additionally, the scope of practice includes the use of:15

- 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 perform minor office procedures. ¹⁶ Minor office procedures are: ¹⁷

- The repair, care and suturing of superficial lacerations and abrasions;
- The removal of foreign bodies located in superficial tissue, excluding the ear or eye; and
- Obtaining and administering saline, sterile water, topical antiseptics and local anesthetics, including local anesthetics with epinephrine.

A naturopathic doctor may only treat a child who is under the age of eight if certain conditions are met. The naturopathic doctor must:18

- 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 in order to treat a child under the age of two;
- Complete three hours per year of education or practicum training related to pediatrics, in order to treat a child who is two or older; and
- Complete five hours per 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:

¹⁶ § 12-37.3-105(1)(d), C.R.S.

¹⁵ § 12-37.3-105(1)(c), C.R.S.

¹⁷ § 12-37.3-102(8), C.R.S.

¹⁸ §§ 12-37.3-105(2)(e) and 12-37.5-105(2)(f), C.R.S.

- Discloses that the naturopathic doctor is registered as a naturopathic doctor and is not a licensed physician;
- 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.¹⁹

Specifically, a naturopathic doctor is prohibited from:²⁰

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

The Act does not create 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.²¹

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:²²

- 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.²³

The Director is also granted the authority to:24

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

²⁰ § 12-37.3-105(2), C.R.S.

²¹ § 12-37.3-105(6), C.R.S.

¹⁹ § 12-37.3-105(2)(g), C.R.S.

²² § 12-37.3-105(4)(b), C.R.S.

²³ § 12-37.3-104(1)(a), C.R.S.

²⁴ § 12-37.3-112(1), C.R.S.

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.²⁵

The Advisory Committee consists of nine members appointed by the Director:²⁶

- 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. ²⁷ The Director is authorized to remove any member for misconduct, incompetence or neglect of duty.²⁸

Also, members do not receive compensation for serving on the Advisory Committee, but are entitled to reimbursement for actual and necessary expenses while performing duties related to the Advisory Committee.²⁹

Registration

In order to register as an ND, an applicant must:³⁰

- 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 an ND 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.³¹

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

²⁶ § 12-37.3-103(1)(b)(I), C.R.S.

²⁵ § 12-37.3-103(1)(a), C.R.S.

²⁷ § 12-37.3-103(1)(c)(I), C.R.S. ²⁸ § 12-37.3-103(1)(d), C.R.S.

²⁹ § 12-37.3-103(3), C.R.S.

³⁰ § 12-37.3-106(2), C.R.S.

³¹ § 12-37.3-106(3), C.R.S.

education and examination and who is not currently licensed, certified or registered as an ND in another jurisdiction.³²

Additionally, NDs 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 2010.³³

A naturopathic doctor is required to disclose certain information to any patient, such as how to file a complaint.³⁴ The ND must obtain written acknowledgement that the patient received the required disclosures and maintain the acknowledgement for seven years after providing services to the patient.³⁵

An ND is also required to develop a written plan to ensure the security of patient records³⁶ and inform patients in writing how to access patient records in case the practitioner dies, retires or otherwise ceases to provide care to patients.³⁷

Any ND 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.³⁸

Naturopathic doctors must maintain professional liability insurance in the amount of at least \$1 million.³⁹

Grounds for Discipline

The grounds for discipline include:⁴⁰

- 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;

³² § 12-37.3-106(4), C.R.S.

³³ § 12-37.3-109, C.R.S.

³⁴ § 12-37.3-111(1), C.R.S.

³⁵ § 12-37.3-111(2), C.R.S.

³⁶ § 12-37.3-115(1), C.R.S.

³⁷ § 12-37.3-115(3), C.R.S.

³⁸ § 12-37.3-111(3), C.R.S. ³⁹ § 12-37.3-114(1), C.R.S.

⁴⁰ § 12-37.3-112(1), C.R.S.

- 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 where the ND agrees to limit his or her practice based on the restrictions imposed by a physical illness, physical condition, or a behavioral or mental health disorder;
- 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 in lieu of discipline is ineligible to apply for a registration under the Act for at least two years.⁴¹

The Director also has the authority to fine NDs up to \$5,000 for committing any act listed in the grounds for discipline. Any fines collected pursuant to the Act are directed to the General Fund.⁴²

Professional Competency

Naturopathic doctors must maintain continued professional competency in order to renew or reinstate a registration.⁴³

At a minimum, a continued professional competency program established by the Director must include:⁴⁴

- 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.

⁴² § 12-37.3-112(2), C.R.S.

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⁴¹ § 12-37.3-112(3), C.R.S.

⁴³ §§ 12-37.3-108(1)(a) and 12-37.3-108(1)(d)(I), C.R.S.

⁴⁴ § 12-37.3-108(1)(b), C.R.S.

Program Description and Administration

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The third, fourth and fifth sunset criteria question:

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; and

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.

In part, COPRRR utilizes this section of the report to evaluate the agency according to these criteria.

The Naturopathic Doctor Act (Act) is created in section 12-37.3-101, et seq., Colorado Revised Statutes (C.R.S.). The purpose of the Act is to provide regulatory oversight of naturopathic doctors (NDs).

The regulation of NDs is vested in the Director of the Division of Professions and Occupations (Director and Division, respectively) within the Department of Regulatory Agencies. The Director is responsible for, among other things, rulemaking, policymaking and, when necessary, imposing formal discipline on practitioners.

Also, the Naturopathic Medicine Advisory Committee (Advisory Committee) was created within the Act to advise the Director on the regulation of the practice of naturopathic medicine, as well as implementation of the Act.

The Advisory Committee consists of nine members appointed by the Director: 45

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

The Act does not require the Advisory Committee to convene on a regulator basis; it only meets when necessary.

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⁴⁵ § 12-37.3-103(1)(b)(I), C.R.S.

Table 1 highlights the total expenditures for the regulation of NDs in fiscal years 16-17 through 17-18.

Table 1
Total Program Expenditures in Fiscal Years 13-14 through 17-18

Fiscal Year	Total Expenditures	FTE
13-14	\$90,957	0.80
14-15	\$83,006	0.60
15-16	\$69,266	0.60
16-17	\$56,286	0.50
17-18	\$88,554	0.75

The slight fluctuation in total expenditures for administration of the regulatory oversight of NDs is attributable to the increase and decrease in staff.

In fiscal year 17-18, the Division devoted 0.75 full-time equivalent (FTE) employees to provide regulatory oversight of NDs. The FTE are as follows:

- Administrative Assistant III—0.20 FTE is responsible for, among other things, receiving complaints, case management, case summary preparation, and researching various cases concerning NDs.
- Administrator III—0.20 FTE is responsible for, among other things, case management, correspondence, summary as well as researching various cases.
- Program Management II—0.35 FTE is responsible for the overall management of the ND program, including complaint resolution, stakeholder engagement, case summary review and ND application review and approval.

The aforementioned FTE do not include staffing in the centralized offices of the Division, which include the following:

- Director's Office,
- Office of Investigations,
- Office of Expedited Settlement,
- Office of Examination Services, and
- Office of Licensing.

Registration

The eighth sunset criterion questions whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

In order to practice as an ND, the State of Colorado requires candidates to secure a registration from the Director. To be eligible for an ND registration, candidates must complete a four-year, graduate-level program accredited by the Council on Naturopathic Medical Education (CNME) and approved by the U.S. Department of Education. Applicants are also required to pass the Naturopathic Physicians Licensing Examination (NPLEX).

Table 2 shows the total number of registered NDs in fiscal years 13-14 through 17-18.

Table 2
Registered Naturopathic Doctors

Fiscal Year	Original	Endorsement	Renewal	Reinstatement	Total Number of Registered NDs*
13-14	66	0	N/A	N/A	66
14-15	34	0	57	0	99
15-16	37	0	99	1	119
16-17	17	0	97	3	131
17-18	19	0	102	1	132

^{*}As of June 30 of each fiscal year.

As Table 2 indicates, the total number of registered NDs has increased in each of the past five fiscal years. Also, regulatory oversight of NDs commenced in fiscal year 13-14, which explains the high number of original registrations.

In fiscal year 17-18, the fee to obtain an original ND registration from the Director was \$950.

Examinations and Continuing Competency

The eighth sunset criterion questions whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

The North American Board of Naturopathic Examiners (NABNE) developed and administers the NPLEX. In order for candidates to be eligible to take the NPLEX, they are required to complete an approved naturopathic medical program accredited by CNME that offers a minimum four-academic-year, and an in-residence curriculum in biomedical and clinical didactic studies. ⁴⁶ The CNME program must also include clinical training.⁴⁷

The NPLEX contains two parts:⁴⁸

- Part I Biomedical Science, and
- Part II Core Clinical Science.

Part I is an "integrated examination that consists of 200 questions [covering] topics [including,] anatomy, physiology, biochemistry and genetics, microbiology and immunology and pathology." Each of the aforementioned questions is multiple-choice. Candidates are required to complete Part I in two sessions (morning and afternoon), and the sessions are 2.5 hours, each. Part I relates "to the biomedical basis for the patient's condition, not diagnosis or treatment."

Part II is a case-based examination that covers the topics of diagnosis, among other things, physical, clinical, laboratory diagnosis, diagnostic imaging and interpretation and application of research studies. Part II consists of 400 items. Part II is administered in three sections, and it takes three days to complete all of the sections. Candidates must complete each section within 3.5 hours.⁵⁰

The NPLEX is administered at nine sites:51

- Bridgeport, Connecticut;
- Glen Ellyn, Illinois;
- Toronto, Ontario;
- Gurabo, Puerto Rico;
- Mesa, Arizona;

• Vancouver, British Columbia;

⁴⁶ North American Board of Naturopathic Examiners. *Eligibility Requirements*. Retrieved July 15, 2019, from https://www.nabne.org/eligibility-requirements/

⁴⁷ North American Board of Naturopathic Examiners. *Eligibility Requirements*. Retrieved July 15, 2019, from https://www.nabne.org/eligibility-requirements/

⁴⁸ North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved July 10, 2019 from https://www.nabne.org/exam-overview/

⁴⁹ North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved July 10, 2019 from https://www.nabne.org/exam-overview/

⁵⁰ North American Board of Naturopathic Examiners. *NPLEX Examination Overview*. Retrieved July 10, 2019 from https://www.nabne.org/exam-overview/

⁵¹ North American Board of Naturopathic Examiners. *Test Sites*. Retrieved July 15, 2019, from https://www.nabne.org/test-sites/

- San Diego, California;
- Portland, Oregon; and
- Bothell, Washington.

Table 3 highlights the number of NPLEX examinations given nationwide for calendar years 2014 through 2018, including pass rates for Part I and II.

Table 3
Number of NPLEX Examinations Nationwide and Pass Rates

Calendar Year	Number of Examinations Given	Pass Rate	Number of Part II Examinations Given	Pass Rate
2014	520	74%	460	82%
2015	516	79%	476	82%
2016	563	76%	514	80%
2017	481	77%	517	88%
2018	491	78%	505	87%

As Table 3 indicates, the pass rates, nationally, for Parts I and II for the examination have remained fairly consistent in past five calendar years. The data provided are for first-time test takers.

In addition to passing the NPLEX, NDs must maintain continued professional competency in order to renew or reinstate a registration. ⁵²

At a minimum, a continued professional competency program established by the Director must include:⁵³

- 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.

Complaints and Disciplinary Actions

The seventh sunset criterion requires COPRRR to examine 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.

⁵² §§ 12-37.3-108(1)(a) and 12-37.3-108(1)(d)(I), C.R.S.

⁵³ § 12-37.3-108(1)(b), C.R.S.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

Anyone can file a complaint against NDs, including other practitioners and patients.

Table 4 delineates the nature of complaints filed with the Division in fiscal years 13-14 through 17-18.

Table 4
Nature of Complaints Filed Against Naturopathic Doctors in Fiscal Years 13-14
through 17-18

Nature of Complaints	FY 13-14	FY 14-15	FY 15-16	FY 16-17	FY 17-18
Practicing without a Registration	0	13	2	5	5
Standard of Practice	0	0	1	0	5
Scope of Practice	0	0	1	0	2
Sexual Misconduct	0	0	0	0	0
Substance Abuse	0	0	0	0	0
Felony Conviction	0	1	0	1	0
Other	1	1	0	0	53
Total	1	15	4	6	65

As Table 4 indicates, there have been relatively few practice-related complaints filed against registered NDs in the past five fiscal years. Instead, most of the complaints received by the Division were related to administrative issues, such as practicing without a registration and using the term "physician" on their website. In fiscal year 14-15, there were 13 complaints related to NDs practicing without a valid registration. Generally, these complaints were related NDs who did not renew their registration when the registration was due.

The "Other" category in Table 4 consists of complaints against NDs who were using the term "physician" on their websites. The Act, in section 12-37.3-110(3)(a), C.R.S., prohibits NDs from using the term "physician." As the Table indicates, the largest number of these complaints was in fiscal year 17-18.

Additionally, Table 5 illustrates the total number of disciplinary actions the Director imposed on NDs in fiscal years 13-14 through 17-18.

Table 5
Total Number of Final Agency Actions in Fiscal Years 13-14 through 17-18

Type of Action	FY 13-14	FY 14-15	FY 15-16	FY 16-17	FY 17-18
Revocations	0	0	0	0	0
Suspensions	0	0	0	0	0
Revocations/Suspensions held in abeyance or stayed or stayed suspended	0	0	0	0	0
Stipulations	0	0	0	0	0
Letters of Admonition	0	0	0	1	1
Other (cease and desist orders)	0	0	4	4	1
Total Disciplinary Actions	0	0	4	5	2
Dismissals	0	2	5	1	0
Letters of Concern	0	1	0	2	38
Total Dismissals	0	3	5	3	38

As highlighted in Table 5, there were few disciplinary actions imposed on NDs in the past five fiscal years. The most common form of discipline utilized by the Director in fiscal years 13-14 through 17-18 was cease and desist orders. Nine of the eleven disciplinary actions imposed on NDs in the past five fiscal years were cease and desist orders from the Director to NDs who were practicing on an expired registration.

The Director, in fiscal years 16-17 and 17-18 issued two letters of admonition (LOAs) to NDs. LOAs are the lowest form of discipline and are generally imposed on practitioners for minor violations of a practice act or applicable rules.

In fiscal year 16-17, the lone LOA was issued to an ND for practicing naturopathic medicine and holding himself out to be an ND prior to becoming registered. The LOA issued in fiscal year 7-18 was for an ND who was practicing hormone replacement therapy, which is a practice beyond the scope of naturopathic medicine.

Also, there were many dismissals, which include letters of concern, in the past five fiscal years. The letters of concern were issued to NDs for using the term "physician" on their website, which is prohibited in the Act. A letter of concern is not formal discipline and is considered a dismissal.

The Director also has the authority to impose fines on NDs for violations of the Act or applicable rules. In fiscal years 13-14 through 17-18, no fines were imposed on NDs.

Collaborative Agreements - Children Under Two

Section 12-37.3-105(2)(e)(III)(A), C.R.S., requires NDs who treat children under two years of age to develop and execute a written collaborative agreement with a licensed physician who is a pediatrician or family physician. The collaborative agreement includes the duties and responsibilities of the ND and licensed physician according to each party's standard of care and respective practice act.⁵⁴

By rule, the collaborative agreements must:55

- Be signed by both parties,
- Contain the responsibilities and duties of each party,
- Contain the process for the ND to consult with the licensed physician,
- Contain the process for the ND to refer a patient to a licensed physician to facilitate the patient's effective treatment, and
- Be kept on file by both parties for seven years.

Section 12-37.3-119(2)(a), C.R.S., requires this sunset review to gather and report the following information:

- The number of children under two years of age treated by NDs,
- The conditions for which NDs treated children under the age of two, and
- The number and description of adverse events that may have occurred.

In fiscal year 15-16, 16 NDs treated approximately 152 children under the age of two with no adverse events.

In fiscal year 16-17, 14 NDs reported treating approximately 178 children under the age of two with no adverse events.

In fiscal year 17-18, 18 NDs reported treating approximately 175 children under the age of two with no adverse events.

In fiscal years 15-16 through 17-18, the most common conditions NDs reported treating included:

- Allergies,
- Eczema, and
- Digestive issues.

⁵⁴ § 12-37-3-105(2)(e)(III)(A), C.R.S.

⁵⁵ 4 CCR 749-1 § 16(A)(3)(a), Office of Naturopathic Doctors Registration, Practice and Discipline Rules.

Collateral Consequences - Criminal Convictions

The ninth sunset criterion requires COPRRR to examine whether the agency under review, through its licensing processes, imposes any sanctions or disqualifications based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

Section 12-37.3-112(1)(h), C.R.S., authorizes the Director to deny, revoke, suspend an ND's registration is he or she is convicted of a felony, an offense of moral turpitude or a crime that would constitute a violation of the Act, or a plea of guilty or *nolo contendere* or a deferred sentence.

In fiscal years 13-14 through 17-18, the Director did not deny, revoke or suspend the registration of any NDs based on past criminal history.

Analysis and Recommendations

The final sunset criterion questions whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest. The recommendations that follow are offered in consideration of this criterion, in general, and any criteria specifically referenced in those recommendations.

Recommendation 1 - Continue the Naturopathic Doctor Act for nine years, until 2029.

A sunset review of the Naturopathic Doctors Act (Act) was completed in 2016 by the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within the Department of Regulatory Agencies (DORA). The continuation recommendation, among other things, stated that since regulatory oversight was fairly new in Colorado, there was not sufficient data to appropriately evaluate the program. As such, the sunset report recommended continuation of the program for five years. The General Assembly however, continued the Act for three years. Importantly, the 2016 sunset report identified few complaints and disciplinary actions against naturopathic doctors (NDs). In fact, the report stated that the majority of complaints against NDs were related to unregistered practice.

The first sunset review criterion asks whether regulation is necessary to protect the health, safety and welfare of the public. The Act was created by the General Assembly in 2013, and in June 2014, NDs were required to obtain a registration prior to practicing. The Act creates a "director model" program, which authorizes the Director of the Division of Professions and Occupations (Director and Division, respectively) within DORA to, among other things, register NDs and impose discipline on practitioners who violate the Act or applicable rules.

Since the Act was implemented in 2014, there have been very few complaints, and even fewer disciplinary actions imposed on registered NDs. In fact, the Director imposed discipline 11 times since regulatory oversight began. Nine of the disciplinary actions were cease and desist orders, which were issued because the NDs were practicing on an expired registration. Importantly, the cease and desist orders were not practice-related issues (i.e., harming a consumer); instead, the discipline was based on an administrative issue, where the practitioner failed to maintain a current registration.

Due to the lack of harm to consumers identified during this sunset review, the central question is whether the State of Colorado should continue to require NDs to become registered prior to practicing.

It could be argued that the implementation of the registration program in Colorado has ensured only competent, qualified practitioners have been providing services to consumers, which at least partially explains the low number of complaints and disciplinary actions.

Importantly, COPRRR completed a sunrise review in 1993. The report recommended against regulation due to insufficient harm to consumers.

However, in 1998, 2005 and 2008, COPRRR conducted sunrise reviews of NDs and determined that there was sufficient consumer harm to warrant governmental intervention in the marketplace through formal regulation.

As highlighted earlier in this recommendation, since the inception of regulatory oversight began in 2014, there have been few instances of harm to consumers. Since COPRRR recommend regulation on several occasions because harm was identified, it appears that the regulatory program for NDs has served to enhance consumer protection.

As such, the General Assembly should continue the Act for nine years, until 2029. A nine-year continuation is reasonable because the analysis of the regulatory program did not identify systemic or structural issues where consumers were being harmed. As such, the current level of regulation, including the requirements and continued competency, appear to be providing adequate consumer protection.

Recommendation 2 - Repeal the Naturopathic Medicine Advisory Committee.

The Naturopathic Medicine Advisory Committee (Advisory Committee) was originally created to provide guidance and advice on the initial development of the rules and policies associated with the registration of NDs. The Advisory Committee consists of nine members appointed by the Director:⁵⁶

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

Since the rules and policies have been implemented, the utilization of the Advisory Committee has diminished. In fact, five of the past 10 Advisory Committee meetings were cancelled due to a lack of tasks to accomplish.

As such, the Advisory Committee is no longer necessary and should be repealed from the Act. The elimination of the Advisory Committee will not compromise the Director's ability to utilize expert advice, such as convening *ad hoc* committees representing industry experts, to address any regulatory issues that arise.

⁵⁶ § 12-37.3-103(1)(b)(I), C.R.S.

Importantly, removing the Advisory Committee from the Act will not limit members of the profession or other stakeholders from engaging in the rulemaking process.

Therefore, the Advisory Committee should be repealed. This recommendation addresses the first criterion, which asks whether regulation is necessary to protect the public from harm. Since the Advisory Committee does not meet regularly to address regulatory issues, it is not serving as a mechanism to protect the public and should be repealed from the Act.

Recommendation 3 - Repeal the collaborative agreement requirement.

Currently, section 12-37.3-105(2)(e)(II)(A), Colorado Revised Statutes (C.R.S.), prohibits NDs from treating children who are less than two years of age unless they demonstrate in each year in which they treat children under the age of two successful completion of five hours of education or practicum training solely related to pediatrics in accordance with continuing professional competency requirements, including subject matter related to recognizing a sick infant and when to refer an infant for more intensive care.

Additionally, the Act requires NDs who treat children under the age of two to develop and execute written collaborative agreements with licensed physicians who are pediatricians or family physicians. The collaborative agreement must include duties and responsibilities of each party according to each party's standard of care and practice act, and a process for consulting with and referring to a licensed physician to facilitate the effective treatment of children under the age of two.⁵⁷

The Act also requires NDs to report the number of children treated, conditions they were treated for and any adverse events that occurred. Since the inception of regulatory oversight in 2014, NDs have treated many children under the age of two, and there have not been any adverse events reported to the Division. It appears that NDs are practicing safely with children under the age of two, which calls into question the need for a collaborative agreement.

The second sunset criterion requires the review of the Act and rules determine whether they are the least restrictive form of regulation consistent with public protection. It could be argued that requiring a written collaborative agree between an ND and a licensed physician prior to providing care is overly restrictive.

As stated earlier, NDs who treat children under the age of two are required to complete five hours per calendar year of education or practicum training solely related to pediatrics, which includes subject matter related to recognizing a sick infant and when to refer an infant for more intensive care. As such, NDs who treat children under the age of two should possess the competency to determine when to

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⁵⁷ 12-37.3-105(2)(e)(III)(A), C.R.S.

refer a child for more intensive care, which calls into question the need for the collaborative agreement requirement.

Importantly, NDs who fail to comply with the provision to refer a child who is under the age of two when necessary is subject to potential formal discipline under the Act. Specifically, section 12-37.3-112(e), C.R.S., states that failing to refer a patient to an appropriate health-care professional when services required by the patient are beyond the level of competence or the scope of practice may be grounds for formal discipline by the Director.

Therefore, the General Assembly should repeal the requirement that NDs develop and execute collaborative agreements with licensed physicians when treating children under the age of two. Doing so is consistent with the second sunset criterion, which asks whether the existing Act and rules are the least restrictive form of regulation consistent with public protection.

Repealing the collaborative agreement will not compromise consumer protection; instead, it will remove an unnecessary barrier for NDs to practice.

Therefore, the General Assembly should repeal the collaborative agreement requirement.

Recommendation 4 - Provide immunity from liability for the Director, Division staff, consultants and complainants.

Currently, the Act is silent on whether the Director, Division staff, witnesses, consultants or complainants are immune from civil liability. The Director and Division staff likely fall under the general governmental immunity provision that applies to staff acting in their official capacities. However, adding the referenced language to the Act would allow any claims of liability to be more readily dismissed, which could prevent the need to adjudicate an issue further via the court system. Doing so may serve to save time and resources for the Division with adjudications. Although there have not been any cases associated with immunity from civil liability, this recommendation serves to provide clarity in the Act.

The first sunset criterion asks whether regulation is necessary to protect the public. The absence of immunity for witnesses and complainants may prevent them from filing a complaint against a practitioner, or participating in the disciplinary process because of the threat of a lawsuit, which could compromise public protection. Importantly, there have not been any issues associated with immunity from liability related to the regulation of NDs, but the addition of immunity from liability language exists in a variety of practice acts in Colorado, such as the Audiologist Practice Act (section 12-29.9-111, C.R.S.) and the Direct-Entry Midwives Practice Act (section 12-37-109.5, C.R.S.).

Therefore, the General Assembly should provide immunity from civil liability for the Director, Division staff, consultants and complainants.

Recommendation 5 - Repeal references to the North American Board of Naturopathic Examiners and the Council on Naturopathic Medical Education.

Currently, section 12-37.3-106(2)(d), C.R.S., requires candidates for ND registration to successfully pass either a Director-approved examination or a comprehensive competency-based national naturopathic licensing examination administered by the North American Board of Naturopathic Examiners (NABNE) or a nationally recognized, Director-approved successor entity.

Similarly, section 12-37-3-102(2)(a)(III), C.R.S., requires NDs to graduate from a naturopathic medical education program that is accredited or has achieved candidacy status for accreditation by the Council on Naturopathic Medical Education (CNME) or an equivalent accrediting body for naturopathic medical programs recognized by the United States Department of Education.

NABNE and CMNE should be removed from the statute.

Naming specific organizations in statute can be problematic. Organizations can change their names, they can merge with other organizations or they may cease operations entirely. More problematic, however, is the fact that by naming organizations in statute, the General Assembly cedes the state's ability to deviate from the standards established by those organizations. Worse, these organizations are not subject to the state's rulemaking or transparency requirements. Thus, private organizations can establish state registration standards with very little public input, transparency or state participation.

The Director has the authority to select a different examination, but naming NABNE creates a presumption that this is the examination to be selected. As such, the statute grants NABNE a competitive advantage over any other examination.

Education programs are required to be approved by the United States Department of Education, but naming CNME in the statute creates a presumption that only CNME programs fulfill the education requirement for NDs.

The better practice is to authorize the regulator, in this case the Director, to adopt the appropriate examination and education via rule. Repealing the references to NABNE and CNME, however, provides the state greater flexibility in the event problems arise or other examinations are developed in the future.

The second sunset criterion asks if regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent

with the public interest. Naming specific organizations in statute limits the Director's authority and flexibility, which is contrary to the goal to protect the public interests.

Therefore, the General Assembly should repeal the statutory references to NABNE and CNME.

Appendix A - Title 12 Recodification Table

This table shows provisions of Article 37.3 of Title 12 of the Colorado Revised Statutes that were relocated as a result of the passage of House Bill 19-1172, concerning an organizational recodification of Title 12.

Prior to October 1, 2019	October 1, 2019 and Thereafter	Prior to October 1, 2019	October 1, 2019 and Thereafter
12-37.3-101	12-250-101	12-37.3-105(5)(a)	12-250-106(5)(a)
12-37.3-102 IP	12-250-103 IP	12-37.3-105(5)(b)	12-250-106(5)(b)
12-37.3-102(1)	12-250-103(1)	12-37.3-105(5)(c)	12-250-106(5)(c)
12-37.3-102(1.3)	12-250-103(2)	12-37.3-105(6)	12-250-106(6)
12-37.3-102(1.5)	12-250-103(3)	12-37.3-105(7)	12-250-106(7)
12-37.3-102(2)	12-250-103(4)	12-37.3-106	12-250-107
12-37.3-102 IP(3)	12-250-103 IP(5)	12-37.3-106(1)	12-250-107(1)
12-37.3-102 IP(3)(a)	12-250-103 IP(5)(a)	12-37.3-106 IP(2)	12-250-107 IP(2)
12-37.3-102(3)(a)(l)	12-250-103(5)(a)(l)	12-37.3-106(2)(a)	12-250-107(2)(a)
12-37.3-102(3)(a)(II)	12-250-103(5)(a)(II)	12-37.3-106(2)(b)	12-250-107(2)(b)
12-37.3-102(3)(a)(III)	12-250-103(5)(a)(III)	12-37.3-106(2)(c)	12-250-107(2)(c)
12-37.3-102(3)(b)	12-250-103(5)(b)	12-37.3-106(2)(d)	12-250-107(2)(d)
12-37.3-102(4)	12-250-103(6)	12-37.3-106(2)(e)	12-250-107(2)(e)
12-37.3-102(5)	Repealed	12-37.3-106(3)	12-250-107(3)
12-37.3-102(5.5)	12-250-103(7)	12-37.3-106 IP(4)	12-250-107 IP(4)
12-37.3-102(6)	Repealed	12-37.3-106(4)(a)	12-250-107(4)(a)
12-37.3-102(7)	12-250-103(8)	12-37.3-106(4)(b)	12-250-107(4)(b)
12-37.3-102 IP(8)	12-250-103 IP(9)	12-37.3-106(4)(c)	12-250-107(4)(c)
12-37.3-102(8)(a)	12-250-103(9)(a)	12-37.3-107	12-250-108
12-37.3-102(8)(b)	12-250-103(9)(b)	12-37.3-108	12-250-109
12-37.3-102(8)(c)	12-250-103(9)(c)	12-37.3-108(1)(a)	12-250-109(1)(a)
12-37.3-102 IP(9)	12-250-103 IP(10)	12-37.3-108 IP(1)(b)	12-250-109 IP(1)(b)
12-37.3-102(9)(a)	12-250-103(10)(a)	12-37.3-108(1)(b)(l)	12-250-109(1)(b)(l)
12-37.3-102(9)(b)	12-250-103(10)(b)	12-37.3-108(1)(b)(II)	12-250-109(1)(b)(II)
12-37.3-102(9)(c)	12-250-103(10)(c)	12-37.3-108(1)(b)(III)	12-250-109(1)(b)(III)
12-37.3-102(10)	12-250-103(11)	12-37.3-108 IP(1)(c)	12-250-109 IP(1)(c)
12-37.3-102(11)	12-250-103(12)	12-37.3-108(1)(c)(l)	12-250-109(1)(c)(l)
12-37.3-102(12)(a)	12-250-103(13)(a)	12-37.3-108(1)(c)(II)	12-250-109(1)(c)(II)
12-37.3-102(12)(b)	12-250-103(13)(b)	12-37.3-108(1)(c)(III)	12-250-109(1)(c)(III)
12-37.3-103	12-250-104	12-37.3-108(1)(d)(l)	12-250-109(1)(d)(l)
12-37.3-103(1)(a)	12-250-104(1)(a)	12-37.3-108(1)(d)(II)	12-250-109(1)(d)(II)
12-37.3-103 IP(1)(b)(l)	12-250-104 IP(1)(b)	12-37.3-108(2)	12-250-109(2)
12-37.3-103(1)(b)(l)(A)	12-250-104(1)(b)(l)	12-37.3-109	12-250-110
12-37.3-103(1)(b)(l)(B)	12-250-104(1)(b)(II)	12-37.3-110	12-250-111
12-37.3-103(1)(b)(l)(C)	12-250-104(1)(b)(III)	12-37.3-110(1)	12-250-111(1)
12-37.3-103(1)(b)(l)(D)	12-250-104(1)(b)(IV)	12-37.3-110(2)	12-250-111(2)
12-37.3-103(1)(b)(II)	Repealed	12-37.3-110(2.5)	12-250-111(3)

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12-37.3-103(1)(c)(l)	12-250-104(1)(c)(l)	12-37.3-110 IP(3)	12-250-111 IP(4)
12-37.3-103(1)(c)(II)	12-250-104(1)(c)(II)	12-37.3-110(3)(a)	12-250-111(4)(a)
12-37.3-103(1)(d)	12-250-104(1)(d)	12-37.3-110(3)(b)	12-250-111(4)(b)
12-37.3-103(2)	12-250-104(2)	12-37.3-110(3)(c)	12-250-111(4)(c)
12-37.3-103(3)	12-250-104(3)	12-37.3-110(4)	12-250-111(5)
12-37.3-104	12-250-105	12-37.3-110(5)	12-250-111(6)
12-37.3-104 IP(1)	12-250-105 IP(1)	12-37.3-111	12-250-112
12-37.3-104(1)(a)	12-250-105(1)(a)	12-37.3-111 IP(1)	12-250-112 IP(1)
12-37.3-104(1)(b)	12-250-105(1)(b)	12-37.3-111(1)(a)	12-250-112(1)(a)
12-37.3-104(1)(c)	12-250-105(1)(c)	12-37.3-111(1)(b)	12-250-112(1)(b)
12-37.3-104(1)(d)	Repealed	12-37.3-111(1)(c)	12-250-112(1)(c)
12-37.3-104(1)(e)	12-250-105(1)(d)	12-37.3-111(1)(d)	12-250-112(1)(d)
12-37.3-104(1)(f)	12-250-105(1)(e)	12-37.3-111(1)(e)	12-250-112(1)(e)
12-37.3-105	12-250-106	12-37.3-111(1)(f)	12-250-112(1)(f)
12-37.3-105 IP(1)	12-250-106 IP(1)	12-37.3-111(2)	12-250-112(2)
12-37.3-105(1)(a)	12-250-106(1)(a)	12-37.3-111(3)	12-250-112(3)
12-37.3-105(1)(b)	12-250-106(1)(b)	12-37.3-112	12-250-113
12-37.3-105 IP(1)(c)(I)	12-250-106 IP(1)(c)(I)	12-37.3-112 IP(1)	12-250-113 IP(1)
12-37.3-105(1)(c)(l)(A)	12-250-106(1)(c)(l)(A)	12-37.3-112(1)(a)	12-250-113(1)(a)
12-37.3-105(1)(c)(I)(B)	12-250-106(1)(c)(l)(B)	12-37.3-112(1)(b)	12-250-113(1)(b)
12-37.3-105(1)(c)(l)(C)	12-250-106(1)(c)(l)(C)	12-37.3-112(1)(c)	12-250-113(1)(c)
12-37.3-105(1)(c)(l)(D)	12-250-106(1)(c)(l)(D)	12-37.3-112(1)(d)	12-250-113(1)(d)
12-37.3-105(1)(c)(I)(E)	12-250-106(1)(c)(l)(E)	12-37.3-112(1)(e)	12-250-113(1)(e)
12-37.3-105(1)(c)(l)(F)	12-250-106(1)(c)(l)(F)	12-37.3-112(1)(f)	12-250-113(1)(f)
12-37.3-105(1)(c)(II)	12-250-106(1)(c)(II)	12-37.3-112(1)(g)	12-250-113(1)(g)
12-37.3-105(1)(d)	12-250-106(1)(d)	12-37.3-112(1)(h)	12-250-113(1)(h)
12-37.3-105 IP(2)	12-250-106 IP(2)	12-37.3-112(1)(i)	12-250-113(1)(i)
12-37.3-105(2)(a)	12-250-106(2)(a)	12-37.3-112(1)(j)	12-250-113(1)(j)
12-37.3-105(2)(b)	12-250-106(2)(b)	12-37.3-112(1)(k)	12-250-113(1)(k)
12-37.3-105(2)(c)	12-250-106(2)(c)	12-37.3-112(1)(l)	12-250-113(1)(l)
12-37.3-105(2)(d)	12-250-106(2)(d)	12-37.3-112(1)(m)	12-250-113(1)(m)
12-37.3-105 IP(2)(e)	12-250-106 IP(2)(e)	12-37.3-112(1)(n)	12-250-113(1)(n)
12-37.3-105(2)(e)(l)	12-250-106(2)(e)(l)	12-37.3-112 IP(1)(o)	12-250-113 IP(1)(o)
12-37.3-105(2)(e)(II)(A)	12-250-106(2)(e)(II)(A)	12-37.3-112(1)(o)(l)	12-250-113(1)(o)(l)
12-37.3-105(2)(e)(II)(B)	12-250-106(2)(e)(II)(B)	12-37.3-112(1)(o)(II)	12-250-113(1)(o)(II)
12-37.3-105(2)(e)(III)(A)	12-250-106(2)(e)(III)(A)	12-37.3-112(1)(p)(l)	12-250-113(1)(p)(l)
12-37.3-105(2)(e)(III)(B)	12-250-106(2)(e)(III)(B)	12-37.3-112(1)(p)(II)	12-250-113(1)(p)(II)
12-37.3-105(2)(e)(III)(C)	12-250-106(2)(e)(III)(C)	12-37.3-112(1)(p)(III)	12-250-113(1)(p)(III)
12-37.3-105(2)(e)(III)(D)	12-250-106(2)(e)(III)(D)	12-37.3-112(1)(q)	12-250-113(1)(q)
12-37.3-105 IP(2)(e)(IV)	12-250-106 IP(2)(e)(IV)	12-37.3-112(1)(r)	12-250-113(1)(r)
12-37.3-105(2)(e)(IV)(A)	12-250-106(2)(e)(IV)(A)	12-37.3-112(1)(s)	12-250-113(1)(s)
12-37.3-105(2)(e)(IV)(B)	12-250-106(2)(e)(IV)(B)	12-37.3-112(1)(t)	12-250-113(1)(t)
12-37.3-105(2)(e)(IV)(C)	12-250-106(2)(e)(IV)(C)	12-37.3-112(2)	12-250-113(2)

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12-37.3-105(2)(e)(IV)(D)	12-250-106(2)(e)(IV)(D)	12-37.3-112(3)	Repealed
12-37.3-105(2)(e)(V)	12-250-106(2)(e)(V)	12-37.3-112(4)	12-250-113(3)
12-37.3-105 IP(2)(f)	12-250-106 IP(2)(f)	12-37.3-112(5)	12-250-113(4)
12-37.3-105(2)(f)(I)	12-250-106(2)(f)(I)	12-37.3-112(6)(a)	12-250-113(5)
12-37.3-105(2)(f)(II)	12-250-106(2)(f)(II)	12-37.3-112(6)(b)	Repealed
12-37.3-105 IP(2)(f)(III)	12-250-106 IP(2)(f)(III)	12-37.3-112(7)(a)	12-250-113(6)
12-37.3-105(2)(f)(III)(A)	12-250-106(2)(f)(III)(A)	12-37.3-112(7)(b), (7)(c)	Repealed
12-37.3-105(2)(f)(III)(B)	12-250-106(2)(f)(III)(B)	12-37.3-112(8)	12-250-113(7)
12-37.3-105(2)(f)(III)(C)	12-250-106(2)(f)(III)(C)	12-37.3-112(9) to (14)	12-250-113(8)
12-37.3-105(2)(f)(III)(D)	12-250-106(2)(f)(III)(D)	12-37.3-113	12-250-114 [similar]
12-37.3-105(2)(g)	12-250-106(2)(g)	12-37.3-113	12-20-407(1)(c)
12-37.3-105(2)(h)	12-250-106(2)(h)	12-37.3-114	12-250-115
12-37.3-105(2)(i)	12-250-106(2)(i)	12-37.3-114(1)	12-250-115(1)
12-37.3-105(2)(j)	12-250-106(2)(j)	12-37.3-114(2)	12-250-115(2)
12-37.3-105(3)(a)	12-250-106(3)(a)	12-37.3-114(3)	12-250-115(3)
12-37.3-105 IP(3)(b)	12-250-106 IP(3)(b)	12-37.3-114.5	12-250-116
12-37.3-105(3)(b)(l)	12-250-106(3)(b)(l)	12-37.3-115	12-250-117
12-37.3-105(3)(b)(II)	12-250-106(3)(b)(II)	12-37.3-115 IP(1)	12-250-117 IP(1)
12-37.3-105(3)(b)(III)	12-250-106(3)(b)(III)	12-37.3-115(1)(a)	12-250-117(1)(a)
12-37.3-105(3)(b)(IV)	12-250-106(3)(b)(IV)	12-37.3-115(1)(b)	12-250-117(1)(b)
12-37.3-105(3)(c)	12-250-106(3)(c)	12-37.3-115(1)(c)	12-250-117(1)(c)
12-37.3-105(3)(d)	12-250-106(3)(d)	12-37.3-115(2)	12-250-117(2)
12-37.3-105 IP(4)	12-250-106 IP(4)	12-37.3-115(3)	12-250-117(3)
12-37.3-105(4)(a)	12-250-106(4)(a)	12-37.3-115(4)	12-250-117(4)
12-37.3-105 IP(4)(b)	12-250-106 IP(4)(b)	12-37.3-116	12-250-118
12-37.3-105(4)(b)(l)	12-250-106(4)(b)(l)	12-37.3-116(1) to (4)	12-250-118
12-37.3-105(4)(b)(II)	12-250-106(4)(b)(II)	12-37.3-117	12-250-119
12-37.3-105(4)(b)(III)	12-250-106(4)(b)(III)	12-37.3-117(1)	12-250-119(1)
12-37.3-105(4)(c)	12-250-106(4)(c)	12-37.3-117(2)	12-250-119(2)
12-37.3-105(4)(d)	12-250-106(4)(d)	12-37.3-117(3)	12-250-119(3)
12-37.3-105(4)(e)	12-250-106(4)(e)	12-37.3-117(4)	12-250-119(4)
12-37.3-105(4)(f)	12-250-106(4)(f)	12-37.3-118	12-250-120
12-37.3-105(4)(g)	12-250-106(4)(g)	12-37.3-119	12-250-121
12-37.3-105(4)(h)	12-250-106(4)(h)	12-37.3-119(1)	12-250-121(1)
12-37.3-105(4)(i)	12-250-106(4)(i)	12-37.3-119(2)(a)	12-250-121(2)(a)
12-37.3-105 IP(5)	12-250-106 IP(5)	12-37.3-119(2)(b)	12-250-121(2)(b)