



**COLORADO**

**Department of  
Regulatory Agencies**

Colorado Office of Policy, Research &  
Regulatory Reform

# 2019 Sunrise Review

Ayurvedic Doctors, Practitioners and Health Counselors



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October 15, 2019



**COLORADO**

**Department of  
Regulatory Agencies**

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 General Assembly established the sunrise review process in 1985 as a way to determine whether regulation of a certain profession or occupation is necessary before enacting laws for such regulation and to determine the least restrictive regulatory alternative consistent with the public interest. Since that time, Colorado's sunrise process has gained national recognition and is routinely highlighted as a best practice as governments seek to streamline regulation and increase efficiencies.

Section 24-34-104.1, Colorado Revised Statutes, directs the Department of Regulatory Agencies to conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

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 its evaluation of the sunrise application for the regulation of Ayurvedic doctors, practitioners and health counselors and is pleased to submit this written report.

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

Sincerely,

A handwritten signature in black ink that reads 'Patty Salazar'.

Patty Salazar  
Executive Director



## Table of Contents

Background .....	1
Licensure .....	1
Certification .....	2
Registration .....	2
Title Protection .....	2
Regulation of Businesses .....	3
Sunrise Process .....	3
Methodology .....	4
Profile of the Profession .....	5
National Ayurvedic Medical Association Certification Board.....	6
Proposal for Regulation .....	9
Summary of Current Regulation .....	10
Federal Laws and Regulations.....	10
The Colorado Regulatory Environment.....	10
Regulation in Other States.....	11
Analysis and Recommendations.....	12
Public Harm.....	12
Need for Regulation .....	19
Alternatives to Regulation .....	19
Collateral Consequences .....	20
Conclusion.....	21
Recommendation - Do not regulate Ayurvedic professionals in Colorado. ....	22

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## Background

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).

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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.

## Sunrise Process

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA's Colorado Office of Policy, Research and Regulatory Reform (COPRRR) must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:<sup>1</sup>

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

(II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence;

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<sup>1</sup> § 24-34-104.1(4)(b), C.R.S.

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(III) Whether the public can be adequately protected by other means in a more cost-effective manner; and

(IV) Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation.

## Methodology

During the sunrise review process, Colorado Office of Policy, Research and Regulatory Reform (COPRRR) staff performed a literature search; contacted and interviewed the sunrise applicant; and interviewed Ayurvedic professionals and other stakeholders. To determine the number and types of complaints filed against Ayurvedic professionals in Colorado, COPRRR staff contacted the Attorney General's Office, Consumer Protection Section; the Colorado Medical Society; Better Business Bureau serving Greater Denver and Central Colorado; the Colorado Medical Board staff; and the Division of Professions and Occupations staff who provide regulatory oversight of naturopathic doctors.

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## Profile of the Profession

Ayurvedic medicine was developed in India more than 3,000 years ago.<sup>2</sup> It is a natural system of medicine, and is “based on the idea that disease is due to an imbalance or stress in a person’s consciousness.”<sup>3</sup> Ayurvedic medicine “encourages lifestyle interventions and natural therapies to regain a balance between the body, mind, spirit and the environment.”<sup>4</sup> Further, Ayurvedic “treatment combines products (mainly derived from plants, but may also include animal, metal and mineral), diet, exercise (e.g., yoga) and lifestyle.”<sup>5</sup>

Ayurvedic medicine is premised on the belief that every person is comprised of five basic elements found in the universe: space, air, fire, water and earth.<sup>6</sup> These elements combine in the body to form three life forces or energies called doshas. The doshas are:<sup>7</sup>

- Vata (space and air),
- Pitta (fire and water), and
- Kapha (water and earth).

Ayurvedic professionals believe that the vata dosha controls basic body functions, such as how cells divide. This dosha also controls the mind, breathing, blood flow, heart function, and the ability to eliminate waste through the intestines. Examples of circumstances that may disrupt the vata dosha include eating too soon after a meal, fear and grief.<sup>8</sup>

It is believed that interruptions in the vata dosha may result in the development of conditions such as anxiety, asthma, heart disease, skin problems or rheumatoid arthritis.<sup>9</sup>

The pitta dosha controls metabolism and hormones linked to a person’s appetite. Examples of adverse conditions within the pitta dosha are: high blood pressure, heart disease and infections.<sup>10</sup>

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<sup>2</sup> WebMD. *What is Ayurveda?* Retrieved June 19, 2019, from <https://www.webmd.com/balance/guide/Ayurvedic-treatments#1>

<sup>3</sup> John Hopkins Medicine. *What is Ayurveda?* Retrieved June 19, 2019, from <https://www.hopkinsmedicine.org/health/wellness-and-prevention/ayurveda>

<sup>4</sup> John Hopkins Medicine. *What is Ayurveda?* Retrieved June 19, 2019, from <https://www.hopkinsmedicine.org/health/wellness-and-prevention/ayurveda>

<sup>5</sup> National Center for Complementary and Integrative Health. *Ayurveda Medicine: In Depth*. Retrieved September 18, 2019, from <https://nccih.nih.gov/health/ayurveda/introduction.htm>

<sup>6</sup> WebMD. *What is Ayurveda?* Retrieved June 19, 2019, from <https://www.webmd.com/balance/guide/Ayurvedic-treatments#1>

<sup>7</sup> WebMD. *What is Ayurveda?* Retrieved June 19, 2019, from <https://www.webmd.com/balance/guide/Ayurvedic-treatments#1>

<sup>8</sup> WebMD. *What is Ayurveda?* Retrieved June 19, 2019, from <https://www.webmd.com/balance/guide/Ayurvedic-treatments#1>

<sup>9</sup> WebMD. *What is Ayurveda?* Retrieved June 19, 2019, from <https://www.webmd.com/balance/guide/Ayurvedic-treatments#1>

<sup>10</sup> WebMD. *What is Ayurveda?* Retrieved June 12, 2019, from <https://www.webmd.com/balance/guide/Ayurvedic-treatments#2>



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The kapha dosha controls things such as muscle growth, body strength and stability, weight and a person's immune system. Interruptions to this life force, Ayurvedic professionals believe, may lead to the development of ailments such as asthma, cancer, diabetes or obesity.<sup>11</sup>

Once an Ayurvedic professional identifies imbalances, he or she will create a treatment plan to regain balance between all three of the aforementioned elements. Additionally, Ayurvedic professionals customize preventative wellness to the unique constitution of every individual.<sup>12</sup>

Ayurvedic professionals produce descriptions of acute and chronic conditions, and develop extensive holistic treatment protocols. Preventative care and treatment of disease are included in Ayurveda's eight branches, which include:<sup>13</sup>

- Kaayachikitsa - internal medicine;
- Baalachikitsa - pediatrics;
- Bhuta Vidya - psychiatry;
- Shalaky Tantra - ear, nose and throat treatment;
- Shalya Tantra - surgery (not practiced in the United States);
- Vishagara Vairodh Tantra - toxicology;
- Jarachikitsa/Rasayana - geriatrics and rejuvenation; and
- Vajikarana - aphrodisiac therapy, fertility and conception.

Ayurveda also offers a comprehensive cleansing protocol, known as panchakarma. This practice utilizes five primary therapies to release and eliminate accumulated toxins from deep within tissues to return the doshas to their proper seats in the body.<sup>14</sup>

## National Ayurvedic Medical Association Certification Board

There are three scopes (levels) of practicing Ayurvedic professionals: Ayurvedic doctors (ADs), Ayurvedic practitioners (APs), and Ayurvedic health counselors (AHCs). The National Ayurvedic Medical Association Certification Board (Board) offers certification for AHCs and APs.

According to representatives with the National Ayurvedic Medication Association, the certification for ADs will be available in October 2019. As a result, certification requirements remain unknown as of this writing.

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<sup>11</sup> WebMD. *What is Ayurveda?* Retrieved June 12, 2019, from <https://www.webmd.com/balance/guide/Ayurvedic-treatments#2>

<sup>12</sup> National Ayurvedic Medical Association. *What is Ayurveda?* Retrieved July 29, 2019, from <https://www.ayurvedanama.org/what-is-ayurveda>

<sup>13</sup> National Ayurvedic Medical Association. *What is Ayurveda?* Retrieved July 29, 2019, from <https://www.ayurvedanama.org/what-is-ayurveda>

<sup>14</sup> National Ayurvedic Medical Association. *What is Ayurveda?* Retrieved July 29, 2019, from <https://www.ayurvedanama.org/what-is-ayurveda>

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In order to qualify for AHC certification, a candidate must complete a minimum of six credits of college level anatomy and physiology or equivalent. Candidates must also undergo a least 600 hours of training, which is associated with client/patient encounters.<sup>15</sup>

Current guidelines for client/patient encounters include:<sup>16</sup>

- Experience history and/or outcomes of clients/patients in order to acquire significant clinical knowledge and experience. This experience can be gained in a variety of ways, including observation, internship, externship, small group work or apprenticeship (working under and alongside the practitioners in a graduated responsibility model).
- Carry out procedures such as history taking; prakrti (individual constitution) and vikrti (pathological condition) assessments; pulse, tongue and nail diagnosis; as well as other appropriate methods in order to gain assessment fluency. This cannot be accomplished by passive observation, but can be attained in a variety of settings including intern, small group or apprenticeship (working under and alongside the practitioner in a graduated responsibility model).
- Carry out clinical application of Ayurveda as per category designation.

There are currently, three settings for client/patient encounters:<sup>17</sup>

- Observation: witness preceptor working with a client/patient with limited student involvement.
- Student-client encounter with direct supervision of preceptor. This includes working one-on-one or in small groups of two or three.
- Student-client one-on-one, in a more intimate setting with the student doing complete intake, recommendations and follow-up, to be supervised directly or via externship. All but five initial encounters should be in-person.

In order to be eligible for certification, candidates for AHC are required to have a minimum of 50 client/patient encounters.

Once a candidate completes the aforementioned requirements, he or she is eligible to take the AHC examination, which is a multiple-choice examination consisting of 100 questions. The examination must be completed within 2.5 hours. The AHC examination contains five sections:

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<sup>15</sup> National Ayurvedic Medical Association. *Education Requirements*. Retrieved August 9, 2019, from [https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements\\_06-12-19.pdf](https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements_06-12-19.pdf)

<sup>16</sup> National Ayurvedic Medical Association. *Education Requirements*. Retrieved August 9, 2019, from [https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements\\_06-12-19.pdf](https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements_06-12-19.pdf)

<sup>17</sup> National Ayurvedic Medical Association. *Education Requirements*. Retrieved August 9, 2019, from [https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements\\_06-12-19.pdf](https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements_06-12-19.pdf)

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- Foundations of Ayurveda,
  - Concepts of Ayurveda,
  - Assessment and diagnosis,
  - Recommendations,
  - Treatment and interventions, and
  - Categories of Cikitsa.

The cost to register for the AHC examination is \$375.<sup>18</sup>

Candidates for AP certification are required to complete a least six college level credits in anatomy and physiology or equivalent. Candidates must also complete a minimum of 1,500 hours of training, which includes the same client/patient encounters as AHCs.<sup>19</sup>

To be eligible for AP certification, candidates must complete a minimum of 150 client/patient encounters.<sup>20</sup>

Once the minimum education and training hours have been fulfilled, candidates are eligible to take the AP examination. The examination contains 80 multiple-choice questions, and must be completed in 2.5 hours. The AP examination also consists of five sections, which are identical to the sections in the AHC examination.

The cost to register for the AP examination is \$450.<sup>21</sup>

Once AHC and AP practitioners achieve certification, they are required to complete 30 hours of continuing education every two years.

According to the sunrise application, there are approximately 70 Ayurvedic professionals in Colorado, and there are 41 members of the Colorado Ayurvedic Medical Association.

According to the Colorado Ayurvedic Medical Association website, there are three Ayurvedic schools in Colorado.

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<sup>18</sup> National Ayurvedic Medical Association Certification Board. *Certification Handbook*. Retrieved August 9, 2019, from [https://static1.squarespace.com/static/58d3f6009f7456f359631c49/t/5d6daa76666cc100013552d1/1567468203956/NAMACB\\_Handbook+v8-13-19.pdf](https://static1.squarespace.com/static/58d3f6009f7456f359631c49/t/5d6daa76666cc100013552d1/1567468203956/NAMACB_Handbook+v8-13-19.pdf)

<sup>19</sup> National Ayurvedic Medical Association. *Education Requirements*. Retrieved August 9, 2019, from [https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements\\_06-12-19.pdf](https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements_06-12-19.pdf)

<sup>20</sup> National Ayurvedic Medical Association. *Education Requirements*. Retrieved August 9, 2019, from [https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements\\_06-12-19.pdf](https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5d01515e5a663f00013b5413/1560367455095/Educational+Requirements_06-12-19.pdf)

<sup>21</sup> National Ayurvedic Medical Association Certification Board. *Certification Handbook*. Retrieved August 9, 2019, from [https://static1.squarespace.com/static/58d3f6009f7456f359631c49/t/5d6daa76666cc100013552d1/1567468203956/NAMACB\\_Handbook+v8-13-19.pdf](https://static1.squarespace.com/static/58d3f6009f7456f359631c49/t/5d6daa76666cc100013552d1/1567468203956/NAMACB_Handbook+v8-13-19.pdf)

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## Proposal for Regulation

The Colorado Ayurvedic Medical Association (Applicant) submitted a sunrise application to the Colorado Office of Policy, Research and Regulatory Reform within the Department of Regulatory Agencies for review in accordance with the provisions of section 24-34-104.1, Colorado Revised Statutes (C.R.S.). The application identifies licensure of Ayurvedic professionals for three scopes of practice: Ayurvedic doctor (AD), Ayurvedic practitioner (AP) and Ayurvedic health counselor (AHC), collectively referred to as Ayurvedic professionals, as the appropriate level of regulation. The sunrise application did not highlight specific minimum requirements for licensure, such as the passage of an examination or minimum level of education.

The Applicant asserts that licensing Ayurvedic professionals would limit the practice of Ayurveda to those professionals who are qualified to offer complementary health-care services. Regulation will serve to protect the public seeking holistic and natural care with Ayurveda, and enable the practice of Ayurveda to be wholly integrated into the U.S. health-care system.

The Applicant submitted a mandatory continuing education application in accordance with section 24-34-901, C.R.S., requesting 30 credits of mandatory continuing education every two years. The requirements are uniform for the three disciplines and include:

- Ethics Quiz - 2 credits
- Topics on Ayurveda - 28 maximum credits - 19 minimum credits
- Optional topics in wellness - 9 credits maximum

The number and type of continuing education credits mirrors the National Ayurvedic Continuing Education initiative utilized by National Ayurvedic Medical Association professional members.

Finally, the sunrise application delineated that criminal history should be utilized in determining an Ayurvedic professional's eligibility to practice in Colorado.

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## Summary of Current Regulation

### Federal Laws and Regulations

Currently, there are no federal laws or regulations governing Ayurvedic doctors, practitioners or health counselors, collectively referred to as Ayurvedic professionals.

### The Colorado Regulatory Environment

In 2013, the General Assembly enacted the Colorado Natural Health Consumer Protection Act (Act). The Act, among other things, authorizes complementary and alternative health-care practitioners to practice without being required to obtain a license, certification or registration.<sup>22</sup> Complementary and alternative health-care services include:<sup>23</sup>

- Healing practices using food, food extracts, dietary supplements, nutrients, homeopathic remedies and preparations and the physical forces of heat, cold, water, touch, sound and light;
- Stress reduction healing practices; and
- Mind-body and energetic healing practices.

The Act also delineates numerous prohibited activities including, but not limited to:<sup>24</sup>

- Performing surgery or any invasive procedure, including a procedure that requires entry into the body through skin, puncture, mucosa, incision or other intrusive methods;
- Administering or prescribing X ray radiation to another person;
- Prescribing, administering, injecting, dispensing, suggesting or recommending a prescription or legend drug or a controlled substance or device;
- Administering ionizing radioactive substances for therapeutic purposes;
- Using a laser device that punctures the skin, incises the body or is otherwise used as an invasive instrument;
- Administering medical protocols to pregnant women or to a client who has cancer;
- Performing spinal adjustments, manipulation or mobilization; and
- Recommending the discontinuation of a course of care, including a prescription drug, that was recommended or prescribed by a health-care professional.

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<sup>22</sup> § 6-1-724(2)(f)(I), C.R.S.

<sup>23</sup> § 6-1-724(3)(b)(II), C.R.S.

<sup>24</sup> §§ 6-1-724(6)(a)(b)(c)(e)(f)(j)(l) and (s), C.R.S.

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The Act requires any person who is providing complementary and alternative health-care services to provide a written statement to clients. The statement must include the following:<sup>25</sup>

- Name, business address, telephone number and any other contact information for the practitioner;
- The fact that the complementary and alternative health-care practitioner is not licensed, certified or registered by the State of Colorado as a health care professional;
- The nature of the complementary and alternative health-care services to be provided;
- A listing of any degrees, training, experience, credentials or other qualifications the person holds regarding the complementary and alternative health-care services he or she provides;
- A statement that the client should discuss any recommendations made by the complementary and alternative health-care practitioner with the client's primary care physician, obstetrician, gynecologist, cardiologist, pediatrician or other board-certified physician; and
- A statement indicating whether or not the complementary and alternative health-care practitioner is covered by liability insurance applicable to any injury caused by an act or omission of the complementary and alternative health-care practitioner in providing complementary and alternative health care services.

Violations of the Act do not

limit the right of any person to seek relief or any other available civil or common law remedy for damages resulting from the negligence of a person providing complementary and alternative health care services.<sup>26</sup>

## Regulation in Other States

Currently, Ayurvedic professionals are not regulated in any state.

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<sup>25</sup> § 6-1-724(7)(a), C.R.S.

<sup>26</sup> § 6-1-724(11), C.R.S.

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## Analysis and Recommendations

### Public Harm

The first sunrise criterion asks:

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

Before moving forward in the analysis of harm concerning Ayurvedic doctors (ADs), Ayurvedic practitioners (APs) and Ayurvedic health counselors (AHCs), collectively referred to as Ayurvedic professionals, it is important to identify what constitutes harm to the public.

As health-care providers, it is reasonable to expect harm to come in the form of physical harm to patients.

In order to determine whether the regulation of Ayurvedic professionals is necessary to protect the public, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) staff requested that the sunrise applicant provide specific examples of harm, which are highlighted below and accompanied by COPRRR's analysis.

#### Example 1

In 2015, a lawsuit was filed in the City and County of Denver, District Court alleging deception, racketeering activity, neglect and harm visited upon the plaintiff. Generally, the lawsuit states that a company operated a "hospital" or "in-patient" medical detoxification facility. The plaintiff sought treatment from the company for alcohol dependence and abuse. The company claimed that their treatment program utilized state-of-the-art techniques for substance abuse with cutting-edge medical interventions for repairing neurotransmitters and normalizing the brain's chemistry. In order to repair the neurotransmitters, the company utilized the practice of amino acid intravenous therapy.

The company also advertised that, in addition to the amino acid intravenous therapy, they provided addiction counseling, psychotherapy, bio-feedback therapy, acupuncture and massage therapies to form a total treatment and rehabilitation program.

Also, the company claimed on the internet, in brochures and in its referral packets that it employs licensed addiction counselors, life coaches, as well as practitioners skilled in alternative healing such as addictionologists, Ayurvedic practitioners, chiropractic doctors, massage therapists and acupuncturists.

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The lawsuit was ultimately settled in 2017, and COPRRR was unable to ascertain the details of the settlement.

### **Analysis**

*This example delineates an instance where a company was accused of deception, racketeering activity, neglect and harming a consumer related to the treatment of alcohol dependence and abuse.*

*Importantly, the company, in its advertising material, referenced that it employed a variety of professionals, including Ayurvedic professionals. However, the lawsuit did not reference any instances related to Ayurvedic professionals harming consumers; instead, they were simply included in the advertising material.*

*Further, the lawsuit did not highlight substandard practice or competency-related issues related to Ayurvedic professionals, which calls into question the need for the creation of a regulatory program in Colorado.*

### **Example 2**

A 2017 article from the *Indian Journal of Gastroenterology* stated, among other things, that the use of Ayurvedic herbal medicines (AHM) may have been associated with liver dysfunction. A study, which spanned less than a year, identified 94 patients with severe liver injury who presented to outpatient clinics or emergency rooms, were observed to have been exposed to AHM. Of the 94 patients, the injuries of 2.3 percent were ascribed to AHMs. Investigators found that some of the patients had elevated levels of heavy metal and/or highly volatile organic compounds.<sup>27</sup>

Additionally, the article stated that the AHMs contained higher than permissible levels of arsenic and mercury.

### **Analysis**

*The article demonstrates instances where there may be elevated levels of dangerous chemicals that can contribute to liver issues. However, the article does not state where the patients lived, whether in the United States or elsewhere. If the patients lived in the United States and there were dangerous herbal remedies in the marketplace, the federal government may be the appropriate regulatory authority to assume oversight.*

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<sup>27</sup> Indian Journal of Gastroenterology (January-February 2018) 37(1)5-7. *Ayurvedic and Herbal Medicine-Induced Liver Injury: It Is Time to Wake Up and Take Notice*. Retrieved September 10, 2019, from <https://link.springer.com/content/pdf/10.1007%2Fs12664-018-0820-6.pdf>



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*Additionally, the article does not clearly articulate whether the patients who had liver-related issues were given AHMs by an Ayurvedic professional or if they consumed them on their own, which is an important distinction when determining whether the unregulated practice is harming consumers due to competency issues. Without additional information, it is impossible to determine whether the actions or competency of Ayurvedic professionals contributed to the adverse conditions of the patients.*

*As a result, this example does not support the need for regulation.*

### **Example 3**

In 2008, a woman in Iowa filed a lawsuit alleging intentional misrepresentation, negligent misrepresentation and conspiracy.

According to an *Iowa Gazette* article, the woman was prescribed the herb Garbhupal Ras when she was four months pregnant. The woman began feeling lethargic, her hands and feet went numb and she suffered severe back and abdominal pain.<sup>28</sup>

The woman had tests done and they showed she had a blood lead level of 102 micrograms per deciliter, which is more than 20 times the level considered safe by the U.S. Centers for Disease Control and Prevention. The woman underwent chelation therapy while pregnant, but her child was born with an elevated blood lead level of 60 micrograms per deciliter.<sup>29</sup>

Tests conducted by the Iowa Department of Public Health indicated that the herb Garbhupal Ras was comprised of nearly three percent lead.<sup>30</sup>

### **Analysis**

*The article identified an instance where the recommendation of the Ayurvedic professional to use the herb Garbhupal Ras appeared to harm the consumer (the woman and her child). The herb contained elevated levels of lead.*

*Importantly, the article does not mention the outcome of the lawsuit. Therefore, it is impossible to conclude if intentional misrepresentation, negligent misrepresentation or conspiracy occurred.*

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<sup>28</sup> *Iowa Gazette*. “Vedic City Women Charges Herbs Caused Lead Poisoning: Sues Maharishi Corporations.” Retrieved September 10, 2019, from <http://yadlachim.org/?CategoryID=194&ArticleID=639>

<sup>29</sup> *Iowa Gazette*. “Vedic City Women Charges Herbs Caused Lead Poisoning: Sues Maharishi Corporations.” Retrieved September 10, 2019, from <http://yadlachim.org/?CategoryID=194&ArticleID=639>

<sup>30</sup> *Iowa Gazette*. “Vedic City Women Charges Herbs Caused Lead Poisoning: Sues Maharishi Corporations.” Retrieved September 10, 2019, from <http://yadlachim.org/?CategoryID=194&ArticleID=639>

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*Also, this example does not highlight any issues associated with competency related to the Ayurvedic professional. Instead, it identifies an instance where the herb contained elevated levels of lead. This appears to be an issue with the product (Garbhupal Ras) rather than the direct actions of the Ayurvedic professional.*

*As a result, regulation of the profession would not address this unfortunate incident because it was not competency related, which calls into question the need to implement regulatory oversight of Ayurvedic professionals.*

#### **Example 4**

A 2019 article in the *Vancouver Sun* illustrated concerns with herbs that contain elevated levels of lead in Canada. In fact, the article states, among other things, that a company in Canada had its natural health products license canceled due to concerns with good practices in manufacturing, packaging and labelling of products.<sup>31</sup>

Additionally, the article stated that a 64-year-old Canadian man suffered from toxic lead poisoning after taking an Ayurvedic herbal remedy he purchased in India in order to treat his diabetes.<sup>32</sup>

#### **Analysis**

*This example illustrates concerns with manufacturing, packaging and labeling of herbal products in Canada, as well as the lead poisoning of a Canadian man after taking Ayurvedic herbal remedies he purchased in India.*

*The example does not highlight any issues associated with Ayurvedic professionals harming consumers through the practice of Ayurveda. Instead, it illustrates issues with herbal remedies. Since this example does not demonstrate consumer harm related to the practice of Ayurveda, it does not support the need for regulation.*

#### **Example 5**

This example was derived from an internet article, *Complementary & Alternative Medicine Law Blog*, which contains questions as to whether the practice of Ayurveda crosses into the unlicensed practice of several regulated professions. For instance, the article questions whether certain techniques within Ayurveda such as pulse diagnosis and herbal recommendations would be

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<sup>31</sup> *Vancouver Sun*. "Lead and Mercury Poisonings in Herbal Products Prompt Surrey Clinic Shutdown." Retrieved September 10, 2019, from <https://vancouversun.com/news/local-news/lead-and-mercury-poisonings-in-herbal-products-prompt-clinic-shutdowns-recalls-warnings-and-new-rules>

<sup>32</sup> *Vancouver Sun*. "Lead and Mercury Poisonings in Herbal Products Prompt Surrey Clinic Shutdown." Retrieved September 10, 2019, from <https://vancouversun.com/news/local-news/lead-and-mercury-poisonings-in-herbal-products-prompt-clinic-shutdowns-recalls-warnings-and-new-rules>

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considered diagnosing, treating or prescribing, and whether these recommendations cross into the realm of practicing medicine without a license.

The article also questions, among other issues, whether spa treatments could potentially cross into the field of cosmetology and massage therapy; both professions require a state license to practice.<sup>33</sup>

### Analysis

*This article does not highlight any instances where Ayurvedic professionals harmed consumers. Instead, it details uncertainty concerning whether some of the techniques used by Ayurvedic professionals cross into professions that require a license.*

*This article did not detail any instances where unregulated Ayurvedic professionals were harming consumers. Therefore, the example does not support the need for regulation.*

### Example 6

This example was extrapolated from a *Los Angeles Times* newspaper article dated August 1, 2005. The article stated that a self-described Ayurvedic spiritualist provided services to clients. He was charged with practicing medicine without certification, illegally possessing a controlled substance and defrauding a client of more than \$200,000.<sup>34</sup>

There was also an allegation that the Ayurvedic spiritualist sexually assaulted one of his clients and her stepdaughter.

### Analysis

*The example presented above details serious allegations against the Ayurvedic spiritualist, such as practicing medicine without the required credentials, possessing controlled substances, defrauding a client and sexual assault.*

*Importantly, this article is more than 15 years old, and the Ayurvedic spiritualist was in California not Colorado. But if this situation did occur in Colorado, there are several tools available to address the allegations.*

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<sup>33</sup> Cam Law Complementary & Alternative Medicine Law Blog. *Holistic Healing Laws Practice if Ayurveda*. Retrieved September 10, 2019, from <https://www.camlawblog.com/articles/health-trends/holistic-healing-laws-practice-of-ayurveda/>

<sup>34</sup> *Los Angeles Times*. "Topanga Healer Facing Legal Ills" Retrieved September 10, 2019, from <https://www.latimes.com/archives/la-xpm-2005-aug-01-me-babu1-story.html>

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*First, if the Ayurvedic spiritualist was in Colorado and a complaint was filed with the Colorado Medical Board alleging that he was practicing medicine without a license, the Medical Board could issue a cease and desist order, which could address the continued practice of medicine by the professional.*

*Also, if the Ayurvedic spiritualist illegally possessed a controlled substance, defrauded a client or sexually assaulted two women, he could have been prosecuted through the criminal justice system, which ensures a level of protection to consumers from these types of harm.*

*Since there are existing mechanisms in place to protect consumers, from the types of harm described her, the addition of a regulatory program related to Ayurvedic professionals is unnecessary.*

### **Example 7**

In 2004, the Centers for Disease Control and Prevention (CDC) issued a publication indicating that from 2000 to 2003, there were 12 cases of lead poisoning among adults in five states who consumed Ayurvedic medications.

The following examples were highlighted in the CDC article:<sup>35</sup>

- A woman in New Hampshire was admitted to the emergency room with diffuse abdominal pain, nausea and vomiting. Tests revealed that she had elevated levels of lead in her blood. She reported that she obtained Ayurvedic medications from an Ayurvedic professional in India.
- A woman in California visited an emergency room with nausea, vomiting and lower abdominal pain. The woman had elevated levels of lead in her blood. The woman reported taking nine different Ayurvedic medications from an Ayurvedic professional in India.
- A California man visited an emergency room for back and abdominal pain. The man had elevated levels of lead in his blood. The man reported that he took Ayurvedic medications from an Ayurvedic professional in India.

### **Analysis**

*The CDC article illustrates that there were issues associated with lead poisoning most likely associated with taking Ayurvedic medications. The common variable in each of the examples was that the patients consumed the medications in India, not the United States.*

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<sup>35</sup> Centers for Disease Control and Prevention. *Lead Poisoning Associated with Ayurvedic Medications---Five States, 2000–2003*. Retrieved September 10, 2019, from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5326a3.htm>

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*Additionally, the article did not highlight instances where the Ayurvedic professionals lacked competency to practice or even harmed consumers. Instead, the article identified issues associated with the Ayurvedic medications. Since no competency issues were identified, the article calls into question the need to regulate Ayurvedic professionals in Colorado.*

### **Example 8**

Quackwatch published an article related to Ayurvedic medicine and professionals. The article detailed a lawsuit filed in 1995 alleging that an Ayurvedic professional represented himself as a licensed health professional and treated a patient with leukemia. After treating the patient, the health professional declared that the leukemia had been eradicated. However, the leukemia had not been eradicated, and the patient died four months later.<sup>36</sup>

The article also stated that in 2003, a survey of 14 out of 70 Ayurvedic products that are manufactured in South Asia and sold in the Boston area contained elevated levels of lead, mercury and/or arsenic that exceed regulatory standards.<sup>37</sup>

### **Analysis**

*The article details an instance where an Ayurvedic professional represented himself as a licensed health professional, which is a violation of the current Medical Practice Act. As such, if this example would have occurred in Colorado, the Medical Board could have issued a cease and desist order to the person.*

*Also, this example highlights issues with Ayurvedic products that may contain unsafe levels of lead, mercury and/or arsenic. Importantly, these elevated levels are product-related issues and not related to the competency Ayurvedic professionals. As such, it is questionable whether regulation of Ayurvedic professionals is necessary.*

In an attempt to identify consumer harm related to Ayurvedic professionals, Colorado Office of Policy, Research and Regulatory Reform staff contacted a number of organizations, including: the Attorney General's Office, Consumer Protection Section; Colorado Medical Board staff; the Colorado Medical Society; Division of Professions and Occupations staff, who provide administrative support for the regulation of naturopathic doctors; and the Better Business Bureau serving Greater Denver and Central Colorado. Each of the aforementioned organizations stated that they had not received any complaints against Ayurvedic professionals in the past few years.

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<sup>36</sup> Quackwatch. *A Few Thoughts on Ayurvedic Mumbo-Jumbo*. Retrieved September 10, 2019, from <https://www.quackwatch.org/04ConsumerEducation/chopra.html>

<sup>37</sup> Quackwatch. *A Few Thoughts on Ayurvedic Mumbo-Jumbo*. Retrieved September 10, 2019, from <https://www.quackwatch.org/04ConsumerEducation/chopra.html>

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Therefore, it is reasonable to conclude that Ayurvedic professionals are not causing widespread harm to consumers who utilize their services.

Also, most of the examples highlighted above indicate that the consumer harm is product-related, not practice-related, which calls into question the need to regulate Ayurvedic professionals.

## **Need for Regulation**

The second sunrise criterion asks:

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

This criterion addresses the proposition of whether the state should require a certain level of education and/or impose a requirement that ADs, APs, and AHPs acquire a certain level of education and/or pass an examination before practicing in Colorado.

This sunrise review has determined that there is insufficient evidence to conclude that the unregulated practice of Ayurveda harms the public. As such, there is insufficient evidence to justify requiring Ayurvedic professionals to possess a minimum level of education or pass an examination in order to practice in Colorado. As a result, the implementation of minimum requirements could potentially impose an unnecessary barrier to entry for professionals.

There is no need to demonstrate initial competency, so the need for mandatory continuing education appears to also be unnecessary.

## **Alternatives to Regulation**

The third sunrise criterion asks:

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

Public protection for consumers who utilize Ayurvedic professionals could potentially be realized in a more cost-effective manner by requiring APs and AHCs to obtain a certification from the National Ayurvedic Medical Association Certification Board (NAMACB).

According to representatives with the National Ayurvedic Medication Association, the certification for ADs will be available in October 2019.

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NAMACB requires APs and AHCs to pass an examination. The examinations test the following:

- Foundations of Ayurveda,
- Concepts of Ayurveda,
- Assessment and diagnosis,
- Recommendations,
- Treatment and interventions, and
- Categories of Cikitsa.

The NAMACB Ethics and Disciplinary Review Panel may deny an application for certification for any of the following:<sup>38</sup>

- Misrepresentation of any item on the application;
- Conviction of a criminal felony that may indicate lack of moral fitness to practice a health-care profession/healing art;
- Having been judged liable in a judicial or administrative proceeding based upon allegations related to professional competence or other conduct related to a health-care profession/healing art; or
- Currently facing a limitation, suspension or revocation of a license to practice a health-care profession in any U.S. state or regulation that relates to a health-related profession.

The sunrise review did not identify any instances of harm to consumers by Ayurvedic professionals concerning competency. As such, implementing a requirement that these professionals achieve a certification from the Board prior to practicing is unnecessarily restrictive.

## Collateral Consequences

The fourth sunrise criterion asks:

Whether the imposition of any disqualifications on applicants for licensure, certification, re-licensure, or re-certification based on criminal history serves public safety or commercial or consumer protection interests.

The sunrise application delineated that criminal history should be utilized in determining an Ayurvedic professional's eligibility to practice in Colorado.

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<sup>38</sup> National Ayurvedic Medical Association Certification Board. *Certification Handbook*. P14. Retrieved August 9, 2019, from [https://static1.squarespace.com/static/58d3f6009f7456f359631c49/t/5d6daa76666cc100013552d1/1567468203956/NAMACB\\_Handbook+v8-13-19.pdf](https://static1.squarespace.com/static/58d3f6009f7456f359631c49/t/5d6daa76666cc100013552d1/1567468203956/NAMACB_Handbook+v8-13-19.pdf)

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Importantly, the examples of harm identified for this sunrise review contained few substantiated instances concerning criminal conduct that harmed consumers.

As such, the imposition of a background check to identify issues that would disqualify Ayurvedic professionals from practicing in Colorado appears to be an unnecessary requirement.

## Conclusion

The sunrise application requested licensure, which is the most restrictive form of regulation, for Ayurvedic professionals. Further, the sunrise application states that licensing Ayurvedic professionals would enable Ayurveda to be wholly integrated into the U.S. health-care system in order to:

- Give clients/patients access to the full range of health-care options,
- Prevent drug/herb interactions by regulating scopes of practice,
- Prevent unqualified practitioners from making suggestions that would otherwise be contraindicated given a client/patient's pre-existing condition or medical diagnosis, and
- Ensure that Ayurveda recommendations be given in coordination and cooperation with the client/patient's licensed health-care team.

Currently, there are safeguards in place to provide protections to consumers related to complementary and alternative health-care practitioners. The Colorado Natural Health Consumer Protection Act (Act), among other things, authorizes complementary and alternative health-care practitioners to practice without being required to obtain a license, certification or registration.<sup>39</sup>

The Act also delineates numerous prohibited activities including, but not limited to:<sup>40</sup>

- Performing surgery or any invasive procedure, including a procedure that requires entry into the body through skin, puncture, mucosa, incision or other intrusive method;
- Administering or prescribing X-ray radiation to another person;
- Prescribing, administering, injecting, dispensing, suggesting or recommending a prescription or legend drug or a controlled substance or device; and
- Administering ionizing radioactive substances for therapeutic purposes.

Essentially, Ayurvedic professionals are able to practice under the Act, but cannot perform any of the aforementioned prohibited services. The implementation of the Act serves to protect consumers by limiting the type of complementary and alternative health-care services that can be offered to consumers.

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<sup>39</sup> § 6-1-724(2)(f)(l), C.R.S.

<sup>40</sup> §§ 6-1-724(6)(a)(b)(c)(e)(f)(j)(l) and (s), C.R.S.



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Additionally, the National Ayurvedic Medical Association Certification Board (Board) offers certifications for Ayurvedic practitioners and Ayurvedic health counselors. Importantly, certification for Ayurvedic doctors will not be available from the Board until October 2019. Requiring Ayurvedic professionals to obtain a certification prior to practice in Colorado is an alternative to state regulation. However, the sunrise review did not identify any instances of harm to consumers by Ayurvedic professionals concerning competency. As such, implementing a requirement that these professionals achieve a certification from the Board prior to practicing is unnecessarily restrictive.

In an attempt to identify consumer harm related to Ayurvedic professionals, Colorado Office of Policy, Research and Regulatory Reform staff contacted a number of organizations, including: the Attorney General's Office, Consumer Protection Section; Colorado Medical Board staff; the Colorado Medical Society; Division of Professions and Occupations staff, who provide administrative support for the regulation of naturopathic doctors; and the Better Business Bureau serving Greater Denver and Central Colorado. Each of the aforementioned organizations stated that they had not received any complaints against Ayurvedic professionals in the past few years. Therefore, it is reasonable to conclude that Ayurvedic professionals are not causing widespread harm to consumers who utilize their services.

In sum, implementing a program to provide regulatory oversight of Ayurvedic professionals is not necessary for several reasons. First, the majority of examples of harm did not include the actions of Ayurvedic professionals harming consumers. Instead, these examples highlighted the dangers of herbal medicines that contain elevated levels of, among other things, lead and mercury. Most of the herbal medicines were obtained in India. As such, the issue, or potential issue, within the Ayurvedic community is product-related, not competency or practice-related. That is, the products appear to have the potential for harming consumers as opposed to the professionals, who are the subject of this sunrise review.

As a result, the limited examples of harm to the public concerning Ayurvedic professionals identified during this sunrise review do not justify regulatory oversight in Colorado.

**Recommendation - Do not regulate Ayurvedic professionals in Colorado.**