Sunrise Analysis: Regulation of Herbal Therapists

A Report to the Governor and the Legislature of the State of Hawai‘i

Report No. 14-14
December 2014

THE AUDITOR
STATE OF HAWAI‘I

Office of the Auditor

The missions of the Office of the Auditor are assigned by the Hawai‘i State Constitution (Article VII, Section 10). The primary mission is to conduct post audits of the transactions, accounts, programs, and performance of public agencies. A supplemental mission is to conduct such other investigations and prepare such additional reports as may be directed by the Legislature.

Under its assigned missions, the office conducts the following types of examinations:

1. Financial audits attest to the fairness of the financial statements of agencies. They examine the adequacy of the financial records and accounting and internal controls, and they determine the legality and propriety of expenditures.

2. Management audits, which are also referred to as performance audits, examine the effectiveness of programs or the efficiency of agencies or both. These audits are also called program audits, when they focus on whether programs are attaining the objectives and results expected of them, and operations audits, when they examine how well agencies are organized and managed and how efficiently they acquire and utilize resources.

3. Sunset evaluations evaluate new professional and occupational licensing programs to determine whether the programs should be terminated, continued, or modified. These evaluations are conducted in accordance with criteria established by statute.

4. Sunrise analyses are similar to sunset evaluations, but they apply to proposed rather than existing regulatory programs. Before a new professional and occupational licensing program can be enacted, the statutes require that the measure be analyzed by the Office of the Auditor as to its probable effects.

5. Health insurance analyses examine bills that propose to mandate certain health insurance benefits. Such bills cannot be enacted unless they are referred to the Office of the Auditor for an assessment of the social and financial impact of the proposed measure.

6. Analyses of proposed special funds and existing trust and revolving funds determine if proposals to establish these funds are existing funds meet legislative criteria.

7. Procurement compliance audits and other procurement-related monitoring assist the Legislature in overseeing government procurement practices.

8. Fiscal accountability reports analyze expenditures by the state Department of Education in various areas.

9. Special studies respond to requests from both houses of the Legislature. The studies usually address specific problems for which the Legislature is seeking solutions.

Hawai‘i’s laws provide the Auditor with broad powers to examine all books, records, files, papers, and documents and all financial affairs of every agency. The Auditor also has the authority to summon persons to produce records and to question persons under oath. However, the Office of the Auditor exercises no control function, and its authority is limited to reviewing, evaluating, and reporting on its findings and recommendations to the Legislature and the Governor.

THE AUDITOR
STATE OF HAWAI‘I
Kekuanao‘a Building
465 S. King Street, Room 500
Honolulu, Hawai‘i 96813

Sunrise Analysis: Regulation of Herbal Therapists

Report No. 14-14, December 2014

Regulation of herbal therapists is not warranted

Office of the Auditor
465 S. King Street
Rm. 500
Honolulu, HI 96813
Ph. (808) 587-0800

Jan K. Yamane
Acting State Auditor
State of Hawai'i

The primary guiding principle for legislators should be whether or not an unregulated profession presents a clear and present danger to the public's health, safety, and welfare. If the answer is no, regulation is unnecessary and wastes taxpayers' money.

— Council on Licensure, Enforcement and Regulation

Recommendations

Responses

Prior Studies

For the full text of this and other reports, visit our website: http://auditor.hawaii.gov/

Proposed measure contradicts existing law and is problematic

Senate Bill No. 2439 of the 2014 regular session proposes to establish new regulatory requirements for individuals engaging in the practice of herbal therapy. The bill defines an herbal therapist as "a person with knowledge, skills, and experience in the direct personal health care of individuals based on herbal practices, including the utilization of herbal formulas to improve health and wellness, and who has met the standards and requirements pursuant to a license issued under this chapter."

The purpose of the bill is to establish licensing requirements for contemporary herbal healers from all ancestries and for the benefit of the public as a whole. Licensing requirements would apply to any person who practices, offers to practice, or advertises the practice of herbal therapy, except those covered under Act 162, Session Laws of Hawai'i 1998, *Relating to the Practice of Medicine*. The bill also proposes a five-member board of herbal therapy to establish exam qualification requirements, issue licenses, establish fees and fines, and carry out disciplinary actions, among other powers and duties.

Under current law, traditional Native Hawaiian healers who have been recognized by a kūpuna council convened by Papa Ola Lokahi, a Native Hawaiian health board, are exempt from all provisions under Chapter 453, HRS, *Medicine and Surgery*. The intent of this law was to allow traditional Native Hawaiian healers to provide medical care for patients and place the traditional Hawaiian healing community (rather than the state) in charge of certifying healers. SB No. 2439 (2014) seeks to reverse this law by making the government, through a board of herbal therapy, responsible for determining who is qualified to engage in traditional Native Hawaiian healing. Furthermore, in addition to minor technical flaws in the bill, SB No. 2439 places the burden of establishing standards for qualification on the board, which may prove an extremely difficult task.

Regulation of herbal therapists does not meet sunrise criteria

The *Hawai'i Regulatory Licensing Reform Act*, Chapter 26H, HRS, limits regulation of certain professions and vocations to situations in which it is reasonably necessary to protect the health, safety, and welfare of consumers. Proponents of regulation could not provide evidence that herbal therapy presents a clear and present danger to consumers. Moreover, the reason behind the proposed regulation is proponents' attempt to seek licensing in order to practice traditional Native Hawaiian medicine without going through the kūpuna council recognition process provided in existing law. If SB No. 2439 were enacted, Hawai'i would become the first state in the nation to regulate herbal therapists. The cost of regulation would likely be prohibitive since it would be spread among a small number of herbal therapist licensees; and existing alternatives to regulation—specifically, state and federal agencies—provide an adequate degree of protection for consumers.

Agency response

The Department of Commerce and Consumer Affairs shared our concern that regulation of herbal therapists could artificially increase the costs of herbal therapy to consumers. The department also concurred with our conclusion that Section 453-2(c), HRS, already provides an appropriate process for review and approval of Native Hawaiian healers.

Sunrise Analysis: Regulation of Herbal Therapists

A Report to the Governor and the Legislature of the State of Hawai‘i

Submitted by

THE AUDITOR
STATE OF HAWAI‘I

Report No. 14-14
December 2014

Foreword

This analysis of the need to regulate herbal therapists was prepared in response to Senate Concurrent Resolution No. 31, Senate Draft 1, of the 2014 Legislative session, which asked us to examine the regulation of herbal therapists proposed in Senate Bill No. 2439 of the 2014 legislative session. The report presents our findings and recommendations on whether regulating herbal therapists complies with policies in Hawai‘i’s “sunrise” law (Chapter 26H, Hawai‘i Revised Statutes) and the probable effects of the proposed regulation.

We wish to express our appreciation for the cooperation and assistance extended by staff of the Department of Commerce and Consumer Affairs and other organizations and individuals whom we contacted during the course of our evaluation.

Jan K. Yamane
Acting State Auditor

Table of Contents

List of Exhibits

Chapter 1
Introduction

This report responds to Senate Concurrent Resolution No. 31, Senate Draft 1 (SCR No. 31, SD 1), of the 2014 Legislature, which requests the Auditor to conduct a sunrise review of the licensure and regulation of herbal therapists as proposed in Senate Bill (SB) No. 2439, Regular Session of 2014.

The *Hawai‘i Regulatory Licensing Reform Act*, Chapter 26H, Hawai‘i Revised Statutes (HRS), requires the Auditor to analyze new regulatory measures that would subject unregulated professions and vocations to licensing or other regulatory controls. These analyses are known as "sunrise" reviews. The Auditor must assess whether the proposed regulation is necessary to protect the health, safety, and welfare of consumers and is consistent with other regulatory policy provisions of the act. In addition, the Auditor must examine the probable effects of the proposed regulation and assess alternative forms of regulation.

Background

Herbal medicine—also known as herbalism, botanical medicine, or phytomedicine—is a medical approach based on the use of plants or plant extracts that may be consumed or applied to the skin. Since ancient times, herbal medicine has been used by many different cultures throughout the world to treat illness and to assist bodily functions. Written records of the use of herbal medicine date back more than 5,000 years.[1] For most of history, herbal medicine was the only type of medicine. To this day, as many as one third to one half of modern drugs were originally derived from plants.

Herbal products are complex mixtures of organic chemicals that may come from any raw or processed part of a plant, including leaves, stems, flowers, roots, and seeds. Herbal remedies in the form of extracts, tinctures, capsules, and tablets as well as teas may be recommended by healthcare practitioners of many different disciplines in treating a wide variety of medical conditions. Nearly 20 percent of adults in the U.S. report taking an herbal product.[2]

Herbal supplements are classified as dietary supplements by the U.S. *Dietary Supplement Health and Education Act* of 1994. That means herbal supplements—unlike prescription drugs—can be sold without

[1] National Geographic Society

[2] U.S. National Library of Medicine

being tested to prove they are safe and effective. However, herbal supplements must be made according to good manufacturing practices.

The most commonly used herbal supplements in the U.S. include echinacea, St. John's wort, ginkgo, garlic, saw palmetto, and ginseng. Herbal medicine is used to treat a wide variety of conditions, including asthma, eczema, premenstrual syndrome, rheumatoid arthritis, migraine, menopausal symptoms, chronic fatigue, irritable bowel syndrome, and cancer.

Herbs are generally available in several different forms: teas, syrups, oils, liquid extracts, tinctures, and dry extracts (pills or capsules). Teas can be made from dried herbs that are soaked for a few minutes in hot water, or by boiling herbs in water and then straining the liquid. Syrups made from concentrated extracts and added to sweet tasting preparations are often used for sore throats and coughs. Oils are extracted from plants and often used as rubs for massage, either by themselves or as part of an ointment or cream.

Healthcare providers who commonly rely on herbal medicine for treatment include naturopaths and practitioners of traditional Chinese medicine and Ayurvedic medicine, which originated in India. Herbalists, chiropractors, and pharmacists may also use herbs to treat illness. Massage therapists use herbs and their aromatic oils (also known as essential oils) to relieve aches and pains or inflammation. Some medical doctors and osteopathic physicians also recommend herbal remedies during office visits.

Herbal therapists in Hawai'i

As of July 2014, there were more than 9,000 licensed complementary and alternative medicine (CAM) providers in Hawai'i. These included 698 acupuncturists, 464 chiropractors, 769 osteopaths, 7,295 massage therapists, and 119 naturopaths. Many members of these professions include herbal therapy in their practices. In addition, although only the laws for acupuncturists and naturopaths specifically include herbal medicine in their scope of practice, no law prevents other health care professionals from doing the same. There is only one herbal practitioner in Hawai'i who has met the criteria for professional membership in the American Herbalists Guild, and this individual is also a licensed naturopath.

Traditional Chinese medicinal healers

There are an estimated 15 herb shops in Honolulu's Chinatown. The shops have shelves of jars or small drawers containing various dried herbs. Labels are generally in Chinese, and there are no familiar brand names. Exhibit 1.1 shows a Chinese herbal medicine store.

Exhibit 1.1
Photo of a Chinese Herbal Medicine Shop in Downtown Honolulu

Source: Institute for Clinical Acupuncture and Oriental Medicine

One downtown Honolulu doctor of acupuncture stated there are many categories of herbal medicine, and each vendor has a unique system of practice. There are about 5,000 species of herbs, of which about 2,000 are used as medicines. Some are more frequently prescribed than others; a typical dispensary stocks about 500 herbs. A visit to an herbalist usually begins with a discussion about the patient's health, including eating and sleeping habits, followed by a pulse check and examination of the tongue. Herbal treatments account for only half the scope of Chinese medicine, which treats the body as a whole and only occasionally targets a specific disease—in contrast to Western medicine.

Chinese herbs are rarely taken as a single dose. In a typical transaction, several items are packaged into a mix that one boils to a soup or tea. Treatment for a slight cold takes at least seven herbs; a serious flu might take 24. The prescription might consist of buds, twigs, seaweed, tree bark, roots, and seeds. More exotic products include sea cucumbers, seahorses, lizards, deer musk glands, shark fins, antlers, and crocodile bile. A boiled-down concoction is digested so the natural ingredients can work in the bloodstream.

Traditional Hawaiian medicinal healers

Hawaiian herbal healers are individuals of Hawaiian ancestry whose knowledge, skill, and experience are based on demonstrated learning of Hawaiian healing practices acquired by direct association with Hawaiian kūpuna (elders) and oral traditions.[3] These healers, known as kahūna laʻau lapaʻau (traditional Hawaiian medicinal healers), treat people who have physical and psychosocial problems with the use of prayers and laʻau (herbs).

The area of traditional laʻau lapaʻau relates to the commonly used laʻau or plant, animal, or mineral products that come from the land and ocean. In traditional Hawaiian medicine, medical kahūna (healers) used careful observation and palpation in making a diagnosis and used herbs in conjunction with massage, manipulation, bone setting, and heat or hydrotherapy. Healers followed a rigorous course of training, sometimes studying for decades. One method of learning anatomy and symptoms involved using a papaʻiliʻili (pebble diagram), laid out in the form of a body. All healing involved a large spiritual component and prayers and chants accompanied every stage from gathering plants to the final pani (ritual end of the treatment).

A *Pacific Health Dialog* research paper included a study of ten healers, varying in age, gender, occupation, education, and years of traditional Hawaiian healing knowledge. Ages ranged from 49 to 87 years, the mean being 70.3 years; 80 percent (eight) were female and 20 percent (two) male. The ten healers represented a total of 316 years of traditional Hawaiian healing knowledge. Criteria used by the healers when selecting laʻau are smell, taste, color of leaves, healthy appearance, and place where it grows. The ten participating healers ranked the following five laʻau as the most important: popolo, uhaloa, hauoi, kukui, and olena.

[3] *Pacific Health Dialog*

Exhibit 1.2
Photos of Hawaiian Medicinal Plants

Popolo (left) and uhaloa (right) are two of the most important herbs in Hawaiian medicine.

Source: Nick Sakovich, The Hawai'i Institute of Healing Arts

The Pacific Health study noted that, according to the healers, 80 percent of Hawaiian healing is spiritual and 20 percent involves the use of la'au. Emphasis within traditional healing is on caring for the whole person—body, mind, and spirit. An individual's spiritual, as well as psychological and sociological, needs are met through prayer before any physical healing takes place. Healers recognize and refer patients with symptoms of serious diseases and conditions (such as heart problems, diabetes, and cancer) to Western physicians for diagnosis. After a diagnosis is made, patients can return to the healer. The majority of healers advise a patient to inform their Western physician before beginning la'au treatment.

Education and training of herbal therapists

The American Herbalists Guild (AHG) reports that no state in the U.S. legally recognizes herbal therapists as accepted members of the health care profession. The AHG is not an accrediting body and does not evaluate schools. However, the AHG does offer guidelines for core competencies in an herbal education. AHG educational guidelines were developed to provide a framework for individuals and schools seeking to develop a comprehensive botanical medicine educational curriculum.

Acupuncturists and naturopaths both have national education and training standards. These two complementary health practices have U.S. Department of Education (DOE)-authorized organizations that accredit education and training programs, which generally consist of four years of schooling in their respective disciplines. Both also have professional organizations that offer certification examinations to graduates of accredited education and training programs. There is also a national organization that represents the Ayurvedic profession in the U.S. The

National Ayurvedic Medical Association, which is not DOE-accredited, provides scopes of practices for three levels of Ayurvedic professionals in the U.S.

Exhibit 1.3 shows the professional organizations, DOE accrediting organizations, and educational requirements for CAM practices in the U.S., which generally include herbal remedies.

Exhibit 1.3
CAM Practices, Professional and Accrediting Bodies, and Educational Requirements

Practice	National Body	DOE Accrediting Organization	Educational Requirements
Acupuncture and oriental medicine	National Certification Commission of Acupuncture and Oriental Medicine	Accreditation Commission for Acupuncture and Oriental Medicine	Four years at master's degree level
Naturopathy	North American Board of Naturopathic Examiners	Council on Naturopathic Medical Education	Four-year Doctor of Naturopathy or Doctor of Naturopathic Medicine program
Ayurvedic medicine	National Ayurvedic Medical Association	N/A	*Ayurvedic Health Counselor* – 600 to 1,000 hours *Ayurvedic Practitioner* – 1,500 to 2,500 hours *Ayurvedic Doctor* – 3,000 to 4,500 hours
Therapeutic herbalism	American Herbalists Guild	N/A	1,600 hours, including 400 hours of clinical work

Source: Office of the Auditor

Senate Bill No. 2439

Senate Bill No. 2439 (2014) proposes to establish new regulatory requirements for individuals engaging in the practice of herbal therapy. The bill defines an herbal therapist as:

> . . . a person with knowledge, skills, and experience in the direct personal health care of individuals based on herbal practices, including the utilization of herbal formulas to improve health and wellness, and who has met the standards and requirements pursuant to a license issued under this chapter.

The Legislature expressed in the bill's preamble that herbal therapy is a complementary and alternative approach for improving the health and wellness of individuals and for treatment of illness, and as such affects public health, safety, and welfare.

The purpose of the bill is to establish licensing requirements for contemporary herbal healers from all ancestries and for the benefit of the public as a whole. Licensing requirements are to apply to any person who practices, offers to practice, or advertises the practice of herbal therapy, except those covered under Act 162, Session Laws of Hawai‘i (SLH) 1998, *Relating to the Practice of Medicine*. The bill also proposes a five-member board of herbal therapy to establish exam qualification requirements, issue licenses, establish fees and fines, and carry out disciplinary actions, among other powers and duties.

Exemption for traditional Hawaiian healers covered by Act 162, SLH 1998

In 1868, the Kingdom of Hawai‘i established the Hawaiian Board of Health to examine Native Hawaiians' fitness to practice medicine, including traditional Hawaiian medicine. In 1893, the Kingdom of Hawai‘i was overthrown and a new republic formed in 1894. The republic created its own laws and repealed many of the Kingdom's laws, including those concerning kahūna and traditional Native Hawaiian healing. In 1919, the Territorial Legislature passed a bill allowing traditional Hawaiian healers to practice medicine after receiving a license from the Board of Health. By the 1940s, the Board of Health created a Board of Examiners that required applicants to pass a test to be eligible for licensure. By the time Hawai‘i became a state in 1959, the law permitting the practice of Hawaiian medicine was deemed obsolete. In 1965, the 1919 law that licensed Hawaiian medicinal practices was repealed as part of an omnibus bill to repeal obsolete laws.

In response to the rapid decline of kahūna and in an effort to preserve traditional Hawaiian healing practices, in 1998 the Legislature passed Act 162, now codified as Section 453-2(c), HRS. Act 162 established a process for continuing the role of traditional Hawaiian healing practices in the recognized and authorized medical arts. The act also exempted traditional Native Hawaiian healers recognized and certified by the panel convened by Papa Ola Lokahi, from statutory provisions relating to the Practice of Medicine in Chapter 453-2, HRS. *Papa Ola Lokahi* refers to the Native Hawaiian Health board described and defined in Public Law No. 102-396, the *Native Hawaiian Health Care Improvement Act* of 1992. *Traditional Hawaiian healing practices* refers to la‘au lapa‘au, la‘au kahea, lomi lomi, ho‘oponopono, and similar practices performed by traditional Native Hawaiian healers.

In 2001 and 2005, the Legislature enacted additional measures which continue to place the authority for recognizing traditional Native Hawaiian healers under the sole jurisdiction of kūpuna councils convened by Papa Ola Lokahi.

Impetus for and testimony on SB No. 2439

Testimony in support of the resolution requesting this sunrise review and on SB No. 2439 was predominantly from students and practitioners involved in traditional Native Hawaiian medicine. The legislator who introduced SCR 31 and SB No. 2439 was approached by students of a late kumu (teacher) who taught Hawaiian herbal medicine classes at the University of Hawai‘i and whose vision was to spread and perpetuate traditional Native Hawaiian healing practices. Traditionally, Native Hawaiian healers do not accept money for their services, treating it as a gift to their patients. According to their written testimony, the late kumu's students want to be able to practice their healing arts full-time, be compensated for those services, and are seeking licensing and regulation in order for their practice to be covered by health insurance.

Herbal therapy is not regulated in any other state

The National Center for Complementary and Alternative Medicine (NCCAM), the federal government's lead agency for scientific research on health interventions, practices, products, and disciplines that originate outside conventional medicine, noted there is no standardized, national system for credentialing complementary health practitioners. State and local governments are responsible for deciding what credentials practitioners must have to work in their jurisdiction.

Currently, no states regulate herbal therapists. However, in some states, including Hawai‘i, naturopathic and acupuncture licensing laws include natural or herbal remedies within the scope of the licensed practice. There are currently no licensing laws in the U.S. that preclude other health professionals or lay persons from using, dispensing, or recommending herbal medicine.

Prior Studies

We have not conducted any studies related to herbal therapists. However, we have published ten sunset evaluation and update reports, one sunrise analysis, one study on the licensing of massage schools, and three proposed mandatory health insurance studies on other complementary and alternative medicine practices, all of which require licensing in Hawai‘i. Exhibit 1.4 lists these reports.

Exhibit 1.4
Prior LAO Reports Relating to CAM Practices

Report No./Title	Profession or Occupation
1. 95-28, *Study of Proposed Mandatory Health Insurance for Acupuncture Services* (1995) 2. 87-20, *Sunset Evaluation Update – Acupuncture* (1987) 3. Unnumbered, *Sunrise Analysis of Proposals to Regulate the Practice of Acupuncture* (February 1985) 4. 84-6, *Sunset Evaluation Report – Acupuncture* (1984)	Acupuncture, Ch. 436E, HRS (previously Ch. 436D, until repealed in 1982)
5. 88-9, *Study of Proposed Mandatory Health Insurance for Chiropractic Services* (1988) 6. 87-21, *Sunset Evaluation Update – Chiropractic* (1987) 7. 84-3, *Sunset Evaluation Report – Chiropractic* (1984)	Chiropractic, Ch. 442, HRS
8. 97-17, *Study on the Licensing of Massage Schools* (1997) 9. 92-17, *Sunset Evaluation Update – Massage* (1992) 10. 87-3, *Sunset Evaluation Report – Massage* (1983)	Massage, Ch. 452, HRS
11. 89-25, *Study of Proposed Mandatory Health Insurance for Naturopathic Care* (1989) 12. 87-2, *Sunset Evaluation Update – Naturopathy* (1987) 13. 85-8, *Sunset Evaluation Report – Naturopathy* (1985)	Naturopathy, Ch. 455, HRS
14. 92-24, *Sunset Evaluation Update – Osteopathy* (1992) 15. 85-7, *Sunset Evaluation Report – Osteopathy* (1985)	Osteopathy, Ch. 460, HRS (repealed in 2008 and consolidated with Medicine and Surgery, Ch. 453, HRS)

Source: Office of the Auditor

All five of these professions were regulated before 1984, when the Legislature began requiring the Auditor to conduct sunrise analyses of unregulated occupations. However, we conducted a sunrise analysis for acupuncture in February 1985 because the law regulating this occupation expired on December 31, 1984. In each of the sunrise/sunset evaluations, with the exception of massage, we recommended continued regulation of the various professions on the grounds that incompetent practitioners could cause significant harm to the health, safety, and welfare of consumers. For massage, we noted that although there is only a slight potential for personal injury, regulation was otherwise warranted to establish the boundaries of practice and diminish the association between massage and prostitution.

Objectives of the Analysis

1. Determine whether regulation of herbal therapists is warranted.
2. Assess the probable effects of the proposed regulation and the appropriateness of alternative forms of regulation.
3. Make recommendations as appropriate.

Scope and Methodology

We assessed the need to license and regulate herbal therapists, as requested in SCR No. 31, SD 1, of the 2014 legislative session, using criteria from Section 26H-2, HRS, of the *Hawai'i Regulatory Licensing Reform Act*. The Legislature's stated policy is to regulate professions or vocations only if there is a need to protect consumers. Regulation is an exercise of the State's police power and should not be imposed or used lightly.

Regulatory policy in Hawai'i

Hawai'i's "sunrise" law requires the Auditor to assess new regulatory proposals that would subject unregulated professions and vocations to licensing or other regulatory controls against the regulation policies provided in Section 26H-2, HRS. These policies state the primary purpose of such regulation is to protect consumers. Specifically:

- The State should regulate professions and vocations only where reasonably necessary to protect consumers;
- Regulation should protect the health, safety, and welfare of consumers and not the profession;
- Evidence of abuses should be given great weight in determining whether a reasonable need for regulation exists;
- Regulation should be avoided if it artificially increases the costs of goods and services to the consumer, unless the cost is exceeded by potential dangers to the consumer;
- Regulation should be eliminated when it has no further benefit to consumers;
- Regulation should not unreasonably restrict qualified persons from entering the profession; and
- Aggregate fees for regulation and licensure must not be less than the full costs of administering the program.

We were guided by the publication *Questions a Legislator Should Ask*, published by the Council on Licensure, Enforcement, and Regulation, a national organization. According to this publication, the primary guiding principle for legislators is whether an unregulated profession presents a clear and present danger to the public's health, safety, and welfare. If it does, regulation may be necessary; if not, regulation is unnecessary and wastes taxpayers' money.

In addition to the regulatory policies in Chapter 26H, HRS, and the guidance from the council, we considered other criteria for this analysis, including whether or not:

- The incidence or severity of harm based on documented evidence is sufficiently real or serious to warrant regulation;
- Any other alternatives provide sufficient protection to consumers (such as federal programs, other state laws, marketplace constraints, private action, or supervision); and
- Most other states regulate herbal therapists for the same reasons.

In assessing the need for regulation, we placed the burden of proof on proponents of the measure to demonstrate the need for regulation. We evaluated their arguments and data against the above criteria. We assessed whether proponents have provided sufficient evidence for regulation. In accordance with sunrise criteria, even if regulation *may* have *some* benefits, we recommend regulation only if it is *demonstrably* necessary to protect the public.

Types of regulation

As part of our analysis, we assessed the appropriateness of regulatory alternatives. The three approaches commonly taken to occupational regulation, from most to least restrictive are:

- *Licensing*, the most restrictive form of occupational regulation, which confers a legal right to practice to individuals who meet certain qualifications. Penalties may be imposed on those who practice without a license. Licensing laws usually authorize a board that includes members of the profession to establish and implement rules and standards of practice;
- *Certification*, which restricts the use of certain titles to persons who meet certain qualifications but does not bar others from offering such services without using the title. Certification is sometimes called title protection. Government certification should be distinguished from professional certification, or credentialing, by private organizations; and

- *Registration*, which is used when a threat to the public's health, safety, or welfare is relatively small or when it is necessary to determine the impact of the operation of an occupation on the public. A registration law simply requires practitioners to register their details on a State roster so the State can keep track of practitioners. Registration can be mandatory or voluntary.

Methodology

We reviewed literature on herbal therapists and its regulation and practices, including standards promulgated by relevant national bodies, and regulation in other states. We inquired about complaints filed with the Hawai'i Better Business Bureau, the Department of Commerce and Consumer Affairs' Regulated Industries Complaints Office, its Office of Consumer Protection, and the State Ombudsman. We also researched regulatory statutes in other states related to herbal therapists.

We contacted relevant personnel at DCCA, complementary and alternative medicine practitioners who use herbal remedies, and other individuals with relevant expertise. We identified the costs and possible impacts of the proposed regulation.

Our work was performed from May 2014 to October 2014 in accordance with the Office of the Auditor's *Manual of Guides.*

Chapter 2
Regulation of Herbal Therapists Is Not Warranted

The proposed regulation of herbal therapists in Senate Bill (SB) No. 2439 of the 2014 regular session contradicts a 16-year old law. Act 162, Session Laws of Hawai‘i (SLH) 1998, exempts traditional Native Hawaiian healers recognized by Papa Ola Lokahi (POL) kūpuna councils from the provisions of Chapter 453, Hawai‘i Revised Statutes (HRS), *Medicine and Surgery*. We found that the proposed regulation is an attempt by a younger generation of traditional Native Hawaiian healers to attain state licensure in order to practice la‘au lapa‘au without going through a kūpuna council recognition process. Therefore, since it is intended to benefit practitioners and not consumers, regulation is not warranted.

Despite this lack of public purpose, we analyzed all of the State's regulatory policies and guidelines for assessing the need for regulation. We found no evidence that herbal therapists pose harm to consumers, including safety risks and abusive practices, and that costs to consumers are likely to increase if regulation is enacted. We also found that existing alternatives to regulation provide adequate protection to consumers.

Summary of Findings

1. The proposed regulatory measure contradicts existing law and is problematic.

2. The proposed regulation of herbal therapists does not meet Hawai‘i's "sunrise" criteria in Chapter 26H, HRS.

Proposed Regulatory Measure Contradicts Existing Law and Is Problematic

Under current law, traditional Native Hawaiian healers who have been recognized by a kūpuna council convened by Papa Ola Lokahi, a Native Hawaiian health board, are exempt from all provisions under Chapter 453, HRS, *Medicine and Surgery*. The intent of this law was to allow traditional Native Hawaiian healers to provide medical care for patients and place the traditional Hawaiian healing community (rather than the State) in charge of certifying healers. SB No. 2439 seeks to reverse this law by making the government, through a board of herbal therapy, responsible for determining who is qualified to engage in traditional Native Hawaiian healing. Furthermore, in addition to minor technical flaws in the bill, SB No. 2439 places the burden of establishing standards for qualification onto the board, which may prove an extremely difficult task.

Regulation of herbal therapists would contradict the exemption for traditional Native Hawaiian healers from medical licensing

In the 1980s, a renewed interest in Hawaiian culture led Native Hawaiian healers to consider state regulation. Throughout the 1990s, traditional Native Hawaiian healers gathered to discuss perpetuation of their practices and concerns regarding the declining number of healers, most of whom were already in their seventies and eighties. Healers discussed and rejected proposals to seek either licensure or a lesser form of regulation (certification or registration, respectively) on the grounds that government regulation would put control of who could practice Native Hawaiian healing into the hands of the State.

Healers also discussed the option of seeking an exemption to Hawai‘i’s medical practice laws to allow Native Hawaiian healers to lawfully practice their craft. In 1998, Act 162 (SLH 1998), later codified in Section 453-2, HRS, exempted traditional Native Hawaiian healers recognized and certified by Papa Ola Lokahi from all provisions of Chapter 453, HRS, *Medicine and Surgery*. Act 162 therefore created a culturally appropriate structure for certification by placing it in the hands of the traditional Native Hawaiian healing community instead of charging the government with determining credentialing standards.

We found that SB No. 2439 (2014) contradicts the purpose and intent of Act 162, because it would shift responsibility for determining who is qualified to practice traditional Hawaiian medicine away from cultural authorities and onto the State.

Senate Bill No. 2439 contains technical flaws

We also found that SB No. 2439 contains technical flaws. For example, the bill does not define “herbal therapy.” It only states that licensing requirements are to apply to any person who practices, offers to practice, or advertises the practice of herbal therapy, except traditional Native Hawaiian healers recognized by Papa Ola Lokahi. This creates difficulty in determining which practitioners will be subject to the proposed regulation.

The National Center for Complementary and Alternative Medicine (NCCAM) divides complementary health approaches into natural products and mind and body practices. NCCAM also studies approaches that do not fit into these two groups, such as the practices of traditional healers, Ayurvedic medicine from India, traditional Chinese medicine, and homeopathy and naturopathy. Thus, “herbal therapy” is not included among the various complementary health approaches for which NCCAM defines usefulness and safety through rigorous scientific investigation.

The terms *herbal medicine*, *botanical medicine*, and *herbalism* are all used to describe herbal therapy practices. Herbal medicine is not a licensed profession in the U.S., and herbal remedies in the form of extracts, tinctures, capsules and tablets as well as teas are recommended

by healthcare practitioners of many different disciplines as a practical way to address a wide variety of medical conditions. Accordingly, all of these practitioners could be construed as engaging in the practice of herbal therapy in conjunction with their respective practices.

We also found that the bill as proposed erroneously places some licensing responsibilities with the director of the Department of Commerce and Consumer Affairs (DCCA) rather than with the board of herbal therapy. DCCA's Regulated Industries Complaints Office (RICO) testified that Section 7(b) of the bill states that, "[u]pon request, the *director* may grant inactive status to a person licensed under this chapter." According to RICO, the board should be responsible for this rather than the director; RICO would have authority to investigate violations and recommend enforcement action, but the board would make final decisions.

Establishing standard qualification and examination requirements will be difficult

SB No. 2439 proposes to establish licensing requirements for contemporary herbal healers from all ancestries. The law would task a five-member board of herbal therapy with developing standards, defining the scope of practice, and establishing examination qualification requirements, among other duties. However, we found there is a wide range of complementary and alternative medicine (CAM) disciplines, with varying training standards. CAM therapies, including herbal medicine, originate from diverse backgrounds. Some are associated with specific philosophies that have evolved over centuries of use, like Chinese and Ayurvedic medicine. These different philosophical approaches make it hard to design acceptable research trials and methods. Moreover, regulating CAM therapies, including herbal therapy, whose efficacy has not been established, could mislead the public into thinking such therapies have been clinically proven effective.

Furthermore, unlike the boards of acupuncture, chiropractic, massage, osteopathy, and naturopathy, the board of herbal therapy would not have the benefit of U.S. Department of Education-authorized organizations to accredit education or training programs for herbal therapy. Likewise, there are no professional organizations that offer certification examinations to graduates of accredited herbal therapy education and training programs.

Establishing requirements for traditional Native Hawaiian medicine practitioners would be especially difficult. According to a 2010 study published in the *Asian Pacific Law and Policy Journal*, traditionally, kahūna practiced independently rather than as an organized and uniform professional group. Kūpuna councils are also struggling with setting workable certification procedures. Of the six kūpuna councils recognized by POL, only one council has a process in place to test and approve applicants for certification. Further, according to POL, each

kūpuna council develops its own policies, procedures, and rules to certify traditional Hawaiian healers.

Regulation of Herbal Therapists Does Not Meet Sunrise Criteria

The *Hawai'i Regulatory Licensing Reform Act*, Chapter 26H, HRS, limits regulation of certain professions and vocations to situations in which it is reasonably necessary to protect the health, safety, and welfare of consumers. Proponents of regulation could not provide evidence that herbal therapy presents a clear and present danger to consumers. Moreover, the reason behind the proposed regulation is proponents' attempt to seek licensure in order to practice traditional Native Hawaiian medicine without going through the kūpuna council recognition process provided in existing law. Furthermore, if SB No. 2439 were enacted, Hawai'i would become the first state in the nation to regulate herbal therapists. The cost of regulation would likely be prohibitive since it would be spread among a small number of herbal therapist licensees. Finally, existing alternatives to regulation—specifically, state and federal agencies—provide an adequate degree of protection for consumers.

Proponents of regulation have not met their burden of proof

State regulatory policies require that the proponents of regulation provide proof that engaging the State's policing powers is reasonably necessary to protect consumers. We found that the advocates of SB No. 2439 whom we interviewed could not provide any documented evidence of harm posed by herbal therapists.

Evidence of abuses by providers of the service is also to be accorded great weight when considering the need for regulation. Advocates claimed that in the late 1800s, when a smallpox epidemic killed thousands of people in Hawai'i, unscrupulous individuals were selling herbal remedies with false claims of efficacy and charging high prices to victims. However, we found this example is not sufficiently relevant or timely to merit serious consideration.

When pressed about the possible harms posed by herbal therapists, advocates also told us that a greater harm to the community is the lack of regulation, which is preventing more herbal therapists from providing la'au treatment to Native Hawaiians, who have a disproportionately higher rate of heart disease, diabetes, and hypertension compared to other ethnicities. We also found that while herbal medicines do pose some risks of harm to consumers in the form of drug interactions and product contamination, regulation of herbal therapists would afford greater benefits to licensees than consumers.

No clear and present danger to consumers

Section 26H-2, HRS, stipulates that regulation of professions and vocations should be undertaken only when it is reasonably necessary to protect the health, safety, or welfare of consumers of the services. Furthermore, in its publication *Questions a Legislator Should Ask*, the Council on Licensure, Enforcement, and Regulation says that the primary guiding principle for legislators should be whether the unregulated profession presents a clear and present danger to the public's health, safety, and welfare. If the answer is no, regulation is unnecessary and wastes taxpayers' money.

We found no indication of any clear and present danger to the health, safety, or welfare of consumers posed by unregulated herbal therapists in Hawai'i or elsewhere. Even proponents acknowledged that the push for regulating traditional Native Hawaiian practitioners is to provide an alternative approach, other than through recognition by POL kūpuna councils, to lawfully engage in the practice of herbal therapy as a livelihood and receive reimbursement from insurance carriers. Moreover, naturopaths and acupuncturists we spoke to were unable to provide any evidence of significant harm posed by herbal therapists.

Drug interactions and product contamination are risks, but do not necessitate state regulation

We did find there is some risk of adverse interaction between natural products, such as herbal medicines or botanicals, and conventional Western pharmaceutical drugs. Because herbs come from plants, they are often perceived as "natural" and therefore safe. However, according to NCCAM, there is considerable uncertainty about the safety of many of these products, in part because the U.S. Food and Drug Administration (FDA) does not require manufacturers to prove the safety and effectiveness of what are considered "dietary supplements" before they are made available to the public.

According to NCCAM, two main safety concerns of herbal products are drug interactions and product contamination. There have been reports of toxicity to specific herbal medicines causing kidney failure and liver damage. Contaminants in herbal products may be particularly problematic in medicines imported from Asia, and the safety of using most herbs with conventional drugs is not well established. Some herbs are known to interact with pharmaceutical drugs. For example, St. John's wort has been shown to interfere with numerous drugs metabolized by the liver including protease inhibitors, chemotherapeutic agents, and oral contraceptives. However, most of this information also comes from case reports rather than systematic investigations.

Furthermore, regulation is warranted where the nature of the services offered by the provider (herbal therapist)—not the product itself (herbs)—jeopardizes the health, safety, or welfare of consumers. Although it is possible an incompetent herbal therapist may prescribe an herbal remedy without diligent consideration of its potential adverse interaction with pharmaceutical drugs, we did not find any incidents of this kind in our research, either in Hawai‘i or nationally.

Regulation would benefit herbal therapists rather than consumers

Hawai‘i's sunrise criteria require a guarded approach to situations in which regulation primarily benefits an occupation instead of consumers. Proponents of herbal therapy regulation noted that currently, no one can legally practice traditional Native Hawaiian medicine unless they are recognized by a kūpuna council. Proponents further asserted that one respected kumu has been trying for years to be recognized by a council, that therefore the process for gaining recognition through traditional cultural practitioners has been prohibitive, and that the passing of aging kahūna will further risk perpetuation of the healing arts. We found that although recognition through kūpuna councils may be problematic, it does not result in a valid reason for warranting regulation—the paramount purpose of which must be to protect consumers, not members of the occupation.

No other states regulate herbal therapists

According to the American Herbalists Guild, no state currently regulates herbalist therapists. However, in a small number of states, including Hawai‘i, naturopathic and acupuncture licensing laws include clauses that define natural remedies, and sometimes specifically herbal remedies, within the scope of the licensed practice. There is currently no state-level licensing for herbal therapists other than those linked to an acupuncture license. Furthermore, legal protections granted to license holders specifically related to the use of herbs are not always clear. However, no current regulation precludes other health professionals or even lay persons from using, dispensing, or recommending herbs.

Regulation may artificially increase the costs of herbal therapy to consumers

A critical policy component to Hawai‘i's regulatory licensing law is that fees for regulation must cover the entire cost of administering the regulatory program. Further, regulation that artificially increases the cost of goods and services to consumers should be avoided where possible. We found that, based on the estimated number of herbal therapists in the state, each licensee's pro-rata share of the regulatory costs would likely be a significant burden to licensees (who generally pass on such costs to consumers). Furthermore, proponents say their intent is specifically to charge patients for traditional Native Hawaiian healing services.

Cost of regulation may be prohibitive

We asked DCCA's Professional and Vocational Licensing Division to provide us the estimated costs for an herbal therapy program, which would include licensing approximately 110 herbal therapists based on qualification requirements to be established by a five-member board. This number was based on information provided by proponents who stated that there are about 100 current students of Hawaiian medicine enrolled at the University of Hawai'i and the Brigham Young University–Hawai'i who are interested in pursuing licensing. In addition, there are an estimated 10 to 15 Chinese herbalists operating in downtown Honolulu who do not possess an acupuncture license. We were unable to determine how many of these Chinese herbalists would pursue state licensing. We excluded acupuncturists and naturopaths from our calculation since licensing laws include clauses that define natural or herbal remedies within the scope of these licensed practices.

The department estimated startup costs of $266,779, with annual recurring costs projected at $251,687. These costs include new positions and administrative overhead expenses. Based on the number of potential herbal therapist licensees, pro-rated costs will result in individual licensing fees of over $2,000 per year. Exhibit 2.1 breaks down the department's estimate for an herbal therapy regulatory program.

Exhibit 2.1
Estimated Costs of Regulating Herbal Therapists

	No. of licensees	Annual fee per licensee	Total cost of regulatory program
First year startup costs	110	$2,425	$266,779
Recurring annual costs	110	$2,288	$251,687

Source: DCCA, Professional and Vocational Licensing Division

In contrast, Exhibit 2.2 shows the licensing and renewal fees for other CAM practices in Hawai'i.

Exhibit 2.2
Fees for Other CAM Practices

Occupation	Initial licensing fee per licensee	Biennial renewal fee per licensee
Acupuncture	$350	$220
Chiropractic	$368	$260
Massage	$177	$120
Naturopathy	$342	$310
Osteopathy	$479	$250

Source: DCCA, Professional and Vocational Licensing Division

Stakeholders we interviewed, including acupuncturists and naturopaths, stated that their licensing fees are nominal and do not increase treatment costs to their patients. Proponents of herbal therapy regulation were concerned about the costs of the program, and how much the licensing fees would be in order to make the program self-sustaining. Nevertheless, they felt that the fees may be a hardship in the beginning but will not be much of a factor in the long run.

Licensing fees to be assessed by DCCA are significant when compared to other CAM practices and coupled with the small number of herbal therapists seeking licensing. As a result, this is likely to increase costs to consumers. Furthermore, we note that a low number of practitioners often suggests a field in which the scope of practice is successfully governed by other regulatory means and is, therefore, in less need of government oversight.

Consumers may have to pay for traditional Native Hawaiian medicine

According to the 2010 study,[4] there is a school of thought among the older Native Hawaiian healing community that healers should not be paid for their services, but can accept hoʻokupu (gifts) for their work. The study argues that Native Hawaiians have also sought out healing kahūna because their services are more affordable than those of Western physicians. However, proponents of herbal therapy regulation intend to charge for their services, which will impact patients who are not accustomed to paying for healers' services.

The same thing happened with lomilomi massage practitioners. Traditionally, lomilomi, like all traditional Native Hawaiian healing practices, was provided for free. Lomilomi practitioners are now licensed under the state's massage therapy licensing law, with some charging as much as $80 per hour for their services. If practitioners who

[4] *Asian Pacific Law and Policy Journal*

are certified in traditional Hawaiian healing disciplines follow the same path as their fee-charging lomilomi counterparts, traditional Hawaiian medicine could become inaccessible to many Native Hawaiians. Hence, what was customarily free may become a financial burden for many and may prevent Native Hawaiians from seeking the healthcare on which they had previously relied.

Other alternatives provide adequate protection to consumers

One of the criteria in assessing whether to regulate an occupation or vocation is whether there are alternatives that would adequately protect consumers. This includes considering whether existing laws, such as unfair and deceptive trade practices laws, may suffice. We found that state regulation of herbal therapists in Hawai‘i is unnecessary because such laws already exist and provide sufficient protection to consumers. There are also other agencies that can investigate complaints against herbal therapists and provide enforcement against alternative medicine fraud.

Other local agencies protect consumers

Consumers can file complaints with the DCCA's Office of Consumer Protection and the Hawai‘i Better Business Bureau. However, we consulted with these agencies and found no evidence of complaints filed by consumers against herbal therapists in Hawai‘i. A lack of complaints, investigations, and enforcement actions normally indicates a lower regulatory risk with minimal impact on public health and safety.

FDA prosecutes alternative medicine fraud

Natural or herbal medicines are not regulated by the federal FDA. However, the FDA monitors herbal medicine manufacturers and distributors and takes enforcement action to protect consumers from fraudulent alternative medicine products. The federal *Dietary Supplement Health and Education Act*, passed in 1994, legally defined herbs as "dietary supplements" and shifted the burden of proof to the FDA to demonstrate that a particular herbal medicine is adulterated and/or unsafe. While natural or herbal supplements may make certain general claims on their product labeling, they must also clearly state that their claims have not been evaluated by the FDA and that their product is not intended to diagnose, treat, cure, or prevent any disease. Recent enforcement actions by the FDA have included illegal product labeling, adulterated product samples, and marketing of unapproved, unauthorized products.

Conclusion

We found that the proponents of herbal therapy regulation have not provided any evidence of harm or abusive practices by herbal therapists in Hawai‘i or elsewhere. Further, the proponents of SB No. 2439, a younger generation of traditional Native Hawaiian healers, are the primary beneficiaries of regulation, hoping to attain state licensing in order to practice their art without going through a kūpuna council recognition process. However, placing the licensing of Native Hawaiian healers under state control is in direct contravention to the purpose and intent of Act 162, SLH 1998, which exempted Native Hawaiian healers from all requirements under the state's medical licensing law.

Recommendation

SB No. 2439 should not be enacted.

Response of the Affected Agency

Comments on Agency Response

We transmitted a draft of this report to the Department of Commerce and Consumer Affairs on December 12, 2014. A copy of the transmittal letter is included as Attachment 1 and the department's response, dated December 18, 2014, is included as Attachment 2.

The department shared our concern that regulation of herbal therapists could artificially increase the costs of herbal therapy to consumers. The department also concurred with our conclusion that Section 453-2(c), HRS, already provides an appropriate process for review and approval of Native Hawaiian healers.

We made minor technical corrections for accuracy, clarity, and style prior to publication.

ATTACHMENT 1

STATE OF HAWAI'I
OFFICE OF THE AUDITOR
465 S. King Street, Room 500
Honolulu, Hawai'i 96813-2917

JAN K. YAMANE
Acting State Auditor

(808) 587-0800
FAX: (808) 587-0830

December 12, 2014

COPY

The Honorable Keali'i S. Lopez
Director
Department of Commerce and Consumer Affairs
335 Merchant Street
Honolulu, Hawai'i 96813

Dear Ms. Lopez:

Enclosed for your information are three copies, numbered 6 to 8, of our confidential draft report, *Sunrise Analysis: Regulation of Herbal Therapists.* We ask that you telephone us by Tuesday, December 16, 2014, on whether or not you intend to comment on our recommendations. If you wish your comments to be included in the report, please submit your hard copy response to our office no later than 4:30 p.m., Thursday, December 18, 2014.

The Governor and presiding officers of the two houses of the Legislature have also been provided copies of this confidential draft report.

Since this report is not in final form and changes may be made to it, access to the report should be restricted to those assisting you in preparing your response. Public release of the report will be made solely by our office and only after the report is published in its final form.

Sincerely,

for Jan K. Yamane
Acting State Auditor

Enclosures

DAVID Y. IGE
GOVERNOR

SHAN S. TSUTSUI
LT. GOVERNOR

STATE OF HAWAII
OFFICE OF THE DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
335 MERCHANT STREET, ROOM 310
P.O. Box 541
HONOLULU, HAWAII 96809
Phone Number: 586-2850
Fax Number: 586-2856
www.hawaii.gov/dcca

KEALI`I S. LOPEZ
DIRECTOR

JO ANN M. UCHIDA TAKEUCHI
DEPUTY DIRECTOR

December 18, 2014

Ms. Jan K. Yamane
Acting State Auditor
Office of the Auditor
465 S. King Street, Room 500
Honolulu, Hawaii 96813-2917

Dear Ms. Yamane:

Thank you for the opportunity to provide comments on the draft report, **Sunrise Analysis: Regulation of Herbal Therapists.**

The Department of Commerce and Consumer Affairs (Department) shares the Auditor's concern that regulation of herbal therapists could artificially increase the costs of herbal therapy to consumers by transforming the practice to a fee for services profession. Also, as a self-funded agency, the Department is sensitive to the regulatory costs that would be placed on a relatively small pool of licensees and the impact those costs ultimately could have on the consuming public.

The Department concurs with the conclusions of the report that the current language in Haw. Rev. Stat. section 453-2(c) already provides an appropriate process for review and approval of Native Hawaiian healers.

Thank you for the opportunity to offer comments.

Sincerely,

Keali'i S. Lopez
Director

c: Celia Suzuki, Licensing Administrator