

**Report of the Task Force
on
Complementary and Alternative Medicine**

**DIRECTED BY
1998 HOUSE BILL 160**

Research Memorandum No. 491

**LEGISLATIVE RESEARCH COMMISSION
Frankfort, Kentucky**

JANUARY 2000

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MEMORANDUM

TO: Members of the Legislative Research Commission

FROM: Tom Burch, Chair
Task Force on Complementary and Alternative Medicine

SUBJECT: Report on Complementary and Alternative Medicine

DATE: January 4, 2000

Attached is the report of the Task Force on Complementary and Alternative Medicine for your consideration. This report which is prepared pursuant to House Bill 160 of the 1998 Legislative Session sets out the proceedings of the Task Force and its recommendations. The recommendations, including the accompanying bill draft, were approved by the Task Force at its November 17, 1999, meeting.

The broad-based membership of the Task Force specifically included representatives of the Commonwealth's medical schools, schools of nonconventional medicine, various medical and health-related licensing boards and associations, the Consumer Protection Division of the Office of Attorney General, and seven members of the General Assembly appointed by the Legislative Research Commission.

The Task Force met thirteen times during the interim. The enabling legislation required the Task Force to study the effects of complementary and alternative medicine,

nonconventional medical treatment, acupuncture, and naturopathy and to consider reports and findings provided by the National Institutes of Health, the American Chiropractic Association, and the American Medical Association.

Moreover, the legislation permits the Task Force to forward to the Kentucky Board of Medical Licensure or the Kentucky State Board of Chiropractic Examiners for consideration or possible approval any alternative medical treatment the study commission finds to be safe and effective.

I would like to publicly thank the members of the Task Force for their work and commend them for the time they devoted to the Task Force's proceedings, both at and in preparation for the meetings. Each member brought a wealth of experience to the Task Force and should be recognized, despite his or her varied constituencies, for the diligence and commitment each exhibited in forging a compromise that ensures public safety.

It was a pleasure to serve as chairman of this Task Force. I hope that our efforts in the interim will facilitate any work in complementary and alternative medicine that may be considered this session.

Task Force on Complementary and Alternative Medicine

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SECTION 1

Background

Complementary and Alternative Medicine Defined

Complementary and Alternative Medicine (CAM) is a broad label for many treatments and includes techniques such as massage, chiropractic, biofeedback, yoga, and systems such as homeopathy and traditional Chinese medicine. Sometimes referred to as "traditional," "natural," "unscientific," "holistic," "nonconventional," or "integrative," these practices are generally practices other than those that are a part of mainstream medicine. The difficulty of devising a comprehensive definition may be attributed to the philosophical underpinnings of many of the modalities, the types of therapies offered, the method of therapies administration, and the ways in which patients and practitioners interact.

The Office of Alternative Medicine of the National Institutes of Health established the "Panel on Definition and Description of Alternative Medicine" at the Complementary and Alternative Medicine Research Methodology Conference. The panel recommended the following definition:

Complementary and alternative medicine is a broad domain of healing resources that encompasses all health systems, modalities, and practices, and their accompanying beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM domain and between the CAM domain and the domain of the dominant system are not always sharp or fixed.

Although the Task Force did not adopt a definition of complementary and alternative medicine, it was influenced by a report to the National Institutes of Health (NIH) on alternative medical systems and practices entitled "Alternative Medicine: Expanding Medical Horizons," which categorizes the various practices into one of seven categories:

1. Alternative systems of medical practice, which include acupuncture, anthroposophically extended medicine, traditional oriental medicine, Ayurveda, Homeopathic medicine, environmental medicine, Native American medicine, Latin American medicine, and community-based practices;
2. Mind-body interventions, which include art therapy, support groups, meditation, psychotherapy, imagery, biofeedback, hypnosis, yoga, dance therapy, and prayer therapy;
3. Manual Healing Methods, which include osteopathic medicine, massage therapy, chiropractic science, and biofeedback therapeutics;
4. Pharmacological and Biological Treatments, which include antineoplastons, cartilage products, EDTA chelation therapy, immunoaugmentative therapy, and other therapies;
5. Herbal Medicine, which include European phytomedicines, Chinese herbal remedies, Ayurvedic herbal medicine, and Native American herbal medicine;
6. Diet and Nutrition, which include vitamins and nutritional supplements, orthomolecular medicine (megavitamin therapy), Gerson therapy, the Kelly regime, the macrobiotic diet, the Livingston-Wheeler regimen, the Wigmore treatment, the Ornish diet, the Pritkin diet, dietary management of food allergies, and the diets of other cultures; and

7. Bioelectromagnetics Applications in medicine, which include application of nonthermal, nonionizing electromagnetic fields for bone repair, nerve stimulation, wound healing, treatment of osteoarthritis, elector acupuncture, tissue rejuvenation, immune system stimulation, and nueroendocrine modulations.

Action Taken

The Task Force on Complementary and Alternative Medicine met 13 times during the 1999-2000 interim. During the course of its meetings, the Task Force members studied acupuncture, hypnosis, aromatherapy, herbal medicine, therapeutic touch, AMMA therapy, naturopathy, and chelation therapy. Generally, the topics and presenters were chosen with input from the Task Force members. To the extent possible, presenters were drawn from Kentucky practitioners.

The methodology used for this study was to have practitioners in the respective fields address the Task Force in accordance with a staff-developed outline. The broad sections of the outline addressed the therapy's description, the therapy's safety, the therapy's effectiveness, the therapy's suitability for integration with conventional medical practices, and the public's demand for the therapy.

In describing each therapy, the practitioner was asked to define the therapy, its use, the desired outcome, the type of patient with whom the therapy is used, and the education, experience, and credentials of the practitioners. The issue of public protection was divided to include information on whether the treatment posed a greater risk than conventional treatment, how the profession regulates itself, and how the federal government and other states regulate the treatment. In looking at the therapy's effectiveness, practitioners were asked to address various indicators of effectiveness, including clinical trials, observational and anecdotal studies, and the therapy's historical success. The fourth area is the suitability of integrating the practice with conventional treatment and wellness practices. The fifth category looked at public demand for the therapy. This inquiry was further divided to include the availability of practitioners, the perceived credibility of the therapy, the cost effectiveness of the therapy, and the availability and access of the therapy, including the availability of third party payment.

A public hearing followed the presentations where members of the public spoke in favor of and in opposition to the use of alternative modalities. Those testifying discussed their personal experiences with and the risks and benefits of alternative medicine. Following the public hearing, representatives of the following professional licensing boards and the professional associations testified on their boards' or associations' positions on the practices studied: the Council for Reliable Health Information, the Kentucky Nurses Association, the Board of Medical License, the Kentucky Medical Association, the Kentucky Physical Therapy Association, the Physical Therapy Board, the Board of Dietitians and Nutritionists, and the Nurses Licensing Board. The final portion of the study was the consideration and adoption of a proposed bill draft on acupuncture and recommendations to be submitted to the 2000 General Assembly.

History

Legislation relating to alternative medicine was first introduced but not enacted in the Commonwealth in the 1996 Legislative Session. The legislation would have permitted a physician to use conventional or nonconventional medical care if the physician had a reasonable expectation of its efficacy and would have required the Board of Medical Licensure, when investigating grievances concerning nonconventional medical treatments, to consult with experts who dedicate a significant portion of their practice to the use of nonconventional treatments. Moreover, the

definition of "dishonorable, unethical, or unprofessional conduct" was amended to require that the representations or statements actually deceived or defrauded the public.

In 1998, four bills were introduced concerning complementary and alternative medicine — House Bills 158, 160, and 243 and Senate Bill 375. House Bill 158 provided for the licensing of naturopaths. House Bill 160, as introduced, provided for the licensing of acupuncturists. House Bill 243 and Senate Bill 375 provided for the enactment of a "Health Freedom Act." That legislation established that the integration of complementary and alternative medicine into one's medical practice does not constitute dishonorable, unethical, or unprofessional conduct if the benefits of the treatment outweigh the potential risk of the harm of the treatment. In addition, the legislation deleted existing language providing it was dishonorable, unethical, or unprofessional conduct for a physician to represent that he could cure diseases or ailments under a system or school of practice other than that in which he has a degree. Additionally, the legislation required that when considering grievances involving complementary and alternative medicine the Board of Medical Licensure consult an expert that dedicates a significant portion of his or her practice to complementary and alternative medicine treatments. The provisions establishing the licensing of acupuncturists were deleted, and of the four bills, only House Bill 160 was enacted to include the establishment of this study commission.

Scope of Study

This report will follow the outline developed by staff for those testifying on an alternative practice, except a description of the practice has been omitted. This report is divided into six sections. Section One provides background information. Section Two sets out Kentucky laws affecting the practice of complementary and alternative practices. Section Three sets out the testimony received on the efficacy of each practice studied and addresses the methodological difficulties proponents and opponents of complementary and alternative medicine alike have encountered in analyzing research on the practices. Section Four addresses issues relating to the safety of each practice and the provisions by which the government and the industry safeguard the public. Section Five focuses on the integration of complementary and alternative practices and conventional medical practices. In addition, this section sets out the barriers to integration. Section Six addresses the increasing demand placed on the medical community for the use of alternative practitioners. The report concludes with Section Seven, which sets out the Task Force's recommendations.

SECTION 2

Laws Affecting the Practice of Complementary and Alternative Medicine

Kentucky statutory law prohibits a person from practicing medicine or opening or maintaining an office in the state for the purpose of engaging in the practice of medicine, unless the person holds a valid license or permit (KRS 311.560). Other provisions restrict the use of the title "Doctor" or "Dr." unless the person holds the appropriate degree from a school, college, or university, and permits a physician to be disciplined for "dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public.

The practice of medicine is defined in KRS 311.550 (Appendix B) as "...the diagnosis, treatment or correction of any and all human conditions ailments, diseases, injuries, or infirmities by any and all means, methods, devices, or instrumentalities." Subsection (11) expressly excludes from the definition of the practice of medicine the practice of Christian Science, the practice of podiatry, the practice of a mid level health care practitioner, the practice of dentistry, the practice of optometry, the practice of chiropractic, the practice of nursing, the practice of physical therapy, the performance of duties for which they have been trained by emergency medical technicians or medical emergency dispatchers certified by the Cabinet for Human Resources, the practice of pharmacy, the sale of medicines and medical instruments and other apparatus in regular mercantile establishments, or the practice of midwifery by women.

A 1963 Attorney General's opinion (OAG 63-443) notes that the definition of the practice of medicine in KRS 311.550 is broad enough to cover the practice of a naturopath. The opinion concludes that "naturopathy" cannot be practiced in this state unless the person has a license to practice medicine or osteopathy or is working under the exceptions set out in subsection (10) of that statute.

SECTION 3

Efficacy of Complementary and Alternative Medicine Practices

This section looks at the effectiveness of various alternative medicine practices. The Task Force did not engage in primary research but relied on the expertise of its members, the majority of whom are conventional and nonconventional health practitioners. The difficulty in conducting this research is illustrated by the testimony of the president of the Kentucky Board of Medical Licensure, who indicated that the Board is not in the position to assess the efficacy of the questioned medical practices and must look to nationally recognized research entities such as the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) for such information.

HB 160 expressly requires the Task Force to use the reports provided by the American Medical Association (AMA), the American Chiropractic Association (ACA), and the NIH in making the Task Force's conclusions. Task Force staff contacted the AMA, the ACA, and the NIH and found little research sponsored by the above-mentioned entities. The AMA has a position on the uses of chelation therapy for arteriosclerosis but does not have statements on the efficacy of the other practices studied. Research forwarded to staff from the ACA was limited to the practice of chiropractic, which was not treated as an alternative practice for purposes of this study. The NIH had a web page on the research it sponsored, much of which was in the formative stage. Preliminary results of some of the research have caused the NIH to recommend that additional or more intensive studies be done in the area. Typically, NIH-sponsored research is published in recognized journals.

This section sets out the arguments opposing and favoring each practice. Presentations on acupuncture, yoga, aromatherapy, herbal medicine, AMMA Therapy, therapeutic touch, naturopathy, and chelation were presented by practitioners. Much of the information favoring a respective practice was given by practitioners testifying before the commission, and the information opposing a respective practice has been compiled from the Task Force members' questions, the testimony given in response to the testimony, and the positions of the various health-related professional associations and licensing boards.

Both the testimony before the Task Force and the literature on the efficacy of alternative medicine practices generally focused on the sufficiency of the research conducted. Many of those testifying against an alternative practice espoused that much of the research on alternative medicine is based on anecdotal reports and does not withstand scientific scrutiny. Those in favor often countered with the argument that much of what is used in conventional medicine has not been held to the same rigorous standards of double-blind testing. A family practitioner who is an epidemiologist and an acupuncturist testified that one of the problems encountered when researching acupuncture is the tendency to apply the principles of Western medicine to Oriental medicine. He said attempts to conduct controlled studies by sham acupuncture (inserting a needle in the wrong knee) are methodologically flawed. One must assume that insertion in the other, although wrong knee, will cause some reaction. He stressed the importance of studying systems from different perspectives that are compatible with the principles of the practice, noting that Oriental medicine, unlike Western medicine, treats symptoms rather than diseases.

Acupuncture

In discussing the efficacy of acupuncture, a nationally-certified acupuncturist and the Secretary/Treasurer of the National Acupuncture Foundation reported to the Task Force that in 1998 the National Institutes of Health issued a Consensus Statement that found acupuncture to be effective for adult post-operative and chemotherapy nausea and vomiting and post-operative dental pain. The statement also found such use promising for addiction, stroke, rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, and asthma.

Additionally, the nationally certified acupuncturist indicated that the World Health Organization has cited acupuncture as treatment for 43 conditions, including allergies, asthma, back pain, carpal tunnel, colds and flu, constipation, depression, gynecological disorders, headaches, heart problems, infertility, insomnia, PMS, sciatica, sports injuries, stress, and tendonitis. In addition, there is increasing evidence based on clinical studies of acupuncture's efficacy in treating headaches, dysmenorrhea, fibromyalgia, stroke, substance abuse, menopause, depression, female infertility, neck pain, low back pain, osteoarthritis, morning sickness, respiratory disease, urinary dysfunction, tennis elbow, and facial pain.

As further support of acupuncture's efficacy, the acupuncturist pointed to the FDA's reclassification of acupuncture needles from a Class 3 to a Class 2 device in 1993. As a Class 3 device, the use of acupuncture needles were restricted to investigation purposes only until evidence was presented to show that acupuncture is a safe practice. Under its new classification as a Class 2 device, acupuncture needles may be used if they are sterilized and used by qualified practitioners as determined by state law. The acupuncturist testifying to the Task Force noted that other clinical studies have reported that acupuncture stimulates bone regrowth; the clotting factor; and the production of dynorphin, endorphin, and other pain modulators; regulates blood pressure and serotonin; and increases red and white blood cell count.

A representative of the Kentucky Board of Licensure and Certification for Dietitians and Nutritionists added that acupuncture has been successful in some limited uses but noted that much of the research in this area has not withstood scientific scrutiny. Other opponents of acupuncture testifying to the Task Force have noted that there are some promising results on acupuncture, but most are based on clinical experiences, case reports, or intervention studies with inadequate designs rather than controlled studies. They advocate that acupuncture be subject to the same scientific scrutiny as other health care.

Another criticism voiced by opponents of acupuncture is the tendency to incorporate the entire system of Oriental medicine within acupuncture's scope of practice. The president of the Kentucky Council for Reliable Health Information points out that Oriental medicine is premised on a collection of prescientific and mystical ideas which arose long before we understood the structure of the body. Under Oriental medicine, the organs of the body are organized into a complex network where organs are ruled by the elements of nature — wood, fire, earth, metal or water. Oriental medicine is unaware of the pancreas and has created an imaginary organ--the "triple warmer" — to complete the symmetry of the six yin and six yang organs. It also includes the elements of sympathetic magic, using organs because they are believed to strengthen corresponding human organs and ginseng because its roots resemble the human body. It claims to be able to diagnose the functions of numerous internal organs by assessing the qualities of the pulse at various locations.

Finally, opponents of acupuncture add that there is an absence of good evidence as to acupuncture's effectiveness and have questioned the objectivity of the panel for the NIH Consensus Conference on Acupuncture since the panel consisted of only proponents of the practice, with no critics represented. Furthermore, the president of the Council for Reliable Health Information testified that the panel offered little evidence in the way of positive conclusions. The panel said that the evidence was clear only for certain types of nausea and pain and less clear for many other

conditions. The panel also noted that the quality of research was quite poor and that in some studies fake or "sham" acupuncture has worked as well. Moreover, the speaker pointed out that reviews of the literature for chronic pain, addiction, and asthma, conducted in the 1990's, all concluded that there is little support for the use of acupuncture, and there has not been new research since then to cause those conclusions to change.

Hypnotherapy and Yoga

A Kentucky hypnotist reported to the Task Force that hypnotism has been successful in treating bedwetting, school anxiety, learning problems, and sport performance in children and adults and has been used by some hospitals in anesthetizing patients. Those representatives of the Council for Reliable Health Information and the Kentucky Nurses Association, responding to the hypnotist's testimony on the effectiveness of hypnotism, generally concede that it is effective, but caution that it may be misused and believe it is best left in the hands of existing mental health professionals. Two practitioners in Lexington reported that yoga therapy has been applied to people with bronchial asthma, arthritis, anxiety, blindness, hypertension, depression, low back pain, other forms of chronic pain, cancer, cardiovascular disease, multiple sclerosis, and insomnia. Those responding to the testimony on yoga acknowledged that the medical profession thinks it is useful as an exercise and a relaxation technique but believes that it should be supported by scientific evidence rather than pseudoscientific and metaphysical concepts if it is to become a part of a health care package. In addition, the representative of the State Board of Certification for Dietitians and Nutritionists testified that yoga is effective but that studies on its efficacy are limited.

Aromatherapy and Herbal Medicine

A professor from the University of Louisville School of Nursing discussed aromatherapy and herbal medicine. Aromatherapy is a practice by which essential oils are used for preventive and therapeutic purposes. Generally, the oils inhaled or absorbed through the body's pores are reputed to bring about better health or the cessation of symptoms and diseases. The presenter noted that the efficacy of an essential oil depends on its purity and the oil's quality is affected by the conditions and times in which the herb is grown and harvested. She cautioned that oils are unregulated drugs with many of the same constituents as other medications, and there is a lack of research on aromatherapy. A large number of oils are contraindicated in pregnant women. Proponents and opponents alike recognize the lack of research in aromatherapy. Opponents point out that aromatherapy has not been shown to be medically useful for anything and that many pseudoscientific claims, such as "driving out evil spirits" and restoring harmony and balance," have been associated with its use.

In discussing herbal medicine, the professor testified that herbs are more commonly used for allergies, insomnia, digestive problems, and lung problems. The presenter noted that herbs, when properly prescribed, can be as effective as modern day medications with some diseases and are often used as preventive measures. She indicated that other countries have done extensive testing on the efficacy of herbs and referred to the work done by the German Commission E. Commission E was a special expert panel of physicians, pharmacists, pharmacologists, toxicologists, epidemiologists, and other professionals who are familiar with the vast body of historical and scientific literature concerning herbs and medicinal plants. In assessing the efficacy, the Commission adopted the doctrine of reasonable certainty. That is, assessment of efficacy does not require new clinical studies if there is sufficient scientific evidence in the chemical, toxicological, pharmacological, clinical, and epidemiological literature to warrant the use of the product as a non-

prescription medicine. As of 1998, the Commission had published 461 monographs, of which 254 have been for approved herbs and herb combinations.

In his testimony to the Task Force, the president of the Council for Reliable Health Information acknowledged that some herbal medicines are useful and have been the basis of a number of important drugs. The presenter indicated that claims made that an herb is better than a synthetic drug are not scientifically recognized. An advanced registered nurse practitioner representing the Kentucky Nurses Association expressed concern about the efficacy of herbal medicine since herbs are not subject to federal regulation or standardization. Moreover, she posited that there is a strong disincentive for pharmaceutical companies to study herbs, since they are not patentable, and pharmaceutical companies could not recoup the moneys they have invested in research. One of the most frequent objections raised to Task Force members concerning the use of herbal medicine was variations in quality since the active ingredient has not been identified.

Therapeutic Touch

The advanced registered nurse practitioner reported that therapeutic touch has been used in a variety of clinical settings with a variety of patients and is designed to promote relaxation, decrease pain and anxiety, and increase hemoglobin and the healing of wounds and bones. In response to the nurse practitioner's testimony, the representative of the Council on Reliable Health Information stated that therapeutic touch is premised on the existence of a human energy field that is manipulated to correct imbalances or blockages and bring about healing. The representative of the Council on Reliable Health Information further pointed out that while the human body does have forms of energy and electrical signals such as those from the brain and the heart that can be detected outside the body, there is no such thing as a human energy field in the sense used by therapeutic touch practitioners. He notes that there are scientific instruments designed to detect various types of energy at unimaginably small levels and surely, if this field existed, the energy would be measurable.

AMMA Therapy

AMMA Therapy is a specialized form of massage therapy that combines deep tissue manipulation with the application of pressure, friction, and touch to specific points and the channels on which they are found. The academic dean of the School of Wholistic Nursing at the New York College for Wholistic Health Education and Research testified that the following conditions have been successfully treated with AMMA Therapy: traumas from sprains, strains, fractures, broken bones, arthritis, hypertension, diabetes, gastrointestinal disease, circulatory problems, early stage cancers, auto immune disease such as scleroderma, neuromuscular disease such as myasthenia gravies, chronic fatigue syndrome, asthma, and bronchitis. In addition, she noted that AMMA Therapy has proven exceptionally beneficial for infants and children in treating acute and chronic ear infection, upper respiratory infections, asthma, bronchitis, juvenile arthritis, diabetes, teething, headaches, coughs, and colds.

Speaking in opposition to this practice, the president of the Council for Reliable Health Information noted that AMMA Therapy contains elements of Chinese medicine and massage and is based on pseudoscientific concepts of manipulation of a supposed life energy. He pointed that AMMA Therapy is a copyrighted method and that, in researching the area, he found no references or research papers on the subject.

Naturopathy

The efficacy of naturopathy was discussed by a licensed naturopath representing the American Association of Naturopathic Physicians (AANP) and a naturopath representing the American Naturopathic Association (ANA). The former speaker noted that over the last ten years, 3500 randomized clinical studies of natural medicine have been published, and that scientific studies and observations have upheld the validity of diet, herbal medicine, manipulation, massage, acupuncture, biofeedback, and homeopathy. The latter speaker reported that studies and clinical trials around the world have shown that natural therapies, if used in the naturopathic paradigm, are virtually risk-free. He noted that many of the so-called "clinical breakthroughs" we hear about are in the areas of vitamins, diet, lifestyle, and minerals — areas that have long been recommended by naturopathy. He added that the effectiveness of natural therapies equals or surpasses the traditional allopathic mode, and that superior results have occurred where natural methods were used with allopathic practices.

The president of the Council for Reliable Health Information noted that many of the approaches used by naturopaths are outright pseudoscience, i.e. homeopathy, chelation therapy, colonic irrigation, hair analysis, and some electrical diagnostic devices. He noted that other naturopathic approaches, such as herbal remedies and nutritional supplements may have some basis but have not been shown to be safe and effective. Moreover, he noted that naturopathy is based on an invalid concept that many diseases are based on an accumulation of toxins in the body.

Chelation Therapy

The final practice looked at was chelation therapy for cardiovascular purposes. A physician on the Task Force who represents a school of alternative medicine indicated that there are approximately 25,000 positive reports on the use of chelation for arteriosclerosis. He pointed out that the mainstream literature rests with eight negative reports. The Task Force member reported that he had chelated 3200 of his patients. Of those patients 33 percent have had excellent results; 33 percent have had good results; 15 percent have shown subjective improvement; and the rest have shown fair results. He noted that when objective studies on the patients' blood lipids, cholesterol, skin tone, sparkle in the eye, skin color, and aura were done, all but one had improved. In addition, the physician noted that 85 percent of those who were headed for bypass surgery never had to have it. The physician further points out that the eight negative studies were flawed or contrived for political purposes. He testified that a 22,755 patient meta-analysis found that chelation is most effective to address arteriosclerosis in the brain, heart, kidneys, and peripheral vascular disease, and that a spin-off of the study showed that there was a 90 percent reduction in the control population for cancer.

Both the AMA and the FDA oppose the use of chelation for purposes other than the removal of iron from the blood. The president of the Council for Reliable Health Information reported that the American College for Advancement in Medicine, a group of chelation therapy advocates, had agreed to settle charges by the Federal Trade Commission for unsubstantiated and false advertising that chelation therapy has been proven effective by scientific studies. He stressed that the basic facts of the biochemistry of atherosclerotic plaques and calcium metabolism indicate that chelation is unlikely to work. In responding to the Task Force member's testimony on the positive results of his own patients and those involved in the meta-analysis, the president of the Council on Reliable Health Information indicated that the studies have been uncontrolled and the benefits resulting may be attributable to the placebo effect or other interventions.

SECTION 4

Public Protection

Safety Concerns

This section addresses the safety of each complementary and alternative medicine (CAM) practice and the provisions by which the government and the industry itself safeguard the public. A fundamental tenet of medicine is to “do no harm.” Consequently, a basic concern about complementary and alternative medicine involves the possibility of adverse side effects. While this issue is also common to traditional medicine, most practitioners of traditional medicine are required to disclose the possible risks and the benefits of treatment to their patients and to obtain informed consent to the proposed procedure. Several of those testifying to the Task Force indicated that the risks and benefits of a CAM practice may not be known. Additionally, they maintain that generally proponents of CAM practices tend to overstate the possible effectiveness of CAM therapies. They suggested that practitioners of CAM may not have adequate training or background in medicine that would allow them to properly refer patients to traditional health care providers should a potential problem arise with therapy.

Alternatively, CAM practitioners testified that conventional medicine and common medical mistakes injure and even kill thousands of patients a year and that CAM therapies are not inherently unsafe. They stated that safety issues may be addressed by proper training and certification or licensure standards, where appropriate, and by educating the public on the benefits and limitations of particular therapies. Some proponents stated that licensure or certification would help to “weed out” unethical or unskilled persons and would raise the level of care. Other proponents, however, stated that they did not want licensure or other types of regulation to interfere with CAM practices that clearly do not involve the practice of medicine.

While some practices may be safe, posing no greater risk than standard treatments, other CAM practices may pose a risk of harm. Part of the difficulty with assessing safety arises from the dearth of objective studies with respect to many CAM practices. However, CAM providers assert that studies, since they typically use a medical model, may not be appropriate to assess the safety of CAM practices. Aside from the question of whether a particular CAM practice is harmful or harmless in itself, is the question of whether a person’s use of the CAM practice will mean that a traditional medical provider is not consulted. An additional concern is that some treatments which may be relatively safe for adults may pose risks to children, the elderly, or persons with underlying medical problems.

With regard to CAM therapies, members of the state Board of Medical Licensure testified that the Board is concerned that untrained practitioners of CAM may (1) Use therapies that are harmful to the patient; (2) Use prescribed treatments for a purpose other than indicated; (3) Use therapies that are not harmful in themselves but which may interact with other medications or therapies prescribed by a health care provider; (4) Use therapies that are not harmful in themselves but which may fail to recognize other serious health problems of the patient. The Board of Medical Licensure's position is that every patient should have a full evaluation by a physician or other qualified health care provider to make sure that there are no underlying medical conditions requiring treatment prior to undergoing CAM therapy. In particular, members of the Board of Medical Licensure expressed concern that chelation therapy may be used for conditions that are not medically indicated and that may result in serious adverse health impacts. A main concern of the Attorney General’s Office is that patients, as consumers of health services, be protected from

misleading claims as to the safety of treatments, and that they not pay for treatments which have no hope of providing treatment for certain conditions.

Acupuncture

Several persons testified to the Task Force that acupuncture was not unsafe when properly done. One concern raised with respect to the safety of acupuncture was the lack of controlled clinical research, and some testimony stated that improperly performed acupuncture can cause a number of problems. A nationally certified acupuncturist who is an officer of the National Acupuncture Foundation (NAF) reported that acupuncture when performed by trained individuals is an extremely safe procedure. She indicated that risks fall into two categories: risk to internal organs and complications due to improperly sterilized needles. The acupuncturist reported on a search of injuries attributable to acupuncture in the medical literature since 1958 that was conducted by NAF. As to risks of internal organs, she reported that in China and Japan, where thousands are treated by acupuncture each year, only ten injuries to internal organs were reported; in Korea, no injuries have been reported; and in the United States, only ten incidents of injury have been reported since 1995. Of the ten complications noted in the United States, the acupuncturist reported that one was noted as a "one-in-a-million" complication, and another involved self-inflicted injury by a licensed or certified acupuncturist who was licensed without examination or standards of competency. The national officer further reported that in the 12 years that the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) has certified over 6000 individuals in acupuncture, there have been no complaints of accidental injury caused by a certified practitioner.

Another cause of injury is due to unsterilized needles. The profession and the Center for Disease Control has established standards for clean needle technique. Citing the previous review of medical literature, the national officer reported that seven complications were attributed to unsterile needles in the United States. Of those seven, only three were attributed to treatment by acupuncturists. Of those three, one individual was not licensed or certified, one was licensed without examination, and the background of the other was not mentioned. The national officer reported that the study showed that no injury from unsterile needles has been reported for a certified acupuncturist who has met clean needle technique requirements.

The President of the Council for Reliable Health Information, a representative of the Board of Licensure and Certification for Dietitians and Nutritionists, and representatives of the State Board of Medical Licensure stated that acupuncturists should be held accountable to the same scientific standards and levels of quality assurance that the state licensing boards require for other health professionals. Another issue with respect to acupuncture is the depth of needle insertion or needle breakage, which could pose serious health risks. Also, if electrical stimulation is used, there may be a possibility of pain or other adverse effects.

Hypnotherapy and Yoga

Testimony was presented regarding the safety of hypnotherapy and yoga. The testimony with respect to hypnotherapy indicated that if the therapy was used on someone with a history of sexual or other types of abuse, the therapy should be done in conjunction with a mental health professional. Additionally, some testimony indicated that hypnotherapists might pose safety issues to patients, as there is not a standard for quality assurance with this therapy. Yoga was not described as having any safety issues.

Aromatherapy and Herbal Medicine

A nursing professor from the University of Louisville testified regarding the safety of aromatherapy and herbal medicine. In short, she reported that some herbs may be toxic or may cause side effects and some herbs, while not inherently dangerous, may interact with prescription or other medications. Many of these interactions have not been researched, so the potential side effects may not be known. Therefore, one concern would be that patients using herbs tell their physician, other traditional health care provider, or their pharmacist. The CAM practitioners stated that proper training in the dosage of herbs would address the safety issue. With respect to aromatherapy, no safety issues were raised.

Therapeutic Touch

There were no issues raised with respect to safety of this practice.

AMMA Therapy

A representative of the Board of Licensure and Certification for Dietitians and Nutritionists raised some issues concerning the safety of this practice with respect to nutritional claims that might mislead patients.

Naturopathy

A representative of the Board of Licensure and Certification for Dietitians and Nutritionists raised some issues concerning the safety of this practice with respect to nutritional claims that might mislead patients.

Provisions for Regulation of Therapy

Many CAM practices may fall into areas already regulated by Kentucky law. Generally, those professions that involve the use of therapies for the relief of physical symptoms have been regulated by law. Kentucky law regulates physicians, physician assistants, nurses, nurse practitioners, dietitians and nutritionists, chiropractors, physical therapists, and many other health care practitioners, and prevents those without licensure or certification in a certain area from practicing without that license or certification. For example, Kentucky law has a broad definition of what is the practice of medicine, and consequently, the Kentucky Board of Medical Licensure has adopted a position statement on acupuncture. According to the Board, acupuncture falls within the definition of the "practice of medicine" in KRS 311.550(10) (Appendix B). Therefore, it is the Board's opinion that only medical and osteopathic physicians licensed in the state and those falling within the exemptions in KRS 311.550(10) can practice acupuncture. However, the Board of Medical Licensure also stated that it did not believe that it had the statutory authority or physical or technical resources to assess whether a given CAM practice was effective. Under KRS 312.017 (Appendix C), chiropractors may not use acupuncture on their patients. A 1963 Attorney General's opinion (OAG 63-443) states that naturopathy, defined as "a system of therapeutics in which neither surgical nor medicinal agents are used, dependence being placed only on natural non-medicinal forces," cannot be practiced in Kentucky unless the practitioner has a license to practice medicine or osteopathy issued under KRS Chapter 311; is doing such work as a chiropractor licensed under KRS Chapter 312; is practicing as a physical therapist licensed under KRS Chapter

327; or has some other state license relating to a limited field of healing which would authorize the application of the principles of naturopathy.

There was testimony presented that indicated some practices would be suitable for certification, while others might be more suited to licensure. For example, over 30 states license acupuncturists, presumably because the activity engaged in is more invasive than other types of CAM treatments. However, the states that license acupuncturists vary in how much education and training is required before persons are allowed to be licensed. The recognition of any profession for licensure or certification may indicate the approval of the state as to the practices of that profession.

Industry Regulation

Many presenters stated that there are national or regional organizations that either provide training for or accredit providers of CAM. These organizations were asserted as being the standard for each type of CAM practice. However, the degree varies to which these organizations are widely accepted as offering a standard by which to judge the training or background of a particular CAM provider. Additionally, testimony varied on whether such accreditation should be voluntary or mandatory. The national officer of the Acupuncture Foundation testified that the National Certification Commission for Acupuncture and Oriental Medicine is the agency that accredits colleges offering Masters level programs in acupuncture and oriental medicine and that acupuncture is recognized by the United States Department of Education and the Council on Higher Education Accreditation. The NCCAOM examination is used in every state having a standard, except three. Questions were raised, however, about whether these organizations actually look at the proficiency of providers or whether any person could apply to receive accreditation or training. Additionally, many states differ in their requirements. There may also be competing national organizations which differ in their approaches to a particular CAM practice. For example, the American Association of Naturopathic Physicians provides that naturopaths should be trained in medicine and be licensed, while the Coalition for Natural Health believes that naturopaths should not be licensed, as it is not a “medical practice.”

Governmental Regulation

There are other state and federal laws and programs that may impact CAM. Kentucky laws that may provide for regulation of CAM practices, as noted above, are the consumer protection laws. KRS 367.110 et seq. (Appendix D) provide for consumer protections from unfair, false, misleading, or deceptive acts or practices in the conduct of trade or commerce in Kentucky. During the course of the Task Force study, the representative of the Attorney General’s Office expressed that some CAM practitioners may make false or misleading claims as to the safety and effectiveness of their therapies and that the popularity of certain CAM practices should not overshadow the need for consumer protection. The Attorney General’s office may bring action against a violator or refer the violation to the Commonwealth or County Attorney.

State Regulation

According to the National Conference of State Legislators' Health Policy Tracking Service, some states have passed legislation that would allow doctors of medicine to use alternative treatments even if the treatments are not considered to be generally accepted medical practices, and since 1997, four states — Colorado, Hawaii, Minnesota and Ohio — have enacted laws related to physicians practicing alternative medicine. The Health Policy Tracking Service reports as

illustrated in the following chart that 36 states recognize acupuncturists through licensure, certification, or registration; 11 states license naturopaths; and 27 states license or regulate massage therapists.

Federal Regulation

On the federal level, some CAM practices are regulated while others are not. For example, as noted above, acupuncture needles have been reclassified as a Class 2 medical device by the federal FDA. Drugs are regulated by the FDA, which describe them as substances that “sometimes can be derived from plants used as traditional medicines, and that, among other things, are intended to diagnose, cure, mitigate, treat, or prevent diseases.” Herbs, however, are not regulated by the FDA, as long as they are marketed only as food supplements and not as drugs. An herb manufacturer or distributor can make no specific health claims without FDA approval, as a product “sold as a dietary supplement and touted in its labeling as a new treatment or cure for a specific disease or condition would be considered an unauthorized, and thus illegal, drug.” The manufacture and sale of homeopathic medicines is also regulated by the FDA, and most of the medicines listed in the *Homeopathic Pharmacopoeia of the United States* under the federal Food, Drug and Cosmetic Act are available to the public without a prescription, according to the Health Policy Tracking Service. Additionally, the Federal Trade Commission has jurisdiction over unfair or deceptive acts and practices in or affecting interstate commerce and the false advertisement of food, drugs, devices, services, or cosmetics. For example, the FTC has investigated claims related to chelation therapy for blocked arteries.

State Recognition of CAM Practitioners

States	Recognized Acupuncturists	Recognized Naturopaths	Recognized Massage Therapists
Alabama			X
Alaska	X	X	
Arizona	X	X	
Arkansas	X		X
California	X		
Colorado	X		
Connecticut	X	X	X
Delaware			X
District of Columbia	X		X
Florida	X		X
Georgia			
Hawaii	X	X	X
Idaho			
Illinois	X		
Indiana			
Iowa	X		X
Kansas	X		
Kentucky			
Louisiana	X		X
Maine	X	X	X
Maryland	X		X
Massachusetts	X		
Michigan	X		
Minnesota	X		
Mississippi			

Missouri	X		
States	Recognized Acupuncturists	Recognized Naturopaths	Recognized Massage Therapists
Montana	X	X	
Nebraska			X
Nevada	X		
New Hampshire	X	X	X
New Jersey	X		X
New Mexico	X		X
New York	X		X
North Carolina	X		X
North Dakota			X
Ohio			X
Oklahoma			
Oregon	X	X	X
Pennsylvania	X		
Rhode Island	X		X
South Carolina	X		X
South Dakota			
Tennessee			X
Texas	X		X
Utah	X	X	X
Vermont	X	X	
Virginia	X		X
Washington	X	X	X
West Virginia	X		X
Wisconsin	X		
Wyoming			

Source: Compiled by LRC staff from data supplied by NCSL Health Policy Tracking Service

SECTION 5

Integration with Traditional Practices: Allopathic or Wholistic

Securing appropriate and competent professional expertise in complementary and alternative (CAM) therapies is cause for concern among the patients and the providers. When a patient or consumer seeks alternative treatment, he or she must be educated about the alternative arena and have confidence that the practitioner is well-educated and competent.

Some people testifying about their personal experiences at the public hearing on complementary and alternative medicine said that they found it difficult to locate a physician in Kentucky who had integrated alternative treatments. More often than not the patient had no option but to look outside the code of standard medical practice, in which case the patient had no option but to make a selection among unlicensed practitioners. The patients had little information about the therapists, because Kentucky has no certifying or licensing standards. It is possible that some of these therapists might not have minimal certification from the source of their training. Conceivably this certification could have been awarded for a two-week or less training program or even a correspondence course, although these are not necessarily the rule.

The bridge between allopathic and wholistic medicine and a synergy of resources and results, and a mutual open-mindedness on behalf of the individual and the practitioner is rare, even though both philosophies are based on the collective needs of the individual. Allopathic medicine or conventional medicine is based on the biomedical model and is the form taught in United States medical schools. Problems may arise when an allopathic health professional tries to integrate some alternative therapies because the therapies are difficult to correlate with some traditional techniques. For example, according to a naturopath, in Chinese medicine the multiple active ingredients in herbs are intended to affect the patient's chi, while Western chemical prescriptions are designed to alleviate symptoms. Additionally, a physician in family practice pointed out that the meridians of the body do not correspond to western anatomical systems. Using the wholistic approach, each patient is treated as a whole being, taking into account the person's lifestyle, mental state, environment, and diet — all factors which influence a person's health. At minimum therapists try to restore the patient's own self-healing ability. Additionally, they work on eliminating causes of illnesses, removing obstacles to recovery, and/or encouraging normal internal equilibrium. By contrast, the allopathic practitioners diagnose and treat disease, primarily using prescription drugs and possible surgical procedures.

As the Task Force took testimony from various practitioners and interested parties on several of the more widely used therapies, it learned that on occasion the therapies were integrated with allopathic treatment. On the other hand, most CAM therapies were provided by wholistic practitioners and health and wellness therapists.

Selection of Practitioners

An officer of the National Acupuncture Foundation (NAF) reported that 36 states and the District of Columbia allow the practice of acupuncture by non-physician acupuncturists; 30 states report that the practice of acupuncture is within the scope of practice of licensed medical physicians without specific training. Kentucky is one of the latter states, but few medical doctors in the state indicate that they perform acupuncture.

The officer stated that since acupuncture is widely accepted nationally by the public and by business, growing numbers of acupuncturists across the country are found to be practicing in hospitals and HMOs. She also reported that acupuncture, a component of Oriental Medicine, when not practiced by allopathic physicians, may be an entirely different practice. When practiced by a wholistic specialist, it may include Chinese herbology, exercise and breathing techniques, Oriental body work and massage, nutritional and lifestyle recommendations. A family practitioner and medical educator did not feel that the practice of acupuncture should be restricted to licensed medical doctors, also citing the inherent differences between the types of practices. He added that anatomy and physiology should be prerequisites for anyone who wishes to practice acupuncture.

A certified clinical hypnotherapist explained that hypnotherapy goes hand in hand with traditional medicine, its being more complementary than alternative. Hypnosis when used before surgery helps a person relax and visualize going through the surgery and recovering faster. It stimulates natural pain killers created naturally within the body. A second hypnotherapist said that primarily hypnotherapy is integrated with wholistic practices to facilitate the mind-body-spirit connection. Additionally, it is integrated into sports harmonization of the athlete, programs for exercise and positive attitudes, and stress release for the mentally ill.

Bridging the gap of allopathic vs. wholistic philosophies, in the Dean Ornish Program for reversing heart disease, Mutual of Omaha is covering costs of yoga and meditation as part of the complete rehabilitation package. Although there are referrals by licensed medical physicians, most yoga programs are provided by wholistic therapists and are taught as separate classes outside of medical facilities.

A professor of nursing reported that the American Wholistic Nurses Association teaches a program on aromatherapy that is being offered in about ten sites in the country, but no one had completed the program when she addressed the task force in January. She added that most herbal practitioners are naturopathic or oriental physicians, lay herbalists, and some health care providers with education in herbalism.

Some Nurses Provide Wholistic Therapies

Nurses seem to play a leading role in integrating CAM therapies. An adult nurse practitioner in family practice reported that because nurses seek to employ energy healing or therapeutic touch therapies, there are three levels of educational programs provided and coordinated through the Nurse Healers Association, which established and maintains the standards of practice. An academic dean of a wholistic school of nursing where AMMA Therapy (a specialized form of massage therapy) is taught indicated that at her school, the fourth and major or highest level of training is the certificate awarded to licensed nurses. Recently, she has provided this training to groups of nurses in Kentucky. At the three lower levels of certification, AMMA Therapy is designed as adjunct for the practices of chiropractic, massage therapy, and acupuncture.

A naturopathic doctor and national board member cited a university of Florida study which showed that 50% of conventional health care professionals had used some form of complementary and alternative medicine. At National College of Naturopathic Medicine, more than 5% of the entering class of 1997 were individuals with advanced degrees in allopathic, osteopathic, and chiropractic medicine. Additionally, many naturopathic physicians practice with other wholistic care health providers, an alliance which offers a variety of different arrangements. The Executive Director of the Coalition for Natural Health further elaborated that Naturopathy is not a medical practice; it does not focus on diagnosing and treating disease and employing prescription drugs and surgery. Instead, Naturopaths focus on health and education to create internal and external environments conducive to good health.

Minimal CAM Integration Shown in Survey and Public Hearing

Questions as to whether alternative medicine was used by Kentucky physicians and integrated into their practice was the subject of a survey (Appendix E) conducted by the Kentucky Medical Association (KMA). The Kentucky Medical Association surveyed primary physicians and internists at the request of the Task Force on Complementary and Alternative Medicine. Of the 440 respondents, 251 (59%) indicated that they discussed complementary treatments with less than half of their patients. In descending order, 79 (18%) of the respondents had never discussed complementary medical care with their patients, 52 (12%) of the respondents had discussed complementary medical care with most of their patients, and 10 (2%) of the respondents discussed CAM with all of their patients.

Doctors felt that it was appropriate to discuss complementary treatments with their patients, if available, for the following conditions in descending order: low back pain — 291 or (68%), chronic fatigue syndrome — 279 (65%), migraine — 249 (58%), and irritable bowel syndrome— 235 (55%). Respondents indicated that it was least appropriate for cancer — 84 (20%) and chronic otitis media — 63 (15%).

Of the doctors responding, 118 (27%) reported that they had never provided, recommended, or referred a patient for complementary medicine and 222 (62%) reported that they had provided treatment, referred, or recommended very few of their patients for alternative treatment. Also, only 28 (7%) actually provided the services themselves, while 68 (17%) referred their patients to specific CAM practitioners. Then, only four physicians reported that they had similarly provided, recommended, or referred all their patients. The alternative treatments most often provided by physicians were herbal medicine and nutritional therapy. Physicians most frequently referred patients for the following treatments: chiropractic (246), biofeedback (178), meditation/yoga (118), and acupuncture (112).

As many as 373 (86%) of the respondents reported that medical schools did not offer a course in alternative medicine while they were in medical school. Similarly, 388 (88%) of the respondents reported that they had never received any training in any form of alternative medicine. Of those who received additional/specialized CAM training, the highest number receiving such training was 21 (5%) for general education on CAT, 8 (2%) in acupuncture, and 5 (1%) in manipulation. It is clear that medical patients who seek the CAM therapies must do so outside of the licensed medical profession.

A professor of nursing reported that in a study conducted by students at the University of Louisville, 48 out of 60 Kentuckians used herbs with 22 informing their doctors of such use. The study also showed that 26 of the individuals took allopathic and herbal medicines, either on their own or at the suggestion of wholistic therapists. Of those 26, ten did not tell their doctors that they were using herbs. Also, a practicing acupuncturist in Kentucky cited the 1990 Eisenberg survey on CAM use, emphasizing that over two-thirds of the people who used CAM treatments nationwide did not tell their doctors.

At the March 26, 1999, meeting of the Task Force, 21 people testified at a public hearing, describing their experiences with various CAM therapies. All but two spoke of working primarily with wholistic therapists; one cautioned against non-allopathic therapies; and one spoke of a physician in another state successfully treating an illness with an unorthodox wholistic therapy.

The University of Louisville School of Medicine's representative to the Task Force reported that one member of the faculty of the Department of Anesthesiology and Preoperative Medicine uses acupuncture for pain control and management, two members of the faculty of the Department of Family Medicine provide lectures in complementary and alternative medicine, and that the Department of Psychiatry and Behavioral Sciences has expressed an interest in the use of hypnotherapy.

Spalding Project Links CAM

A professor from Spalding University reported that the school plans to sponsor a demonstration project as a Community-Based CAM Information, Education, and Resource Center. Its primary purpose is to unify resources at the local level. The center's long-range goal is to serve as a prototype for replication in other communities across the country. The project would have a heavy evaluative component, a strong materials development and adaptation component, and a highly qualified medical/health staff to operate the center. It is anticipated that a center of this type would fill the need of connecting patients/clients with appropriate therapies and qualified therapists.

A follow-up determined that the project would not be funded as planned through the National Institute of Health; thus, it is stalled. Spalding did survey the metropolitan Louisville population, seeking to learn if citizens were actually using CAM therapies and to what extent. A second project surveyed nurses to determine if they used CAM therapies or if they sought such training. Analyses have not been completed at this time.

SECTION 6

Public Demand

The use of alternative medicine is becoming increasingly more popular. To date, 36 states and the District of Columbia license, certify, or register acupuncturists; 11 states license naturopaths; four states license homeopaths; and 11 states have enacted Health Freedom Acts which insulate physicians from discipline by their medical licensing boards solely because of the physician's use of alternative medicine.

National Data

Opponents and proponents alike agree that a growing number of people are using alternative medicine. A survey conducted in 1990 by Eisenberg, et al. on the prevalence, costs, and patterns of use of nonconventional medicine found that one in three respondents had used at least one nonconventional therapy in the past year with approximately one-third of those using the therapies reporting that they had seen a provider for nonconventional therapy. The survey indicated that the majority of the respondents used nonconventional therapy for chronic as opposed to life-threatening medical conditions. The survey also showed that approximately 83 percent of those seeking nonconventional treatment for serious medical conditions also sought treatment for serious medical conditions from a medical doctor; and that 72 percent of those using nonconventional medical treatment had not informed their physicians of their use of alternative methods.

By extrapolating the above findings to the U.S. population, the survey's authors deduced that Americans made an estimated 427 million visits to the providers of nonconventional therapy — more than those to primary care physicians. Approximately 13.7 billion dollars were spent on alternative care of which 10.3 billion dollars were paid out-of-pocket, as compared to the 12.8 billion dollars spent out-of-pocket annually for hospitalizations.

A follow-up survey was conducted in 1997. At that time, 42 percent of those queried reported using at least one alternative therapy during the previous year. As in the 1990 survey, alternative therapies were used most often for chronic conditions, including back problems, anxiety, depression, and headaches. The probability of users' visiting an alternative medicine provider increased from 36.3 to 46.3 percent. There was no significant change in the two survey years for the conditions for which the alternative therapies were used most often, the disclosure rate to physicians, and the percentage of users paying entirely out-of-pocket for services provided by alternative medical practitioners.

Extrapolations to the U.S. population suggest a 47.3 percent increase in the total visits to alternative medicine practitioners from 427 million visits in 1990 to 629 million in 1997, thereby exceeding the total visits to all U. S. primary care physicians. An estimated 15 million adults in 1997 or 20 percent of prescription medicine users in the United States took prescription medication concurrently with herbal remedies or high-dose vitamins. Less than 40 percent of those who used at least one or more alternative treatments and who had a physician disclosed that use to their physician.

A representative of the state Board of Medical Licensure reported on a survey published in the Journal of the American Medical Association indicating that two-thirds of the medical schools

offered courses on CAM for their students. The 1997-1998 survey of 117 of the 125 United States medical schools found that most of the CAM courses were electives.

In a footnote to his written remarks to the Task Force, the President of the Kentucky Council for Reliable Health Information acknowledged the growth of interest in alternative medicine but posits that the interest may be driven by heavy advertising and media coverage. He points out that alternative medicine is now big business and is being aggressively marketed by numerous practitioners and distributors, and cautions the Task Force members to reject the notion that a practice is worthwhile because of its long time use or the large quantity of people using it.

Federal Legislation

Several of those testifying before the Task Force cited the creation of the Office of Alternative Medicine within the National Institutes of Health in 1991 as evidence of the increasing prominence of alternative medicine. The Office's charges are to conduct and support basic and applied research and training, disseminate information on complementary and alternative medicine to practitioners, and provide public moneys for research. Among the Office's activities is the creation of a Clearinghouse and the establishment of 13 specialty research centers across the nation that are engaged in conducting ongoing research in areas such as pain management, women's health, and chiropractic.

The Office's budget has increased significantly since its establishment. The Office's budget for fiscal year 1993 was \$2 million and increased in subsequent years to \$3.5 million for fiscal year 1994, \$5.5 million for fiscal year 1995, \$7.8 million for fiscal year 1996, \$12 million for fiscal year 1997, and \$20 million for fiscal year 1998. The Office has subsequently become the National Center for Complementary and Alternative Medicine with a budget of \$50 million in fiscal year 1999. Holding a different view, the president of the Kentucky Council for Reliable Health Information testified that the creation of the OAM was a political decision.

Kentucky Initiatives

Testimony provided by representatives of the Commonwealth's medical schools support a growing, but limited interest in alternative medicine. Each of the state's three medical schools provides its students with some lectures or workshops in complementary and alternative medicine, but none has a required or elective course dealing primarily with such medicine. Specifically, a member of the University of Kentucky College of Medicine's faculty reported that he operates a clinic of integrative medicine and teaches integrative medicine classes at the University. He also noted that the University's Annual Family Practice Review includes sessions on integrative medicine, such as mind, body, and spirit medicine and herbal medicine. The medical college is one of 46 medical schools in the country that was awarded a grant from the Templeton Foundation to incorporate the teaching of spirituality into the entire medical school curriculum.

In testimony to the Task Force, the president of the Pikeville College of Osteopathic Medicine reported that it has seminars to familiarize its students in complementary and alternative medicine. He pointed out that herbal medicine has been the focus of several of the seminars because of the strong presence of herbs in the Appalachian area.

Use by Kentucky Consumers and Physicians

Questions relating to the use of alternative medicine were included in the 1998 Fall Survey conducted by the University of Kentucky's Survey Research Center. Relevant questions addressed

the use of alternative medicine during the prior 12 months by respondents and their families and what factors would generate greater use of alternative medicine. Approximately 58% of the respondents indicated that in the past year they or a family member had used at least one of the listed therapies. Because of the overall low response rate to the survey (27.5%), this figure and the extrapolation of the results cannot be reported with an adequate level of confidence until additional survey work is done for comparison.

The Kentucky Medical Association queried family practitioners and internists on their experiences with complementary medicine at the request of the Task Force. The results from the survey, to the extent they were valid, showed that chiropractic was available in metropolitan, suburban, and rural areas and in small cities and towns; therapeutic massage, herbal medicine, nutritional therapy, biofeedback, meditation, or yoga were available in places other than metropolitan or suburban areas; and that doctors or members of their immediate family who have received complementary treatment have practices in areas other than metropolitan or suburban areas. One hundred sixty-six doctors (38%) reported that they or someone in their immediate family had used complementary medicine.

A nursing professor from the University of Louisville reported to the Task Force on a study conducted by her graduate nursing students showing that 48 out of 60 used herbs with 22 informing their doctors of such use. The study also shows that 26 of the individuals take both allopathic and herbal medicines. Of those 26, ten reported that they did not tell their doctors they were using herbs.

Cost Effectiveness

A board-certified acupuncturist testifying to the Task Force cited a study of patients in six clinics as evidence of acupuncture's cost effectiveness. According to that study: 70% of the patients who had been recommended for surgery were able to avoid surgery because of acupuncture. The following favorable results occurred: 84% of the patients reported seeing their physician less; 58.5% of those seeing a psychotherapist reported seeing their psychotherapist less; 77% of those seeing a physical therapist reported seeing a physical therapist less; 79% reported a reduction in the use of prescribed drugs; and 77% reported they were asking for fewer reimbursements from the insurance companies. The beneficial side effects were that patients reported that they felt better, missed fewer days of work, got along better with others, had less pain, had more energy, were more focused, and could work better. The study showed savings of \$9000 per person for avoided arthroplasty surgery for the knee, savings of \$26,000 per patient for decreased days in hospital or nursing home for stroke patients, 62 % of low back patients were able to return to original or equivalent jobs involving physical labor, as compared to 15% who normally return, and savings of \$13,000 per patient and 79% fewer hospital visits for angina patients.

The nursing professor testifying to the Task Force reported on a study by O'Hara et al. on 12 commonly-used herbs. Those herbs were found to be less costly than their drug counterparts.

In testimony before the Task Force, a licensed naturopath representing the American Association of Naturopathic Physicians (AANP) reported that in 1989 the state of Hawaii had audited health costs associated with naturopathic medicine and concluded that there was no evidence that naturopathic medicine has increased health care costs. The licensed naturopath reported that similarly the British Columbia Government Medical Services Plan had audited naturopathic practice in 1988 and found naturopathic medicine to be cost -effective. She cited an article in a 1991 issue of the Journal of the American Medical Association that suggests that medical costs could be reduced by up to 20% by reducing the rate of intervening medicine and unnecessary surgery.

The licensed naturopath noted that naturopathic medicine is seen as an alternative to some high-tech procedures of orthodox medicine which are costly. Her testimony also noted that American Western Life, an insurer that covers naturopathic care, claims savings of between 31 and 76% for natural treatments for arthritis, ear infections, and high-blood pressure. She said that in accordance with an article in the Wall Street Journal, insiders at American Western say they are making money and will have bigger savings in the future since preventive care will stave off high priced claims.

Availability and Accessibility of Treatments

The Kentucky Medical Association (KMA) addressed the availability of complementary or alternative treatments in a survey of the state's primary physicians and internists. The greatest number of doctors responding (422 responses) reported that these treatments were available in their area: chiropractic (383), therapeutic massage (288), herbal medicine (245), nutritional therapy (233); and acupuncture(162).

The licensed naturopath reported that over 70 insurance companies, unions, and state organizations have health plans covering naturopathic medical services. Audits of naturopathic services and surveys of insurance companies have indicated that naturopathic medicine is less expensive than conventional care, perhaps by as much as half. The actual savings may be higher because none of the audits measured the long term effect of the naturopathic preventive approach in reducing costs associated with serious chronic diseases.

Oregon PacifiCare recently expanded its agreement with Complementary Health Care Plans to expand its network to include naturopathic physicians. In the Northeast, Oxford Health offers alternative medicine coverage for its more than one million members. Oxford requires strict credentialing standards.

A naturopath representing the American Naturopathic Medical Association testified that the availability and accessibility of naturopathy had been less than it should be because of the efforts of conventional medical providers to suppress competition.

Availability of Therapists

The licensed naturopath testifying to the Task Force reported that nationwide the number of naturopathic physicians is growing exponentially. In 1991, there was an average of 91 people applying to naturopathic medical school while in 1998, there was an average of 288 applying. In testimony before the Task Force, the Dean of the School of Wholistic Nursing at the New York College for Wholistic Health Education and Research said that there were 500 or 600 persons trained in AMMA therapy.

SECTION 7

Recommendations

After considerable deliberations, the Task Force has made the following recommendations. The recommendations set out are intended to be used as guiding principles for furthering integrative medicine. The acupuncture bill draft in particular is the result of significant compromise and reflects the efforts of the various constituencies to draft a piece of legislation that provides consumer safeguards.

In General

1. Permit aromatherapy, acupressure, massage, nutrition, reflexology, hypnosis, and vitamin therapy to remain unregulated because of the low risk involved. In approving alternative treatments, draw a line of demarcation between those that present little risk or are not invasive and those that are invasive and potentially dangerous.
2. Require that those alternative medical practices that have potentially serious adverse effects on the patient be allowed, only if the practitioner is licensed or certified; is acting within the scope of his or her practice; and meets sufficient standards to ensure his or her capabilities to practice and to respond appropriately when the adverse effects present themselves.
3. Explore criteria that should be used to evaluate therapies. Criteria should be inspired by compassion and guided by science, and should not merely reflect what the market will bear. The appropriateness of the research (double-blind studies, outcome-based studies, observation, etc.) should be based on the modality used and the risks the modality entails.
4. Encourage dialogue between responsible leaders of the alternative medical community and conventional academic institutions concerning appropriate ways to integrate therapies.
5. Prohibit claims to the public that are false, deceptive, and misleading.

Medical Schools

1. Recommend medical schools to train physicians how to engage in responsible conversations with patients on using alternative therapies.
2. Ensure that alternative treatments are provided by qualified persons.
3. Recommend that medical schools educate their students on complementary and alternative medicine in a fair, non-biased presentation that includes scientific research and outcome-based studies. Course should have an experiential component so that students can experience using complementary and alternative medicine instead of simply arguing its legitimacy in mainstream medicine.

Physicians

1. Endorse the policy of the Kentucky Board of Medical Licensure which recognizes that innovative practices that could benefit patients and improve care should be given reasonable and responsible latitude.
2. Support the concept that the Kentucky Board of Medical Licensure must have as its first and most important concern the safety and health of the public: whether patients are being diagnosed and treated appropriately.
3. Endorse the policy that the Board will continue to protect the citizens of the Commonwealth of Kentucky by:
 - Ensuring that licensees employ and document the medical model in their overall evaluation and treatment of the patient (i.e. history, physical, plan of treatment, and periodic assessment and follow-up);
 - Ensuring that the licensee had the requisite training and skills to perform the particular care and procedure;
 - Ensuring that the licensee honestly and fully explain the various treatment options available for treatment of the particular condition, to include the risks and benefits of such treatment options or procedures;
 - Ensuring that the licensee, when discussing treatment options or procedures that are not yet the standard of care and which are believed might benefit a particular patient, discuss at some level of detail the lack of evidence to be addressed, patient expectations for the treatment, the risk that might be encountered, and the fact that some risk may be presently unknown;
 - Carefully scrutinizing any treatment which results in harm to the patient.

Non-Physicians

1. License acupuncturists (See accompanying bill.)
2. Require non-physicians using alternative therapies to honestly and fully explain the various procedures available for treatment of the particular condition, including the risk and benefits of such treatment.

AN ACT relating to acupuncture.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

SECTION 1. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

As used in Sections 1 to 17 of this Act:

- (1) "Acupressure" means the application of pressure to acupuncture points;
- (2) "Acupuncture needle" means a needle designed exclusively for acupuncture purposes. It has a solid core, with a tapered point and is twelve-hundredths (0.12) of one (1) millimeter to forty-five hundredths (0.45) of one (1) millimeter thick, and is constructed of stainless steel, gold, silver, or other board-approved material that can be sterilized according to the recommendations of the National Centers for Disease Control and Prevention;
- (3) "Acupuncture points" means specific anatomically described locations as defined by the recognized acupuncture reference texts. The texts are listed in the study guide for the National Certification Commission for Acupuncture and Oriental Medicine certification examination;
- (4) "Acupuncture practitioner" means a person licensed to practice acupuncture under Sections 1 to 17 of this Act;
- (5) "Board" means the Board of Medical Licensure;
- (6) "Breathing techniques" means breathing exercises taught to a patient as part of a treatment plan;
- (7) "Cupping" means a therapy in which a jar-shaped instrument is attached to the skin and negative pressure is created by using suction;
- (8) "Dermal friction" means rubbing on the surface of the skin using topical ointments with a smooth-surfaced instrument without a cutting edge that can be sterilized or, if disposable, used one (1) time only;
- (9) "Electrical stimulation" means a method of stimulating acupuncture points by an electrical current of one-thousandth (.001) of one (1) milliamp to one hundred (100) milliamps, or other current as approved by the board. Electrical stimulation may be used transcutaneously without penetrating the skin;
- (10) "Herbal supplemental therapies" means the use of herbs and patent herbal remedies as supplements as part of the treatment plan of the patient;
- (11) "NCCAOM" means the National Certification Commission for Acupuncture and Oriental Medicine or its successor;
- (12) "Needle sickness" means a temporary state of nausea and dizziness that is a potential side effect to needle insertion from which full recovery occurs when the needles are removed; and
- (13) "Practice of acupuncture" means the insertion of needles, with or without accompanying electrical or thermal stimulation at certain acupuncture points or, meridians on the surface of the human body for purposes of changing the flow of energy in the body and may include acupressure, cupping, moxibustion, Gwa Sha, exercise and breathing techniques, nutrition without the use of herbs unless in accordance with the Food and Drug Administration standards, and lifestyle change. The practice of

acupuncture shall not include laser acupuncture, osteopathic manipulative treatment, chiropractic adjustments, physical therapy, surgery, or utilization of diagnostic tests and procedures.

SECTION 2. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) Any person who engages in the practice of acupuncture shall be licensed. The license shall be conspicuously displayed in the licensed acupuncture practitioner's place of business.

(2) An acupuncture practitioner shall use the designation "licensed acupuncturist" or "L.Ac." following his or her name in all advertisements, professional literature, and billings used in connection with his or her practice. A person who is not licensed under Sections 1 to 17 of this Act shall not use any terms, words, abbreviations, letters, or insignia that indicates or implies that he or she is engaged in the practice of acupuncture.

(3) Any person who violates this section shall be guilty of a Class A misdemeanor.

SECTION 3. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) The provisions of Section 2 to 17 of this Act shall not apply to persons licensed, certified, or registered under any other provision of the Kentucky Revised Statutes, including but not limited to physicians, nurse practitioners, dentists, chiropractors, podiatrists, or students enrolled in accredited training programs in these professions. Nothing in Sections 2 to 17 of this Act shall be construed to limit, interfere, or restrict the practice, descriptions of services, or manner in which these persons hold themselves out to the public.

(2) Nothing in Sections 1 to 17 of this Act shall be construed to apply to the activities and services of a student intern or trainee pursuing a program of studies in the practice of acupuncture in an institution approved by the board for teaching the practice of acupuncture if the person is designated an acupuncture intern or student in training and the intern's activities are performed under supervision and constitute a part of the supervised program of study.

(3) Nothing in Sections 1 to 17 of this Act shall be construed to apply to the activities of visiting acupuncturists in performing their duties as teachers at a board-approved institution or board-approved workshop or tutorial.

(4) Nothing in Sections 1 to 17 of this Act shall prohibit a person who is not a licensed acupuncture practitioner from practicing specific noninvasive techniques that constitute the practice of acupuncture, as defined in Section 1 of this Act, such as acupressure, cupping, and dermal friction.

(5) Nothing in Sections 1 to 17 of this Act shall be construed to restrict the activities of a person not licensed under Sections 1 to 17 of this Act to engage in auricular acupuncture for the purpose of treating alcoholism, substance abuse, or chemical dependency if the person:

(a) Provides the board documentation of having successfully completed a board-approved training program in acupuncture for the treatment of alcoholism, substance

abuse, or chemical dependency that meets or exceeds the standards of training set by the National Acupuncture Detoxification Association;

(b) Provides the board documentation of having successfully completed a clean needle technique course; and

(c) Maintains the ethical standards of Sections 1 to 17 of this Act and administrative regulations promulgated by the board under Sections 1 to 17 of this Act.

SECTION 4. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) Prior to July 15, 2002, a person may qualify for provisional licensing on the basis of the person's experience if:

(a) He or she has engaged in the practice of acupuncture for at least three (3) of the past five (5) years with at least five hundred (500) patient visits with at least one hundred (100) different patients in each of the three (3) years;

(b) He or she provides documentation of having completed a "clean needle course" approved by the Acupuncture Advisory Council established by Section 11 of this Act;

(c) He or she provides at least four (4) of the following:

1. Letters from employers specifying the dates and hours worked, the nature of the practice, and the number of acupuncture patient visits;

2. Affidavits from a minimum of twenty (20) patients with current phone numbers and addresses for each, specifying the time, period, and nature of treatment;

3. Affidavits from two (2) other persons with personal knowledge regarding the dates, volume, scope, and type of practice;

4. Affidavits from at least two (2) of the following, other than those supplying information in subparagraphs 1. and 4. of this paragraph: health-care professionals, state or local acupuncture or Oriental medicine associations, and board-approved schools or colleges on the dates, volume, scope, and type of practice; or

5. Copies of patient records with all identifying information removed;

(d) He or she submits an application for licensure on forms provided by the board and pays all required fees;

(e) He or she signs an affidavit attesting that the information contained in the application is true and correct to the best of the applicant's knowledge and belief;

(f) He or she signs a waiver authorizing the board to obtain access to the applicant's records in this state or in any state in which the applicant has practiced acupuncture or any health-care profession; and

(g) He or she submits any other reasonable information the board may require.

(2) Any information provided under paragraphs (a) to (d) of subsection (1) of this section that is submitted in a foreign language shall be accompanied by an accurate translation in English. Each translated document shall bear the notarized affidavit of the translator certifying that the translator is competent in both the language of the original document and in English, and that the translation is a true and complete translation of the original document.

(3) Prior to July 30, 2002, an application for licensing under this section may be submitted to the board. A person may not apply for licensing under this section until he or she has completed all patient visits required under subsection (1)(a) of this section.

(4) The license shall expire one (1) year after the date of its issuance, and shall be nonrenewable. The board may issue a permanent license to an applicant who is issued a provisional license under this section if the applicant provides proof to the board that he or she is currently certified in accordance with NCCAOM requirements and meets other requirements as promulgated by the board in administrative regulations.

SECTION 5. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) The board, on the advice of the Acupuncture Advisory Council, may license a person by endorsement if:

(a) The person holds a current license or certificate as an acupuncturist from another jurisdiction;

(b) The person is in good standing in the other jurisdiction; and

(c) The board determines that the standards under which the person was initially certified or licensed in the other jurisdiction meet or exceed the requirements under Section 6 of this Act.

(2) The applicant for licensing under subsection (1) of this section shall also:

(a) Submit an application for licensure on forms provided by the board and pay all required fees;

(b) Sign an affidavit attesting that the information contained in the application is true and correct to the best of the applicant's knowledge and belief;

(c) Sign a waiver authorizing the board to obtain access to the applicant's records in this state or in any state in which the applicant has practiced acupuncture or any health-care profession; and

(d) Submit any other reasonable information the board may require.

SECTION 6. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) A person may be licensed as an acupuncture practitioner if the person:

(a) Submits an application for licensure on forms provided by the board and pays all required fees;

(b) Submits an official copy of the applicant's current NCCAOM certification;

(c) Signs an affidavit attesting that the information contained in the application is true and correct to the best of the applicant's knowledge and belief; and

(d) Signs a waiver authorizing the board to obtain access to the applicant's records in this state or in any state in which the applicant has practiced acupuncture or any health-care profession.

(2) The board may request the applicant to provide other reasonable information the board may require.

SECTION 7. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) The board may request any reasonable information necessary to clarify whether the information submitted in the application under Sections 4 to 6 of this Act is complete and accurate. The board shall notify each applicant in writing of the action it takes on the application within one hundred twenty (120) days of the board's receipt of the application.

(2) If the board denies an application, it shall notify the applicant of the grounds on which the denial is based. The applicant may then request a hearing from the board in accordance with KRS Chapter 13B.

SECTION 8. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) Any person licensed as an acupuncture practitioner shall annually, on or before June 1 of each year, pay to the board a renewal fee established by the board in administrative regulations. The renewal fee shall not exceed two hundred dollars (\$200). A license that is not renewed by June 1 of each year shall expire for failure to renew in a timely manner.

(2) The board shall notify the licensee of the renewal date at the licensee's last known address. The notice shall include an application and notice of renewal fees. It shall be no excuse that the licensee did not receive the renewal notice.

(3) A sixty (60) day grace period shall be allowed after June 1 of each year during which the acupuncture practitioner may continue to practice. The acupuncture practitioner may renew his or her license upon payment of the renewal fee and a late renewal fee of fifty dollars (\$50).

(4) Any license not renewed by the end of the grace period shall terminate, and the practitioner shall no longer be eligible to practice acupuncture in the Commonwealth. An individual with a terminated license may have his or her license reinstated upon payment of the renewal fee and a reinstatement fee as established by the board in administrative regulations. A person who applies for reinstatement shall not be required to take an examination as a condition of reinstatement if the person's reinstatement application is made within five (5) years of the date of termination.

(5) A suspended license shall expire and terminate if not renewed. Renewal of a suspended license shall not entitle the licensee to practice until the suspension has ended or the right to practice is restored by the board.

(6) A revoked license shall terminate and may not be renewed. If a revoked license is reinstated, the licensee shall pay the renewal fee and the reinstatement fee under subsections (1) and (3) of this section, respectively.

(7) If a person fails to reinstate his or her license within five (5) years of its termination, the license shall not be renewed, restored, reissued, or reinstated. The person shall obtain a new license under the conditions established in Section 6 of this Act.

(8) The board may require that a person applying for renewal or reinstatement of licensing complete continuing education requirements as established in administrative regulations promulgated by the board.

SECTION 9. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) A person licensed under Section 4, 5, or 6 of this Act may apply for inactive status upon submitting an application and paying an inactive status fee.

(2) An inactive license may be reactivated upon application to the board. If a license has been inactive for more than five (5) consecutive years, the licensee shall apply for a

new license and shall meet all the requirements in existence for a license under Section 5 or 6 of this Act. That application for licensing shall require:

- (a) Evidence of the certificate holder's payment of an inactive status fee; and
- (b) Payment of the initial licensing fee..

SECTION 10. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

The board may issue a temporary permit to practice acupuncture to an applicant eligible for licensing if a complete application for licensure has been submitted and all fees have been paid, including a nonrefundable temporary permit fee. The temporary permit shall be nonrenewable and shall be effective only until the meeting of the board at which a decision is made on the applicant's application for licensing. The permit shall not be in effect for more than ninety (90) days.

SECTION 11. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) There is hereby established the Acupuncture Advisory Council under the Board of Medical Licensure. The council shall consist of seven (7) members appointed by the Governor. Four (4) members shall be licensed acupuncture practitioners; one (1) member shall be a licensed physician or osteopath who also practices acupuncture; one (1) member shall be a member of the board; and one (1) member shall be a member of the public who shall not be associated with or financially interested in the practice of acupuncture. The original members shall be appointed as follows: one (1) member for a one (1) year term; two (2) members for a two (2) year term; two (2) members for a three (3) year term; and two (2) members for a four (4) year term. All members thereafter shall be appointed for a term of four (4) years. Any vacancy in the membership of the council shall be filled for the unexpired term by appointment of the Governor.

(2) Each member of the council shall receive one hundred dollars (\$100) for each day of service actually given in carrying out the member's duties under this section and actual and necessary traveling, hotel, and contingent expenses incurred in attending the meetings of the council and performing its duties.

(3) The council shall annually elect a chairman and a secretary. The council shall hold at least two (2) meetings annually, and may hold additional meetings upon the call of the chairman or the written request of at least three (3) council members. The secretary shall keep a record of the minutes of the council's meeting. Four (4) members of the council shall constitute a quorum to conduct business.

(4) The Governor may remove any member for poor attendance at council meetings, neglect of duty, or malfeasance in office.

(5) The advisory council shall:

- (a) Advise the board on the issuance, denial, suspension, or revocation of or restriction on licenses to practice acupuncture;
- (b) Advise the board on issues relating to the receipt, investigation, or conduct of hearings and the imposition of disciplinary actions in relation to complaints against persons engaging in the practice of acupuncture;
- (c) Maintain a record of all advisory council actions;
- (d) Review the patient visit records submitted by applicants for licensing or renewal thereof;

- (e) Advise the board on standards for acupuncture practitioners;
- (f) Review complaints;
- (g) Advise the board on continuing education programs;
- (h) Review the investigation of reports of complaints and recommend to the board whether disciplinary action should be taken;
- (i) Assist the board in promulgating administrative regulations necessary to carrying out the provisions of Sections 1 to 17 of this Act; and.
- (j) Perform other duties as directed by the board.

SECTION 12. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

Before an acupuncture practitioner engages in the practice of acupuncture, he or she shall enter into a written collaborative agreement with a physician. The agreement shall be in accordance with administrative regulations promulgated by the board, and shall not exceed the scope of practice for acupuncture set out in Sections 1 to 17 of this Act.

SECTION 13. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) Before treating a patient, an acupuncture practitioner shall ask the patient whether he or she has been examined by a physician as defined in KRS 311.550 and a chiropractor as defined in KRS 312.015 concerning the patient's illness or injury. If the patient has been examined, the acupuncture practitioner shall review the physician's or chiropractor's diagnosis before initiating treatment.

(2) The acupuncture practitioner shall obtain informed consent from the patient and the practitioner shall disclose to the patient the following written information prior to or at the patient's initial visit:

(a) The practitioner's qualifications, including his or her education, license information, and the scope of practice of acupuncture, in the Commonwealth of Kentucky; and

(b) The side effects of the treatment to be given, including any pain, bruising, infection, needle sickness, broken needles, or other injuries that may occur.

(3) If the patient's circumstances warrant consultation, the practitioner shall obtain from the patient his or her written acknowledgment that the practitioner has advised the patient to consult with his or her primary care physician about the acupuncture treatment.

(4) Prior to engaging in the practice of acupuncture, the practitioner shall ask the patient if he or she has a pacemaker or bleeding disorder.

SECTION 14. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) An acupuncture practitioner shall use sterilized needles in accordance with standards established by the National Centers for Disease Control and Prevention.

(2) An acupuncture practitioner shall comply with all applicable state and municipal reporting requirements imposed on health-care professionals regarding public health.

(3) An acupuncture practitioner shall maintain a record for each patient treated. The record for each patient shall include:

- (a) A signed copy of the information disclosed by the practitioner to the patient under subsections (2) and (3) of Section 13 of this Act;
- (b) Evidence that the practitioner has conducted or overseen an interview concerning the patient's medical history and current physical condition;
- (c) Evidence of the practitioner having conducted a traditional acupuncture examination and diagnosis;
- (d) A record of the treatment, including the acupuncture points treated; and
- (e) The evaluation and instructions given.

(4) An acupuncture practitioner may refer patients to other health-care practitioners and shall request a consultation or written diagnosis from a licensed physician if the patient has a potentially serious disorder, including, but not limited to:

- (a) Hypertension and cardiac conditions;
- (b) Acute, severe abdominal pain;
- (c) Acute, undiagnosed neurological changes;
- (d) Unexplained weight loss or gain in excess of fifteen percent (15%) of the patient's body weight in less than a three (3) month period;
- (e) Suspected fracture or dislocation;
- (f) Suspected systemic infections;
- (g) Serious diagnostic hemorrhagic disorder; and
- (h) Acute respiratory distress without a previous history.

SECTION 15. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) The initial licensing fee and renewal fee shall be set out in administrative regulations promulgated by the board, and each shall not exceed two hundred dollars (\$200).

(2) Fees collected by the board under Sections 1 to 17 of this Act shall be deposited in the State Treasury to the credit of a revolving fund for purposes of implementing Sections 1 to 17 of this Act. No part of the revolving fund shall revert to the general fund of this Commonwealth.

SECTION 16. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) The board may refuse to issue, renew, suspend, revoke, or impose probationary conditions upon a license, impose an administrative fine, issue a written reprimand or admonishment, demand restitution, or any combination thereof regarding any licensee upon proof that the licensee has:

- (a) Committed any act of dishonesty or corruption. If the act constitutes a crime, conviction in a criminal proceeding is not a condition precedent to disciplinary action. Upon conviction of the crime, the judgment and sentence are presumptive evidence at the ensuing disciplinary hearing of the guilt of the licensee or applicant. Conviction includes all instances in which a plea of no contest is the basis of the conviction;

- (b) Misrepresented or concealed a material fact in obtaining a license or in the reinstatement thereof;
- (c) Committed any unfair, false, misleading, or deceptive act or practice;
- (d) Been incompetent or negligent in the practice of acupuncture;
- (e) Violated any state statute or administrative regulation governing the practice of acupuncture or any activities undertaken by an acupuncture practitioner;
- (f) Failed to comply with an order issued by the board or an assurance of voluntary compliance;
- (g) Violated the code of ethics as established by the board by administrative regulation; or
- (h) Violated any applicable provision of any federal or state law.

(2) Five (5) years from the date of a revocation, any person whose license has been revoked may petition the board for reinstatement. The board shall investigate the petition and may reinstate the license upon a finding that the individual has complied with the terms prescribed by the board and is again able to competently engage in the practice of acupuncture.

(3) (a) The board may issue a written admonishment to the licensee, when in the judgment of the board:

- 1. An alleged violation is not of a serious nature; and
- 2. The evidence presented to the board after the investigation, including an appropriate opportunity for the licensee to respond, provides a clear indication that the alleged violation did in fact occur.

(b) A copy of the admonishment shall be placed in the permanent file of the licensee.

(c) The licensee shall have the right to file a response to the admonishment within thirty (30) days of its receipt and to have the response placed in the permanent licensure file.

(d) The licensee may alternatively, within thirty (30) days of the admonishment's receipt, file a request for a hearing with the board.

(e) Upon receipt of a request for a hearing the board shall set aside the written admonishment and set the matter for a hearing under the provisions of KRS Chapter 13B.

(4) At any time during the investigative or hearing processes, the board may enter into an agreed order or accept an assurance of voluntary compliance with the licensee which effectively deals with the complaint.

(5) The board may, upon the agreement of the aggrieved party, use mediation to handle disciplinary matters. The board may appoint any member or members of the board, any staff member, or any other person or combination thereof to serve in the mediation process.

(6) The board may reconsider, modify, or reverse its disciplinary actions.

SECTION 17. A NEW SECTION OF KRS CHAPTER 311 IS CREATED TO READ AS FOLLOWS:

(1) The board, before suspending, revoking, imposing probationary or supervisory conditions upon a licensee, imposing an administrative fine, issuing a written reprimand, or any combination of these actions regarding any licensee under the provisions of

Sections 1 to 17 of this Act, shall set the matter for a hearing under the provisions of KRS Chapter 13B.

(2) After denying an application under the provisions of Sections 1 to 17 of this Act or issuing a written admonishment, the board at the request of the aggrieved party, shall grant a hearing under the provisions of KRS Chapter 13B.

(3) Except for final orders denying an application for or renewal of licensure or emergency orders temporarily suspending, limiting, or restricting an acupuncture practitioner's license, all final orders of the board affecting an acupuncture practitioner's license shall become effective thirty (30) days after notice is given to the licensee, unless otherwise agreed. However, the board may provide that a final order be effective immediately if the board reasonably determines that the practitioner's patients or the general public would be endangered by delay.

(4) Any acupuncture practitioner who is aggrieved by a final order of the board denying a license or rendering disciplinary action against a licensee may seek judicial review of the order by filing a petition with the Circuit Court of the county in which the board's offices are located in accordance with KRS Chapter 13B.

(5) The court shall not award injunctive relief against the board without providing the board the opportunity to be heard.

Section 18. KRS 311.550 is amended to read as follows:

As used in KRS 311.530 to 311.620 and KRS 311.990(4) to (6):

- (1) **"Board"** means the State Board of Medical Licensure;
- (2) **"President"** means the president of the State Board of Medical Licensure;
- (3) **"Secretary"** means the secretary of the State Board of Medical Licensure;
- (4) **"Executive director"** means the executive director of the State Board of Medical Licensure or any assistant executive directors appointed by the board;
- (5) **"General counsel"** means the general counsel of the State Board of Medical Licensure or any assistant general counsel appointed by the board;
- (6) **"Regular license"** means a license to practice medicine or osteopathy at any place in this state;
- (7) **"Limited license"** means a license to practice medicine or osteopathy in a specific institution or locale to the extent indicated in the license;
- (8) **"Temporary permit"** means a permit issued to a person who has applied for a regular or limited license, and who appears from verifiable information in the application to the secretary to be qualified and eligible therefor;
- (9) **"Emergency permit"** means a permit issued to a physician currently licensed in another state, authorizing the physician to practice in this state for the duration of a specific medical emergency, not to exceed thirty (30) days;
- (10) Except as provided in subsection (11) of this section, the **"practice of medicine or osteopathy"** means the diagnosis, treatment, or correction of any and all human conditions, ailments, diseases, injuries, or infirmities by any and all means, methods, devices, or instrumentalities;

(11) The "practice of medicine or osteopathy" does not include the practice of Christian Science, the practice of podiatry as defined in KRS 311.380, the practice of a midlevel health care practitioner as defined in KRS 216.900, the practice of dentistry as defined in KRS 313.010, the practice of optometry as defined in KRS 320.210, the practice of chiropractic as defined in subsection (2) of KRS 312.015, the practice as a nurse as defined in KRS 314.011, the practice of physical therapy as defined in KRS 327.010, *the practice of acupuncture as defined in Section 1 of this Act*, the performance of duties for which they have been trained by emergency medical technicians or medical emergency dispatchers certified by the Cabinet for Health Services, the practice of pharmacy by persons licensed and registered under KRS 315.050, the sale of drugs, nostrums, patented or proprietary medicines, trusses, supports, spectacles, eyeglasses, lenses, instruments, apparatus, or mechanisms that are intended, advertised, or represented as being for the treatment, correction, cure, or relief of any human ailment, disease, injury, infirmity, or condition, in regular mercantile establishments, or the practice of midwifery by women. KRS 311.530 to 311.620 shall not be construed as repealing the authority conferred on the Cabinet for Health Services by KRS Chapter 211 to provide for the instruction, examination, licensing, and registration of all midwives through county health officers;

(12) "Physician" means a doctor of medicine or a doctor of osteopathy;

(13) "Grievance" means any allegation in whatever form alleging misconduct by a physician;

(14) "Charge" means a specific allegation alleging a violation of a specified provision of this chapter;

(15) "Complaint" means a formal administrative pleading that sets forth charges against a physician and commences a formal disciplinary proceeding;

(16) As used in KRS 311.595(4), "crimes involving moral turpitude" shall mean those crimes which have dishonesty as a fundamental and necessary element, including, but not limited to, crimes involving theft, embezzlement, false swearing, perjury, fraud, or misrepresentation;

(17) "Physician assistant" means a person who has graduated from a physician assistant or surgeon assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Education Programs and who has passed the certifying examination administered by the National Commission on Certification of Physician Assistants or who possesses a current physician assistant certificate issued by the board prior to July 15, 1998;

(18) "Supervising physician" means a physician licensed by the board who supervises physician assistants; and

(19) "Supervision" means overseeing the activities of, and accepting responsibility for, the medical services rendered by a physician assistant. The constant physical presence of the supervising physician is not required so long as the supervising physician and physician assistant are or can be easily in contact with one another by radio, telephone, or other telecommunication device. Each team of physicians and physician assistants shall ensure that the delegation of medical tasks is appropriate to the physician assistant's level of training and experience; that the identification of

and access to the supervising physician is defined; and that a process for evaluation of the physician assistant's performance is established.

Section 19. KRS 311.565 is amended to read as follows:

(1) The board may:

- (a) Exercise all the administrative functions of the state~~[in the prevention of empiricism and]~~ in the regulation of the practice of medicine and osteopathy which shall include, but not be limited to, promulgation of reasonable administrative regulations enabling the board to regulate the conduct of its licensees;
- (b) Promulgate reasonable administrative regulations establishing moral, physical, intellectual, educational, scientific, technical, and professional qualifications of applicants for licenses and permits that may be issued by the board;
- (c) Issue, deny, suspend, limit, restrict, and revoke any licenses or permits that may be issued by the board, and to reprimand or to place licensees on probation, in compliance with the provisions of KRS 311.530 to 311.620 *and Sections 1 to 17 of this Act*;
- (d) Appoint an executive director and assistant executive directors and fix their compensation. The executive director shall oversee the work of the board, shall be authorized to discharge the duties of the secretary, as provided by KRS 311.530 to 311.620 *and Sections 1 to 17 of this Act*, and shall carry out the duties of the executive director as set forth elsewhere in this chapter;
- (e) Appoint a general counsel and assistant general counsel and fix their compensation;
- (f) Appoint investigatory personnel and fix their compensation;
- (g) Appoint one (1) or more hearing officers, who need not be members of the board, and fix their compensation. Every hearing officer shall be vested with the full and complete power and authority of the board to schedule and conduct hearings on behalf of and in the name of the board on all matters referred for hearing by the board or secretary thereof, including, among other things, proceedings for placing licensees on probation and for limitation, suspension, and revocation of licenses. All administrative hearings conducted by the board, a member of the board, or a hearing officer appointed by the board, shall be conducted in accordance with KRS Chapter 13B. No hearing officer shall be empowered to place any licensee on probation or to issue, refuse, suspend, limit, or revoke any license;
- (h) Appoint committees of licensees, who need not be board members, to review issues of public or medical interest before the board and to make recommendations to the board on the issues;
- (i) Promulgate administrative regulations to promote the efficient and fair conduct of disciplinary proceedings;
- (j) Promulgate a code of conduct governing the practice of medicine and osteopathy *and the practice of acupuncture under Sections 1 to 17 of this Act*, which shall be based upon generally-recognized principles of professional ethical conduct;

(k) Utilize the services and facilities of professional organizations, and procure and receive the assistance and recommendations of professional organizations in administering KRS 311.530 to 311.620 *and Sections 1 to 17 of this Act*;

(l) Make its personnel and facilities available to other governmental entities under mutually agreeable terms and conditions;

(m) Issue regular licenses without further testing by endorsement from another state having qualifications and standards at least as high as those of this state or by endorsement from the National Board of Medical Examiners, the National Board of Examiners for Osteopathic Physicians and Surgeons, the National Joint Committee of Preregistration Physician Training Programs, or any approved successors thereof;

(n) Issue and renew regular licenses to practice medicine or osteopathy *or to practice acupuncture* in accordance with KRS 311.530 to 311.620 *and Sections 1 to 17 of this Act* and any reasonable regulations of the board;

(o) Issue and renew, or refuse to issue or renew, or cancel and terminate limited licenses pursuant to administrative regulations promulgated by the board; provided however, no person who held a limited license for institutional practice or general practice as of September 1, 1972, shall be denied the renewal of that limited license for nondisciplinary reasons;

(p) Appoint examiners, who need not be members of the board, and employ or contract with the Federation of State Medical Boards of the United States, Inc., or the National Board of Medical Examiners or other organizations, agencies, or individuals to prepare examination questions and grade examination papers;

(q) Determine the schools, colleges, universities, institutions, and training acceptable in connection with licensure under KRS 311.530 to 311.620 *and Sections 1 to 17 of this Act*;

(r) Prescribe the time, place, method, manner, scope, and content of examinations, but at least two (2) examinations shall be held annually;

(s) Prescribe all forms which it considers appropriate, and require the submission of photographs, fingerprints, and personal history data;

(t) Prescribe and collect reasonable fees and charges for examinations, directories, and the issuance and renewal of licenses and permits; and

(u) Impose fines of not greater than five thousand dollars (\$5,000) per violation upon a finding pursuant to disciplinary proceedings that the licensee has violated any provision of KRS 311.595 to 311.597 or duly-promulgated disciplinary regulation of the board.

(2) The board shall develop specific guidelines to follow upon receipt of an allegation of sexual misconduct by a physician licensed by the board. The guidelines shall include investigation, inquiry, and hearing procedures which ensure that the process does not revictimize the alleged victim or cause harm if a physician is falsely accused.

(3) The board, the hearing officer, and investigators hired by the board shall receive training on the dynamics of sexual misconduct of professionals, including the nature of this abuse of authority, characteristics of the offender, the impact on the victim, the possibility and the impact of false accusations, investigative procedure in sex offense cases, and effective intervention with victims and offenders.

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APPENDIX A

HOUSE BILL 160



**GENERAL ASSEMBLY
COMMONWEALTH OF KENTUCKY**

1998 REGULAR SESSION

**HOUSE BILL NO. 160
AS ENACTED**

TUESDAY, MARCH 31, 1998

APPENDIX B

KRS 311.550

APPENDIX C

KRS 312.017

APPENDIX D

Consumer Protection Laws KRS 367.110 et seq.

APPENDIX E

Kentucky Medical Association Complementary and Alternative Therapy Survey

APPENDIX F

Kentucky Board of Medical Licensure Policy Statement:

Complementary and Alternative Therapies