Regulation of Acupuncture

A Complementary Therapy Framework

Executive Summary

September 2004

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As a destination for dream seekers, California has inherited the treasures of cultures Occidental and Oriental. Predictably, government is occasionally required to arbitrate, even regulate, how some traditions and practices are used in the public interest.

Such is the case of acupuncture and Oriental medicine, a healing art with ancient roots and modern branches. In 30 years, the State has evolved a full-scale professional regulatory scheme that licenses more than one in four acupuncturists in the United States.

This practice has flourished in the Golden State in part because of Asian immigration and influence in California. Increasingly though, Californians from all cultural perspectives have sought holistic approaches to maintaining health and have turned to traditional healers to complement or as an alternative to Western medicine.

Throughout this evolution, acupuncturists have sought to define and expand their authority, their role in the health care system, and their standing among health care professionals. These ambitions, however, have at times conflicted with the purpose of state regulation and created controversies that have been difficult for policy-makers to resolve. In two measures, SB 1951 and AB 1943, the Governor and the Legislature asked the Commission to review the scope of practice and the educational requirements for acupuncturists. The Commission also was asked to compare the State's procedure for approving acupuncture schools and administering the licensing examination with the national organizations that accomplish those tasks for other state regulators.

In examining these issues, the Commission identified three underlying tensions or conflicts that make it difficult to assess and reconcile the demands of the profession with the role of state government:

1. The nexus between traditional Oriental and Western medicine is poorly defined. The two paradigms are based on different understandings of how the body works and how it is healed. While allowing acupuncturists to practice independent of Western medical doctors, the State has not defined when and how the two systems should work together. In turn, some acupuncturists are advocating

for authority to make Western diagnoses using Western diagnostic tools.

2. The profession has sought to elevate its standing through the regulatory process. While educational requirements were recently raised, the profession asserts that still higher minimum standards are needed to achieve "parity" with Western primary health care providers. The purpose of the government's educational requirements, however, is clear and limited to preparing entry-level practitioners to perform their scope of practice. They are not intended to serve as a measure of professional status or to favor one sector of the profession over another.

3. Acupuncturists and the Acupuncture Board are concerned that relying on national standards and procedures will hold back the profession in California. Some professional acupuncture associations in the state have strongly resisted efforts to create a national framework for accreditation and examination, which has become the norm in Western medicine. While California acupuncturists are among the nation's leaders in the profession, the national organizations and experts in other states have much to offer the profession as it continues to mature.

Identifying these tensions is important to understanding the controversies, and hopefully providing a clear path for government regulators and the profession. Policy-makers must remember that the regulatory structure exists for the sole purpose of protecting the public. Licensure is not intended to advance the profession or ensure the economic prosperity of a segment of practitioners. Other health professionals can and do use other mechanisms – most of them private – for encouraging excellence among practitioners or integrating health care services.

To protect consumers, the State must regulate acupuncturists and other professionals by appropriately applying the following tools:

- ***A clear scope of practice.*** For the most part, the scope of practice for acupuncturists clearly focuses professionals on some of the traditional Oriental healing methods. Controversy, however, has arisen over their authority to diagnose patients and their role as primary care practitioners. In those aspects, clear statutory language is needed to affirm that consumers have direct access to acupuncturists who can diagnose patients using traditional Oriental techniques and should coordinate treatment and refer patients to Western doctors when appropriate.

- ***Minimum educational requirements.*** Educational requirements should be based solely on providing the skills, knowledge and abilities necessary for entry-level professionals to safely perform the existing scope of practice. The recently enacted educational standards were designed to accomplish this task, but regulators need to ensure that existing practitioners also are equally well-trained. In addition, the national accrediting agency is well positioned to play a larger role in helping California regulators ensure that acupuncture schools are providing quality education.

- ***Quality examination.*** The State needs a rigorous, accurate, fair and secure means of examining candidates for licensure. While the national examining agency has considerable potential to help the State test new professionals, the California examination is currently the stronger tool and should continue to be used.

- ***Informed consumer choice.*** Given a policy predicated on consumer choice, public education is necessary to help patients make informed choices. Toward that end, the State can provide consumers with unembellished research information about the documented efficacy of various treatments, as well as information about the preparation, complaints and enforcement activity associated with individual providers.

To assess these issues identified in the legislation, the Commission conducted public hearings, empanelled an advisory committee of stakeholders, solicited written comments, and consulted with experts around the country.

Because some of the issues required technical analysis, the Commission contracted with experts from the University of California, San Francisco; California State University, Sacramento; and, the RAND Corp. These experts assessed legal aspects of the scope of practice, the details of the educational standards and the accreditation process, and scrutinized the examination instruments used by the Acupuncture Board and the National Certification Commission for Acupuncture and Oriental Medicine. This analysis-based

Acupuncture Efficacy

According to the National Institutes of Health, "Acupuncture is based on the premise that there are patterns of energy flow (Qi) through the body that are essential for health. Disruptions of this flow are believed to be responsible for disease. Acupuncture may correct imbalances of flow at identifiable points close to the skin… The most studied mechanism of stimulation of acupuncture points uses penetration of the skin by thin, solid, metallic needles, which are manipulated manually or by electrical stimulation… Despite considerable efforts to understand the anatomy and physiology of the 'acupuncture points,' the definition and characterization of these points remain controversial."

The National Institutes of Health continues to research the potential for acupuncture. The following summarizes their findings to date: "Promising results have emerged, for example, showing efficacy of acupuncture in adult postoperative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations, such as addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, carpal tunnel syndrome, and asthma, in which acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program."

Source: US National Institutes of Health Consensus Conference proceedings JAMA 1998;280: 1518-1524.

testimony augmented the positions and perspectives offered in the public process. These separate reports also contain a wealth of detailed information and analysis that should assist regulators, policy-makers and the professionals in ways that go beyond the Commission's charge.

As requested, the Commission made recommendations on each of the issues identified in the legislation. In the course of the study, the Commission also identified other issues related to public safety that it believed were important enough to bring to the attention of policy-makers and the public.

The Commission greatly appreciates the time and expertise that so many people provided in the course of this study. But as always, the Commission's conclusions are its own.

Finding 1: While the legal scope of practice clearly defines the modalities that acupuncturists can use, the statute is silent on issues that are important in defining their role as health care providers.

To establish a sound regulatory scheme, policy-makers must clearly define the practice that the State intends to regulate. This legal "scope of practice" is the foundation on which health care regulation is built. The scope determines the minimal educational requirements that will be necessary for a practitioner to enter the field. The scope of practice defines the breadth of the licensure examination. And the scope of practice provides boundaries that are then enforced by regulators.

The statute clearly defines the treatments that acupuncturists may use. The Business and Professions Code is fundamentally a list of modalities and services provided to patients by traditional practitioners in China, Korea, Japan, and now around the world. The statute, however, is silent on many other facets – such as the authority to diagnose patients or limitations on the conditions practitioners may treat – that are detailed in the practice acts for other health care professions.

In 1979, the Legislature eliminated the statutory requirement that medical doctors refer patients to acupuncturists. And the following year, the Legislature in "intent language" referred to acupuncture as a "primary health care profession."

Subsequently, acupuncture – as defined in legal opinions by attorneys for the Acupuncture Board and as practiced in California communities – has incorporated the diagnosis of patients. And while traditional Oriental diagnosis exclusively relied on external physical cues, acupuncturists have been allowed by legal opinions to order blood tests, X-rays, MRIs and other advanced tests that have been developed to

diagnose ailments as they are defined and understood in the Western medical paradigm.

As a result, there is some confusion between the statute and the legal opinions about the role of acupuncturists in the health care system, as well as how that role may be defined in the future.

Professional acupuncture associations say this modernization trend is an essential and natural development of the profession that mirrors the evolution of medical practice in China and other Asian nations.[1] But California, as with other states, already has a means for regulating Western medical practice – supported by separate educational, professional and licensure institutions. And, in fact, many California practitioners have obtained dual licensure.

This murky legal framework – coupled with the trend toward blending Eastern and Western Medicine – complicates efforts to regulate acupuncture, has the potential to confuse the public about the capacity of acupuncturists, and could potentially compromise public health.

Recommendation 1: The Governor and the Legislature should clarify in statute the role of acupuncturists in the health care system. Specifically the statute should:

- ***Keep licensure focused on traditional Oriental medicine.*** Consistent with existing "intent language" and legal opinions, the statute should clarify that licensure is for the practice of traditional Oriental medicine as an alternative and a complement to Western medicine. Practitioners interested in mastering both Eastern and Western methods should continue to seek licensure under both systems.

- ***Define primary care practitioner.*** The statute should make it clear that acupuncturists are primary care practitioners within the context of traditional Oriental medicine, and are responsible for referring patients to primary care practitioners in the Western medical system when appropriate. The law should make it clear that the definition does not impose requirements on health care providers regulated by the Knox-Keene Act.

- ***Authorize and define traditional Oriental diagnosis.*** The scope of practice should include an explicit authorization to conduct traditional Oriental diagnosis. Practitioners who are already licensed and choose to perform biomedical tests in making any diagnosis should be required to complete specific continuing education requirements and take a supplemental examination.

- ***Require disclosure of critical information.*** Patients should receive information on the benefits of coordinating care with MDs and accurate information on the efficacy of traditional therapies. They should receive safety precautions, for example, about single-use disposable needles, alcohol preparation of skin, herb-drug interactions and the potential for herbal contamination. Practitioners should be required to report malpractice settlements.

- ***Allow for acupuncture-only licensure.*** To ensure public access to acupuncture services – for instance, to promising addiction therapy – a separate category of licensure should be created for professionals who provide only acupuncture, and not the array of traditional Oriental therapies. A reduced educational curriculum and examination would have to be developed and implemented.

Finding 2: The new 3,000-hour educational requirement is adequate to prepare entry-level practitioners and to protect the public safety.

A primary goal of educational requirements is to provide some assurance that professionals have the knowledge, skills and abilities necessary to safely practice the profession. And the standard for professional licensing is to ensure that incoming licensees can perform the legally authorized scope of practice as entry-level practitioners.[2]

Effective January 1, 2005, new students in acupuncture schools will need to complete 3,000 hours in training before they will be able to take the licensure examination. That new standard represents a 28 percent increase over the current 2,348-hour requirement.

The higher educational standard was not prompted by a new increase in the scope of practice. Rather, it was justified in part as a belated increase in training warranted by the 1980 legislative change to allow for direct access to acupuncturists. While there is little evidence that patients were endangered by the previous educational requirements, proponents argued the increase in training was critical to patient safety.

The new requirement – and the desire to further raise the standard to 4,000 hours – also is presented as part of a long-term goal of some professional associations to raise the preparation and standing of acupuncturists to the equivalence of Western medical doctors.

The Department of Consumer Affairs asserts that increases in license requirements should be directly related to the scope of a particular profession as defined in law, necessary to ensure the safety of consumers, and should not inappropriately restrict access to practice.[3]

By those standards, there is no evidence to support the need to further increase the educational requirements. But there is evidence, documented by the UCSF analysis and supported by other testimony, that implementing the new requirements will be difficult for some schools, and may result in fewer schools generating fewer students eligible to take the California exam.

Recommendation 2: The number of educational hours should not be increased, and should be focused on traditional Oriental healing practices within a modern framework for patient safety. Specifically, the Acupuncture Board should implement the following policies:

- ***Educate within scope.*** The State's required courses for licensed acupuncturists within schools of traditional Oriental medicine should only be for subject matter needed to competently and safely practice the legal scope of practice.

- ***Devote adequate curriculum to patient safety, including coordination.*** Once the new curriculum has been implemented, an independent evaluation should be conducted to ensure that concerns about minimum training needs have been met. Special attention should be given to patient safety training, including:

  - ✓ Up-to-date infection control practices that meet the standards of the National Institutes of Health, such as exclusive use of single-use needles.
  - ✓ Improving coordination with Western medicine, including recognizing "red flag" conditions, and knowing when and how to refer to and work with physicians.

- ***Teach within area of expertise.*** Courses in physiology, chemistry, biology and other sciences should be taken at colleges and universities that are accredited to grant degrees in those areas. The board also should separately consider requiring successful completion of basic science courses as a prerequisite to educational training in traditional Oriental medicine.

Finding 3: The steadily increasing educational requirements for new entrants into the acupuncture profession potentially creates different levels of competency, and could confuse or mislead the public regarding the knowledge, skills and ability of those previously licensed.

Acupuncture Board regulations require practitioners to take 30 hours of continuing education every two years.[4] However, when the new 3,000-hour standard goes into effect, many practicing acupuncturists will have been licensed with only 1,350 hours of training, and were licensed prior

to the time that acupuncturists could practice independently of M.D.s and were allowed to make diagnoses. In addition, many of the approximately 900 acupuncturists who were initially licensed in the mid-1970s, who were "grandfathered" into licensure with no examination and undefined education requirements, will be practicing under the same scope of practice, presumably with even less formalized training.

Many of the professional organizations that advocated for higher educational standards have asserted that existing practitioners have gained, through experience or continuing education, the knowledge that will now be required before licensure. But in many professions, there is persistent concern that continuing educational regimes do not ensure that practitioners actually learn the latest knowledge, skills and abilities needed to practice safely and competently.

The University of California identified several options to address the unevenness in the education levels among practicing professionals, among them: “catch up” programs to enable practitioners to gain required competencies; test-out options that enable practitioners to demonstrate knowledge or skills in required competency areas; and, grace periods for completing a schedule of supplemental education or examinations. UCSF researchers also suggested the option of implementing differential levels of titling in licensing to reflect formal educational and career experiences.

From a public safety perspective, it is difficult to accept that new students should receive additional training on issues directed at improving patient safety without requiring current licensees to receive at least some of that training in a meaningful way. It is incumbent upon regulators to ensure that patient safety material is incorporated into the clinical practices of long-standing practitioners as well.

Recommendation 3: The Governor and the Legislature should reallocate – and consider increasing the number of – continuing education hours required of currently licensed practitioners as a mechanism to update patient safety requirements. The law should:

- ***Specify courses.*** The Acupuncture Board should identify the coursework necessary to keep practitioners current on "red flag" conditions, emergency procedures, emerging infectious diseases that require referral, exclusive use of single-use disposable needles, other patient safety issues, such as cancer treatment, and how to communicate effectively with Western practitioners.

- ***Require examination***. The State should require testing for material related to patient safety.

Finding 4: The examination of candidates for licensure is a critical quality control measure for assuring competency of providers and is an essential mechanism for ensuring that evolving public policy goals are met.

California's regulator has had difficulties with the acupuncture examination, including documented fraud and criminal charges during the 1980s that spawned security improvements that require continuous refinement. In debating improvements to the examination, policy-makers also have considered replacing the California test with the examination offered by the National Certification Commission for Acupuncture and Oriental Medicine.

Most other California health professionals are licensed based on a national examination. However, the acupuncture profession is still relatively new in its evolution within the United States and the profession in California has evolved somewhat differently than it has developed nationally. Just as different nations take different regulatory approaches to acupuncture, herbs and other modalities of traditional Oriental medicine, so do different states. As the profession evolves in America, a national examination may become the norm.

However, at this juncture, the independent psychometric analysis of the two examinations determined that while both the California and national examinations are statistically sound and meet all other measures of quality, the California examination was somewhat more robust. In addition, by controlling its own examination, California can directly control the evolution of policies and priorities. California has been able to achieve this goal even though the exam is administered by a private firm under contract.

The California examination does need to be refined to ensure that critical knowledge is tested and passed. Further, when the practical component of the examination was canceled in 1999, regulators lost the means to ensure that candidates possess the physical skills necessary for safe practice. Finally, ongoing concerns regarding exam security plague all professional examinations, requiring sophisticated and continuous vigilance.

Recommendation 4: The California Acupuncture Board should continue to control its examination to ensure that the State's policy goals are met. Among the policy goals that the State should ensure:

- ***Demonstrate knowledge of critical components of safe practice.*** "Must-pass" modules should be required for areas of particular concern, including herb-drug interactions, exclusive use of single-use disposable needles, additional infection control measures,

understanding of emerging infectious diseases, "red flag" conditions, first aid procedures, and knowing when and how to refer to physicians.

- ***Competitive examination administration.*** The board should continue to contract out for the secure administration of the California-designed and controlled examination.

- ***Develop strategy for implementing internship.*** This time-tested strategy for proving the practical skills necessary to be successful in many health professions should replace the discontinued practical portion of the examination.

Finding 5: The process used by the Accreditation Commission of Acupuncture and Oriental Medicine appears to be superior to the school approval process used by the Acupuncture Board and could be used by the State to ensure the quality of education for potential licensees.

Prior to taking the California licensing exam, potential licensees must graduate from a school approved by the Acupuncture Board. In addition, schools also must be approved by California's Bureau of Private Postsecondary and Vocational Education, or similar bureaus in other states, which guard against diploma mills and fraudulent business practices.

Most schools also seek accreditation from the organization that has been deputized by the U.S. Department of Education to ensure the quality of education required to qualify for federal financial aid. In the case of acupuncture, that organization is the Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM). The other 39 states and the District of Columbia that license acupuncturists rely on ACAOM accreditation to ensure the quality of acupuncture schools. Students must graduate from an ACAOM-approved school as a condition of licensure in those states. Only California has its own school approval process.

ACAOM is the only accrediting organization that federal officials have approved for accrediting acupuncture programs and state regulatory agencies are not eligible to be deputized by the federal government as accrediting bodies.

Nearly all of the schools that are accredited by the Acupuncture Board also are accredited by ACAOM. ACAOM's process appears to be more rigorous and appears to put more focus on improving the quality of education over time. And – unlike the Acupuncture Board – ACAOM has

an established process for reviewing accredited schools to ensure they are continuing to meet standards.

While ACAOM's curriculum requirements are different than California's, other regulatory boards have relied on national organizations to establish quality and then develop a means for assuring that state-specific curriculum standards are met.

By relying on the federally authorized accrediting body, ACAOM, to assess individual schools, California's regulators would have more time and resources to spend on enforcement, clinic audits, continuous competency improvement of licensees and refining the California examination.

Recommendation 5: California should rely on ACAOM to accredit acupuncture schools, and other institutions for accreditation that are recognized by the Secretary of Education, while developing a mechanism to ensure that state-specific curriculum standards are met. To achieve that goal, policy-makers have two options:

- ***Contract with ACAOM.*** California could establish a memorandum of understanding with ACAOM to certify that California-specific requirements have been met by individual schools and ensure that aggregated information is publicly available.

- ***Require schools to document.*** California could require that schools document that they have met any California-specific legal requirements that exceed national accrediting standards. California uses this model for schools of podiatry.

Finding 6: The California Acupuncture Board has missed significant opportunities to protect the public, particularly in the areas of consumer information and herb-related safety.

Many of the specific issues that the Governor and the Legislature asked the Commission to review have festered because the Acupuncture Board too frequently acted as a venue for promoting rather than regulating the profession. As a result, the board has missed opportunities to protect the public by providing accurate and complete information about the therapies that licensees can provide. The board also has not adequately incorporated emerging scientific evidence into board policies, regulations and public communications.

One critical example is the board's presentation of the scientific evidence regarding the efficacy of acupuncture. The National Institutes of Health found that acupuncture needle therapy is effective for "postoperative and

chemotherapy nausea and vomiting and postoperative dental pain." However, the Acupuncture Board's Web site, fact sheet and consumer brochure implies efficacy for a broader range of ailments. Moreover, those materials do not provide cautionary information to consumers about the limits of what may be expected from traditional Oriental medicine, the need to coordinate with MDs, or how to go about selecting a qualified practitioner.

Also, the NIH in 1997 recommended shifting to the use of single-use needles by acupuncturists instead of following the older practice of sterilizing equipment between uses. This is in part due to the evolution of AIDS and antibiotic-resistant bacteria that can be life-threatening. FDA requires that acupuncture needles be labeled as single use only. However, in California, regulators have not required exclusive use of single-use needles and the law has not been updated to incorporate this fundamental public safety measure.

Much greater attention also needs to be placed on the portion of the scope of practice related to prescribing herbs. These substances are not regulated for purity, potency or effectiveness by the federal Food and Drug Administration nor California authorities. This issue extends beyond the purview of California regulators, and beyond the regulation of this profession. However, since California includes herbs in the scope of practice for acupuncturists, regulators are obligated to take the actions that are within their purview to protect the public.

Herb-drug interactions pose an increasing risk to the public that was not present when ancient herbal practices were developed. Further, in California, herbs from around the globe are used, posing further risk of herb combinations that were unknown in ancient Asian practice, but can result from the intermingling of healing practices.

Recommendation 6: The Governor and the Legislature, through the Sunset Review Process or other mechanisms, should ensure that the California Acupuncture Board becomes a strong advocate for consumers. Among the steps that should be taken:

- ***The board needs to develop a patient safety strategy.*** This strategy should ensure that federal recommendations for improving patient safety – for instance, the exclusive use of single-use needles – are quickly adopted in policies, examinations and written materials such as the consumer brochure. The California regulator could be required to submit, as a regular part of their sunset review, or annual report, what their compliance is with federal recommendations along with new research findings from the NIH. The board should study malpractice trends and publish the results. California regulators

also should bolster efforts to work with individual practitioners and clinics to ensure ongoing compliance with evolving consumer protection laws.

- ***Develop consumer protections for herb products.*** California should empanel legal and scientific experts to explore herb-drug interactions, herb purity and potency, accurate labeling, and reporting of adverse effects. The panel should identify regulatory and other policy steps the State could take to protect consumers.

- ***Restructure the regulator to benefit consumers.*** If policy-makers believe a board is desirable, the majority of the members should not have an economic interest in acupuncture. They should include consumers as well as experts in infection control and research methodology. And the regulator should develop standing advisory panels that are more representative of the various cultures throughout the world that are integrating traditional Oriental medicine into health care and regulatory schemes.

Notes

1. The Acupuncture Board also has "adopted for reference" a document prepared by a professional acupuncture association describing "standards of practice" for acupuncturists (The Council of Acupuncture and Oriental Medical Associations,1997, "Scope of Practice for Licensed Acupuncturists"). That document varies from California statute and regulation. The Acupuncture Board's attorney, Donald Chang, stated that the board's action was the equivalent of receiving a report, October 21, 2003, direct communication).

2. Larry Meyers, Ph.D., Professor, Department of Psychology, California State University, Sacramento, July 2004, written communication regarding "Standards for Educational and Psychological Measurement."

3. Kathleen Hamilton, former Director, California Department of Consumer Affairs, Sacramento, 2004, written communication.

4. California Code of Regulations, Title 16, section 1399.489: "The required number of CE Unit Hours that must be completed in a 2-year renewal period cannot be less than thirty (30)," http://www.acupuncture.ca.gov/ce/ce_require.htm, accessed August 12, 2004.