STATE OF CALIFORNIA OFFICE OF ADMINISTRATIVE LAW

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In re:	DECISION OF DISAPPROVAL
)	OF REGULATORY ACTION
ACUPUNCTURE BOARD)	
)	(Gov. Code, sec. 11349.3)
REGULATORY ACTION:)	
Title 16, California Code of	
Regulations)	OAL File No. 06-0608-01 S
Adopt sections: 1399.490, 1399.491)	
Amend sections: 1399.480, 1399.481,)	
1399.482, 1399.483, 1399.484,	
1399.485, 1399.486, 1399.487,	
1399.488, 1399.489, 1399.489.1	
)	

SUMMARY OF REGULATORY ACTION

In this regulatory action, the Acupuncture Board ("the Board") adopts regulations pursuant to Business & Professions Code section 4933 concerning a thirty (30) hour continuing education requirement every two (2) years for licensees in acupuncture, with four (4) hours in drug/herb interaction. It also adopts regulations relating to the active/inactive status of license holders and mandatory completion of certain courses, as well as distinguishes among categories of courses.

On July 20, 2006, the Office of Administrative Law ("OAL") notified the Board of the disapproval of the above-referenced regulatory action. OAL disapproved the regulations for the following reasons: (1) failure to comply with the "Consistency" standard of Government Code section 11349.1, (2) failure to comply with the "Clarity" standard of Government Code section 11349.1, and (3) failure to comply with the "Necessity" standard of Government Code section 11349.1.

Although there were numerous provisions of the proposed regulations that failed to meet the Consistency, Clarity and Necessity standards, only examples of some of the issues are contained in this disapproval. These examples and all of the Consistency, Clarity and Necessity conflicts with the regulations must be resolved before the regulations can be approved by OAL. All of the issues have been discussed with the Board staff. Because the regulations require significant redrafting, OAL reserves the right to conduct a complete APA review when the regulations are resubmitted.

DISCUSSION

Regulations adopted by the Acupuncture Board must be adopted pursuant to the rulemaking provisions of the Administrative Procedure Act (the "APA"; Gov. Code, secs. 11340 through 11361), unless they are exempted. Any regulatory action a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the requirements of the APA, unless a statute expressly exempts or excludes the act from compliance with the APA. (See Gov. Code, sec. 11346.) No exemption or exclusion applied to the regulatory action here under review. Consequently, before these regulations could become effective, the regulations and the rulemaking record were reviewed by OAL for compliance with the procedural requirements and the substantive standards of the APA, in accordance with Government Code section 11349.1.

A. CONSISTENCY

OAL must review regulations for compliance with the substantive standards of the APA, including the "consistency" standard, in accordance with Government Code section 11349.1. Government Code section 11349, subdivision (d), defines "consistency" as meaning "being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law." As discussed below, aspects of the proposed regulations are inconsistent with the statute being implemented, Business & Professions Code section 4945.

Business & Professions Code section 4945 (b) states that the "board shall require each acupuncturist to complete 50 hours of continuing education every two years as a condition of renewal..." The proposed regulations require only a maximum of 30 hours of continuing education. An inconsistency exists with the governing statute.

The relevant portions of Business & Professions Code section 4945 state, in their entirety:

- (a) The board shall establish standards for continuing education for acupuncturists.
- (b) The board shall require each acupuncturist to complete <u>50</u> hours of continuing education every two years as a condition for renewal of his or her license. No more than five hours of continuing education in each two-year period may be spent on issues unrelated to clinical matters or the actual provision of health care to patients. A provider of continuing education shall apply to the board for approval to offer continuing education courses for credit toward this requirement on a form developed by the board, shall pay a fee covering the cost of approval and for the monitoring of the provider by the board and shall set forth the following information on the application:
 - (1) Course content.

- (2) Test criteria.
- (3) Hours of continuing education credit requested for the course.
- (4) Experience and training of instructors.
- (5) Other information as required by the board.
- (6) That interpreters or bilingual instruction will be made available, when necessary.
- (c) Licensees residing out of state or out of the country shall comply with the continuing education requirements.
- (d) Providers of continuing education shall be monitored by the board as determined by the board.
- (e) If the board determines that any acupuncturist has not obtained the required number of hours of continuing education, it may renew the acupuncturist's license and require that the deficient hours of continuing education be made up during the following renewal period in addition to the current continuing education required for that period. If any acupuncturist fails to make up the deficient hours and complete the current requirement of hours of continuing education during the subsequent renewal period, then his or her license to practice acupuncture shall not be renewed until all the required hours are completed and documented to the board.

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(As amended, Stats.2005, c. 648 (A.B. 1114), section 1.)
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The proposed regulations are inconsistent with (i.e., in conflict with and contradictory to) the statute in the following ways, among others:

EXAMPLE #1:

Section 1399.489 Continuing Education Compliance states: The following provisions apply to all licensees whose license renewal date is prior to January 1, 2007.

. . .

Thereafter, all active licensees shall complete 30 hours every two years as a condition of renewal. (Italics added.)

EXAMPLE #2:

Section 1399.490 Continuing Education Compliance states:

The following provisions apply to all individuals whose license renewal date is after January 1, 2007. . . . (a) When renewing an initial license which has been issued for less than two years, active licensees shall complete the following hours of board-approved continuing education of which a minimum of four (4) hours must be in ethics and practice management:

Period of Initial Licensure	Requiring Continuing	
	Education Hours	
13-16 Months	20	
21-24 Months	25	
17-20 Months	30	
Thereafter, all active licensees shall complete 30 hours		
every two years as a condition of renewal with a minimum		
of four (4) hours in drug/herb interaction. (Italics added.)		

EXAMPLE #3:

Section 1399.491 Inactive License, subsection (b) states:

In order to restore an inactive license to active status, the licensee shall have completed a minimum of 30 hours of approved continuing education, of which four (4) hours must be in the interaction of drugs and herbs within the last two (2) years in compliance with this article. In the event a license has been inactive less than one (1) year, a minimum of fifteen (15) hours of continuing education will be required. (Italics added.)

Each of the above examples demonstrates how the regulation as proposed, is inconsistent with the statutory requirement of 50 hours of continuing education. The only statutory exception to the requirement of 50 continuing education hours is the availability of "rolling over" one renewal period's continuing education hours to the following period. This provision is not addressed in the current regulations and is a discretionary provision provided to the Board if it wishes to renew a license once. The language "may renew the acupuncturist's license" is qualified by the condition that the deficient continuing education courses must be made up within the next renewal period or the license "shall not be renewed until all the required hours are completed and documented to the board." (See Bus. & Prof. Code, sec. 4945 (e).)

B. CLARITY

OAL must review regulations for compliance with the "clarity" standard, as required by Government Code section 11349.1. Government Code section 11349, subdivision (c), defines "clarity" as meaning "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

The "clarity" standard is further defined in section 16 of title 1 of the California Code of Regulations ("CCR"), which provides the following:

In examining a regulation for compliance with the 'clarity' requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:

- (a) A regulation shall be presumed not to comply with the 'clarity' standard if any of the following conditions exists:
- (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
- (2) the language of the regulation conflicts with the agency's description of the effect of the regulation; or
- (3) the regulation uses terms which do not have meanings generally familiar to those 'directly affected' by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or
- (4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; or
- (5) the regulation presents information in a format that is not readily understandable by persons 'directly affected;' or
- (6) the regulation does not use citation styles which clearly identify published material cited in the regulation.
- (b) Persons shall be presumed to be 'directly affected' if they:
- (1) are legally required to comply with the regulation; or
- (2) are legally required to enforce the regulation; or
- (3) derive from the enforcement of the regulation a benefit that is not common to the public in general; or
- (4) incur from the enforcement of the regulation a detriment that is not common to the public in general.

In this rulemaking, numerous provisions of the proposed regulations fail to meet the clarity standard. Examples of clarity issues in the regulations include the following:

EXAMPLE #1:

Business & Professions Code section 4945 indicates that "no more than <u>five</u> hours of continuing education in each two-year period may be spent on issues unrelated to clinical matters or the actual provision of health care to patients." (Emphasis added.)

Proposed regulation section 1399.483 Approval of Continuing Education Courses provides in part, for two categories of courses. Category 1 includes courses related to the knowledge and technical skills required to practice acupuncture and lists three types of classes. Category 2 courses include, but are not limited to, the following:

- A. Acupuncture research and evidence-based medicine as related to acupuncture and oriental medicine.
- B. Practice management and ethics, to achieve improved health of the patient or for the patient's benefit, includes but is not limited to risk management, record keeping,

acupuncture laws and regulations, insurance billing codes, report writing, workers' compensation.

C. Breathing and other exercises, i.e., qi gong and taiji quan.

By creating these new categories and stating that all courses of continuing education "shall fall within the following two (2) categories" a clarity issue is raised as to which category of classes is "unrelated to clinical matters or the actual provision of health care to patients." (Bus. & Prof. Code, sec. 4945.) The ability of a licensee to meet the expectations is further confused by subsection 1399.490 (c), which states: "Licensees are limited to <u>four</u> (4) hours every two (2) years for Category 2 courses." (Emphasis added.)

If it is the Board's intent to create a category of classes which is responsive to the mandates of Business & Professions Code section 4945, it must clarify such. If the Board is setting up an additional categorization, then it adds to the confusion and does not meet the clarity standard. The regulation must be clear as to what courses fit within the statutory guideline of "issues unrelated to clinical matters or the actual provision of health care to patients" so that licensees know which courses meet that requirement.

An additional clarity issue concerns the difficulty a licensee has in figuring out exactly what are the requirements to which they are held, e.g. ethics requirement, herb/drug interaction requirement and the statutory limitation of five hours in issues unrelated to clinical matters or the actual provision of health care to patient, as well as the four hour limitation provided in section 1399.490 (c) for Category 2 courses. It must be clearly set forth so that the licensees can easily understand the expectations.

EXAMPLE #2:

Section 1399.483 (h) states: "Courses outside the United States will not be approved unless the identical course has been previously taught in the United States." The subsection is unclear in that what is meant by "identical." "Identical" should be defined. By "previously taught in the United States," does that mean by any provider, or just the one requesting approval of the course? Does it refer to courses physically being given outside the US or via the internet? Does "identical" mean the same curriculum by the same provider? It is unclear as written.

EXAMPLE #3:

Section 1399.484 refers to a *form* for Course Approval. Section 1399.491 refers to a *form* for Active/Inactive License Application. Section 1399.488 (b) refers to an application *form*. These forms were not part of the rulemaking file. All regulatory requirements of "forms" must be clearly set forth in the regulations. This may be accomplished in a number of ways, including: 1) formally incorporating the forms by reference under section 20, title 1 of California Code of Regulations; 2) printing the forms directly in the California Code of Regulations; or 3) setting forth all regulatory requirements contained in the forms (which are not already established by statute or

another regulation) into the regulation text. In order for the Office of Administrative Law to verify that all regulatory requirements of forms have been clearly established in the regulation text, and that all other requirements of the APA have been satisfied with respect to the forms, the forms must be included in the rulemaking file.

EXAMPLE #4:

Other textual problems which create clarity issues are present: 1) Section 1399.487 must not strike out (a) as there is a (b). It would appear that (4) should be (b), and (b) should be (c), and so on; and 2) there are two sections titled "Continuing Education Compliance." The duplicity creates a clarity issue.

These examples of clarity problems, and all other clarity problems discussed with the Board staff, must be resolved before the regulations can be approved by OAL.

C. NECESSITY

Government Code section 11349.1, subdivision (a)(1) requires that OAL review all regulations for compliance with the "necessity" standard. Government Code section 11349, subdivision (a) defines "necessity" to mean that:

... the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard evidence includes, but is not limited to, facts, studies, and expert opinion.

Section 10, subdivision (b) of Title 1 of the CCR provides that in order to meet the "necessity standard" the rulemaking record must include:

- (1) A statement of the specific purpose of each adoption, amendment, or repeal; and
- (2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An 'expert' within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.

In this rulemaking, the Board's Initial Statement of Reasons is a one and a half page document which has a paragraph titled "**Specific Purpose of each adoption**, amendment, or repeal:" It states:

The specific purpose of this proposal is to require mandatory 4 hours in drug/herb interaction every two years as a condition of renewal for purposes of patient safety. This proposal also specifies two categories that continuing education courses must fall within and limits the number of hours a licensee can take on courses not directly related to acupuncture and Oriental medicine, Western medicine as it relates to acupuncture practice and scope of practice.

In addition, the proposed amendments would clarify and make specific the continuing education requirements for licensees and providers. The Board also proposes to remove the term 'approved' in all affected sections where [sic] the term is redundant and clarify with more specific wording.

The rulemaking file is devoid of "information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision" as is required by Section 10, subdivision (b)(2) of Title 1 of the CCR. Each provision being adopted, amended or repealed, must have (1) a specific purpose, and, (2) an explanation why each provision is required to carry out that purpose. The two paragraphs above do not address the requirement for substantiation of "necessity" as to each provision, but simply describe what the regulations will do. Examples of some of the numerous omissions include the following:

EXAMPLE #1

Section 1399.489, subsection (b) states: "[e]ach acupuncturist at the time of license renewal shall sign a statement under penalty of perjury as to whether or not he or she has complied with the continuing education requirements." There is no explanation in the record as to why a declaration under penalty of perjury is necessary to carry out the purpose of the regulation.

EXAMPLE #2:

Section 1399.483 (e) states: "A maximum of four (4) hours per day will be approved for courses taught simultaneously in two languages." The record does not contain an explanation as to why this is necessary to carry out the described purpose of the regulation.

EXAMPLE #3:

Sections 1399.489.1 and 1399.491 refer to continuing education for licensees whose renewal dates are prior to, or subsequent to, January 1, 2007. There is no explanation in the record as to why subjecting the licensees to different requirements is necessary to carry out the described purpose of the regulation.

EXAMPLE #4:

Section 1399.483 (e)(2) states: "Courses approved for independent or home study require a minimum ten (10) question examination with a minimum passing score of 90% on the examination.[sic]" The record does not contain an explanation as to why these requirements are necessary to carry out the described purpose of the regulation.

CONCLUSION

For the reasons set forth above, OAL has disapproved this regulatory action. If you have any questions, please contact me at (916) 323-6800.

Date: July 27, 2006

ELIZABETH A. HEIDIG

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Director

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