

State of California
Office of Administrative Law

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| In re: |) | DECISION OF DISAPPROVAL OF |
| Acupuncture Board |) | REGULATORY ACTION |
| |) | |
| Regulatory Action: |) | |
| |) | |
| Title 16, California Code of Regulations |) | Government Code Section 11349.3 |
| |) | |
| Adopt sections: |) | |
| Amend sections: 1399.480, 1399.481, |) | OAL File No. 2008-0204-04S |
| 1399.482, 1399.483, |) | |
| 1399.484, 1399.485, |) | |
| 1399.486, 1399.487, |) | |
| 1399.488, 1399.489, |) | |
| 1399.489.1 |) | |
| |) | |
| Repeal sections: |) | |
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DECISION SUMMARY

The Acupuncture Board (“Board”) proposed to amend the California Code of Regulations, Title 16, relating to the Board’s continuing education (“CE”) requirements for acupuncturists. This regulatory action makes extensive revisions to the CE provider approval process, CE course approval process, and listing of approved CE course topics and to that end adopts a one page form entitled “Continuing Education Provider Application Form (Rev. 12/06)”, adopts a seven page form entitled “Request for Continuing Education (CE) Course Approval Form (Rev. 12/06)”, and amends another one page form entitled “Active/Inactive License Application (Rev. 12/06).”

On March 19, 2008, the Office of Administrative Law (“OAL”) notified the Acupuncture Board of the disapproval of the above-referenced regulatory action. OAL disapproved the regulations for the following reasons: (1) failure to comply with the “Clarity” standard of Government Code section 11349.1, (2) failure to comply with the “Consistency” standard of Government Code section 11349.1, (3) failure to comply with the “Necessity” standard of Government Code section 11349.1, (4) failure to comply with the “Reference” standard of Government Code section 11349.1, and (5) failure to comply with the Administrative Procedure Act (“APA”) procedural requirements.

DISCUSSION

Regulations adopted by the Board must generally be adopted pursuant to the rulemaking provisions of the Administrative Procedure Act (Government Code sections 11340 through 11361). 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 Government Code section 11346.) No exemption or exclusion applies to the regulatory action here under review. Consequently, before these regulations may become effective, the regulations and the rulemaking record must be reviewed by OAL for compliance with the procedural requirements and the substantive standards of the APA, in accordance with Government Code section 11349.1.

CLARITY

OAL must review regulations for compliance with the substantive standards of the APA, including the “Clarity” standard, as required by Government Code section 11349.1. Government Code section 11349(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”), OAL’s regulation on “Clarity,” 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 standard 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.”

This regulatory action violates the “clarity” standard because several key terms and phrases are vague, ambiguous, or undefined or are used inconsistently.

1. Proposed section 1399.483(e) prohibits a provider from selling, advertising, or promoting any named brand product or service during a CE course. It also requires:

“A provider shall ensure meaningful disclosure to the audience, at the time of the program, of any relationship between any named product(s) or services discussed and the provider or between any such products or service and any individuals [sic] instructor, presenter, panelist, or moderator.”

The key term “meaningful disclosure” is undefined. A CE provider would not easily understand from the text what the Board considers an acceptable “meaningful” disclosure of a product relationship. This constitutes a presumed clarity violation under Title 1 CCR section 16(a)(1) and (3). A similar clarity problem exists with the proposed section 1399.486(a)(8) mandate for “full disclosure” of all products for sale after completion of the course. That clarity issue is further compounded by the alternative use of the adjective “meaningful” in 1399.483(e) – what is “full” disclosure and how does it differ from “meaningful” disclosure?

Other vague, ambiguous, or undefined key terms which violate the “clarity” standard include:

- a. Proposed section 1399.483(d)(2) – “self-assessment.” When a commenter raised a “clarity” objection to the lack of definition of this term, the Board’s response in the final statement of reasons, p. 3, stated that the Board “felt that it was only necessary that the licensee provide feedback on the course they took and that the provider could design a format based on language provided in 1399.483(c).” That response demonstrates that the Board intends a specific meaning for “self-assessment” not supported by the ambiguous nature of the term itself; e.g., “self-assessment” could logically be interpreted to refer to a self-test regarding mastery of the course material itself rather than the Board’s intended evaluation of the quality and usefulness of the course as set forth in 1399.483(c). This is a presumed clarity violation under Title 1 CCR section 16(a)(1) and (2).
- b. Proposed section 1399.482(h) – “evaluation forms.” OAL assumes that the Board intends this term to mean the sample “Participant Evaluation Form” which is part

of the “Request for Continuing Education (CE) Course Approval Form (Rev. 12/06”. But given the lack of definition or use of the identical title for the participant evaluation form contained in the CE course approval form, this internal inconsistency/ambiguity constitutes a presumed clarity violation under Title 1 CCR section 16(a)(1) and (3).

2. Throughout this regulatory action, the Board changed the term “approved provider” to “provider” by deleting the word “approved.” The Board failed, however, to delete “approved” from the reference to persons or organizations allowed to call themselves an “approved provider” in proposed section 1399.482(a). That failure creates an internal inconsistency between this reference in 1399.482(a) and the actual definition of an approved “provider” which shortens the term to “provider” in proposed section 1399.480. This is a presumed clarity violation under Title 1 CCR section 16(a)(1).

3. Proposed section 1399.484(a)(7) adds a seventh item to a preexisting partial listing of the contents of the “Request for Continuing Education (CE) Course Approval Form (Rev. 12/06)”. The seventh item requires disclosure of a relationship between the provider and a named brand product discussed in the CE class. The seventh item, however, does not appear on the new form. This is an internal inconsistency and a presumed clarity violation under Title 1 CCR section 16(a)(1) and (2).

CONSISTENCY

Government Code section 11349.1(a)(4) requires OAL to review all regulations for compliance with the “Consistency” standard. Government Code section 11349(d) defines “Consistency” as:

“(d) ‘Consistency’ means being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.”

Proposed section 1399.481 is inconsistent with Business and Professions Code section 4945(b) which mandates the content of the CE provider application form. Business and Professions Code section 4945(b) states:

“(b) The board shall require each acupuncturist to complete 50 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 required by the board.
- (6) That interpreters or bilingual instruction will be made available, when necessary.” [Emphasis added in bold].**

Proposed section 1399.481(a) mandates applicants for CE provider approval submit an application form labeled “Continuing Education Provider Application, (Rev. 12/06)” to obtain approval as a CE provider. This CE provider application form is a one page form which requires applicants to provide information covering provider data under penalty of perjury. Despite the reference in Business and Professions Code section 4945(b) to a singular form (“a form”; “the application”), the Board requires use of a second form for CE course approval. Proposed section 1399.484 requires CE providers obtain CE course approval by submission of “Request for Continuing Education (CE) Course Approval Form (Rev. 12/06).” The CE Course Approval form is seven pages long and requires applicants to provide information covering course information, course objectives, course schedule/outline, instructor information, attendance record, participant evaluation form, and sample certificate of completion.

Neither the CE provider application form nor the CE course approval form, however, require CE applicants to provide information about “[t]est criteria” or “[t]hat interpreters or bilingual instruction will be made available, when necessary” as mandated by Business and Professions Code section 4945(b)(2) and (6). That failure violates the “consistency” standard of Government Code section 11349(d).

NECESSITY

Government Code section 11349.1(a)(1) requires OAL to review all regulations for compliance with the “Necessity” standard. Government Code section 11349(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.”

Title 1 CCR section 10(b) provides that in order to meet the “Necessity” standard the rulemaking record must include:

“(1) A statement of the specific purposes 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.” **[Emphasis added in bold]**.

1. Proposed section 1399.481(a) adopts and mandates use of “Continuing Education Provider Application Form (Rev. 12/06)” for all persons seeking approval to be a CE provider. As previously discussed, this form is one page long and contains regulatory content not previously adopted under the APA. It also establishes a \$150 application fee on the first page of the form. The rationale provided by the board for this form is:

“Factual Basis/Rationale. Technical changes only.”

This rationale constitutes inadequate necessity for the form because of the failure to provide a rationale for “each provision” of the form as required by Title 1 CCR section 10(b)(2).

Furthermore, the Board failed to provide a necessity for and specifically justify the \$150 application fee as meeting the fee amount restrictions contained in Business and Professions Code section 4945(b) which states, in pertinent part:

“(b) The board shall require each acupuncturist to complete 50 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.” **[Emphasis added in bold]**.

2. The rationale provided for the CE course approval form mandated in proposed section 1399.484 is similarly lacking. The rationale for the form contained in the initial statement of reasons (“ISR”), p. 5, is:

“Factual Basis/Rationale
Technical and clean up only.”

The Board provides no facts, studies, or expert opinion supporting the rationale for the adoption of each provision of the seven page CE course approval form in violation of Government Code section 11349.1(a) and Title 1 CCR section 10(b)(2).

3. This regulatory action establishes numerous mandatory time periods. None are specifically discussed in either the initial or final statement of reasons and all lack “Necessity” for the time periods chosen.

They include:

- a. Proposed section 1399.484 – Submission of CE course approval form 45 day prior to first course date; 30 days notice to Board before new course date or location; 48 hours notice to Board if course postponed; 3 month time limit for postponed course to be taught before reapplication for approval required; new course application and 45 days notice required to change course content or instructor.
- b. Proposed section 1399.485 – Two years experience in the past five years teaching a similar subject or job experience in the subject matter taught for an acupuncturist instructor; two years teaching experience in the past five years in the specialized area taught for a non-acupuncturist instructor.
- c. Proposed section 1399.488 – 30 days processing time after receipt of a completed CE course provider application form; 30 days processing time for CE course approval application form.
- d. Proposed section 1399.489 – The pro-rata CE hours required for various months of initial licensure prior to license renewal; the limitation of 50% of required CE hours from independent or home study course; the limits on instructor CE credit for courses taught; the one hour CE credit for two hours of licensee time spent on “occupational analysis, an examination development session, item review session or a passing score workshop.”
- e. Proposed section 1399.489.1 – Pro-rata CE hours required to restore an inactive license to active status.

4. Proposed section 1399.483 makes substantial revisions to the type and content of permissible CE courses. Permissible CE courses are now separated into Category 1 (clinical) and Category 2 (business management and licensee “breathing” exercises) and include nine new acceptable Category 1 course topics and two acceptable Category 2 course topics. The rationale for the CE course content changes refers only to the September 2004 Little Hoover Commission report (not included in the file), Business and Professions Code section 4934.2(b) (the Board shall study the quality and relevance of their courses), and AB 1114 (Stats. 2005, Chap. 648).

This rationale does not discuss or provide any facts, studies or expert opinion explaining why the nine new Category 1 course topics and two new Category 2 course topics were adopted as permissible CE courses.

REFERENCE

Government Code section 11349.1(a)(5) requires OAL to review all regulations for compliance with the “Reference” standard. Government Code section 11349(e) defines “Reference” as:

“(e) ‘Reference’ means the statute, court decision, or other provision of law which the agency implements, interprets, or makes specific by adopting, amending, or repealing a regulation.”

1. The Board’s initial statement of reasons, p. 4, states that part of the factual basis/rationale for the amendments to proposed section 1399.483 (“Approval of Continuing Education Courses”) is the Board’s implementation of Business and Professions Code section 4934.2(b). OAL agrees with the Board’s articulated rationale. Consequently, the Board should add Business and Professions Code section 4934.2 as a reference citation to section 1399.483. It should also be added as a reference citation to proposed sections 1399.480, 1399.481, 1399.482, 1399.484, 1399.485, 1399.486, 1399.487, and 1399.488.

2. The Board should add Business and Professions Code section 4955 as a reference citation for proposed section 1399.489 (“Continuing Education Compliance”) because the Board amended proposed section 1399.489 to classify misrepresentation of CE completion as “unprofessional conduct” prohibited by Business and Professions Code section 4955.

INCORRECT APA PROCEDURES

1. Inadequate Summary and Response to Public Comment.

Government Code section 11346.9(a), provides that an agency proposing regulations shall prepare and submit to OAL a “final statement of reasons.” One of the required contents of a final statement of reasons is a summary and response to all timely and relevant public comments. Specifically, Government Code section 11346.9(a)(3) requires the final statement of reasons to include:

“**A summary of each objection or recommendation** made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. This requirement applies only to objections or recommendations specifically directed at the agency’s proposed action or to the procedures followed by the agency in proposing or adopting the action. . . .”
[**Emphasis added in bold**].

The Board received several lengthy 45-day comments and testimony at the public hearing on February 23, 2007 regarding the proposed regulations. Portions of those comments were inadequately summarized and/or responded to in the Board's final statement of reasons because the Board simply cross-referenced the commenter's letter rather than specifically summarizing each objection or recommendation and providing a specific response as required by Government Code section 11346.9(a)(3).

For example, commenter Bill Mosca representing the California State Oriental Medical Association (CSOMA) submitted a four page email dated February 15, 2007, with an attached thirteen page suggested redraft of the regulatory action. Commenter Mosca's objections and recommendations regarding proposed section 1399.483(e) were as follows:

"1399.483(e). Prohibition on Product Promotion.

This section, as initially drafted, would prohibit any and all *discussion* of named brand products during a course.

While we strongly agree that continuing education coursework should be non-promotional, it is essential that the Board distinguish between *promotion* of a product and *discussion* of a product.

The prohibition of discussion would, we believe, pose a significant obstacle to the appropriate and desirable exchange of non-promotional product information. This section would have a particular inhibitory effect on courses pertaining to the clinical use of herbal patent medicines. In fact, this section may well prohibit such courses altogether.

We have proposed revised language that permits reasonable discussion of products while preserving the non-promotional intent of the original language."

Commenter Mosca's proposed changes to section 1399.483(e) were:

"(e) A provider is prohibited from selling, advertising, and/or discussing promoting any named brand product during a course in the same room or obligate path as the educational activity. No product advertisements will be permitted in the program room. A provider shall ensure that any discussion of named brand products is objectively selected and presented with favorable and unfavorable information and balanced discussion of prevailing information on the product(s), competing products, and alternative treatments. A provider shall ensure meaningful disclosure to the audience, at the time of the program, of any significant relationship between any named brand product(s) discussed and the provider or between any such product(s) and any individual instructor, speaker, presenter, panelist, or moderator. However, a provider may offer for sale products after the course has been completed as long as it is made clear to

all participants that they are under no obligation whatsoever to stay for the sales presentation or purchase any products. Nothing in this subdivision shall be interpreted as ~~prohibiting~~ restricting a provider from discussing generic named products during a course.”

The Board’s summary and response to commenter Mosca’s objections and recommendations regarding proposed section 1399.483(e) was as follows:

“**COMMENT:** . . . Additionally, written comments were received from CSOMA (see email dated February 15, 2007) suggesting additional and clarifying language to the board’s proposed language for this section.

“**BOARD RESPONSE:** . . . The board did agree with some of CSOMA’s recommendations. As a result of written and public testimony, modifications to the proposed language were made and the modified language was made available to the public during the 15-day notice period, with no subsequent comments being received.”

The Board’s summary wholly fails to specifically identify the commenter’s objections or recommended substantial modifications to proposed section 1399.483(e) or identify specifically what recommended changes the Board agreed with and the reasons for rejecting the other recommended changes. Both the summary and response violate the requirements of Government Code section 11346.9(a)(3).

All other instances in which the Board shortcut the summary and response process by simply cross-referencing a commenter’s letter similarly violate Government Code section 11346.9(a)(3).

2. Regulatory content of forms not adopted under the APA.

Proposed section 1399.481(a) adopts form “Continuing Education Provider Application Form (Rev. 12/06)”, proposed section 1399.484(a) adopts form “Request for Continuing Education (CE) Course Approval Form (Rev. 12/06)”, and proposed section 1399.489.1 amends form “Active/Inactive License Application (Rev 12/06)”. All forms appear to contain regulatory content not previously adopted pursuant to the APA. The Board failed to bring that regulatory content into the CCR by any of the three permissible methods; i.e., printing the forms in the CCR, writing out the regulatory content of each form into the body of the regulation, or incorporating the forms by reference pursuant to the requirements of Title 1 CCR section 20. Failure to do so violates the prohibition on underground regulations contained in Government Code section 11340.5(a).

3. Text not in compliance.

The rulemaking text fails to comply with the requirements of Title 1 CCR section 8 because none of the forms are properly shown in underline/strikeout or alternatively labeled as “adopt” for the new forms. In addition, copies of the forms are not attached to

the regulation text for filing with the Secretary of State as required by Government Code section 11343(c). The final regulation text contains several underline/strikeout errors from what is currently printed in the CCR. Several regulations incorrectly show the third level hierarchy in regulation text as "A." or "C." instead of "(A)" or "(C)". [Correct third level hierarchy is shown in existing provisions of proposed section 1399.485].

4. Documents relied on not in rulemaking record.

The rulemaking record fails to contain copies of all data or documents relied on in support of these regulatory changes as required by Government Code section 11347.3(b)(7). The Board identified the following documents as data relied on in multiple locations in the initial statement of reasons:

"Underlying Data

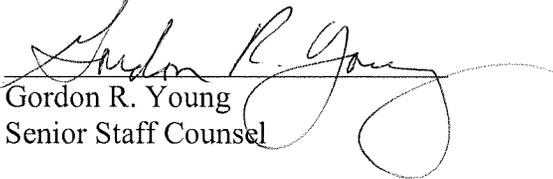
May 2003 Licensee CE Survey; August 2002 CE Focus Group Report; April 2004 CE Review Panel Decisions; May 2004 CE Review Panel Decisions; June 2004 CE Subcommittee Report; July 2004 Distance Education Workshop Decision."

In addition, the Board implicitly relied on the "September 2004 Little Hoover Commission study" by referencing it as providing a factual basis/rationale for various regulatory changes. Neither the six documents listed above nor the Little Hoover Commission study were included in the rulemaking record in violation of Government Code section 11347.3(b)(7).

CONCLUSION

OAL disapproved this regulatory action for the reasons set forth above. If you have any questions, please contact me at (916) 323-8916.

Date: March 26, 2008


Gordon R. Young
Senior Staff Counsel

For: SUSAN LAPSLEY
Director

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