STATE OF CALIFORNIA
OFFICE OF ADMINISTRATIVE LAW

In re:	)	
DENTAL BOARD OF CALIFORNIA	)	DECISION OF DISAPPROVAL OF REGULATORY ACTION
	)	(Gov. Code, section 11349.3)
REGULATORY ACTION: Title 16, California Code of Regulations	)	OAL File No. 05-0414-01 S
Amend Sections: 1016 and 1017	)	

SUMMARY OF REGULATORY ACTION

This regulatory action revises the continuing education requirements for licensees of the Dental Board of California.

DECISION

On May 26, 2005, the Office of Administrative Law (OAL) disapproved the above referenced regulatory action for the following reasons: a document relied upon may not have been included in the rulemaking record; documents included in the rulemaking record may not have been made available to the public; a revision to section 1017(b) violates the requirements for incorporation by reference; changes to section 1017 would appear to apply retroactively without authority to do so; the final statement of reasons does not contain a summary and response to all comments; and for failure to comply with the clarity and necessity standards of Government Code section 11349.1.

DISCUSSION

The adoption of regulations by the Dental Board of California ("Board") must satisfy requirements established by the part of the California Administrative Procedure Act ("APA") that governs rulemaking by a state agency. Any rule or regulation adopted by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage.

Before any rule or regulation subject to the APA may become effective, the rule or regulation is reviewed by the Office of Administrative Law ("OAL") for compliance with the procedural

requirements of the APA and for compliance with the standards for administrative regulations in Government Code Section 11349.1. Generally, to satisfy the standards a rule or regulation must be legally valid, supported by an adequate record, and easy to understand. In this review OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulation. This review is an independent executive branch check on the exercise of rulemaking powers by executive branch agencies and is intended to improve the quality of rules and regulations that implement, interpret and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on rules and regulations before they become effective.

1. A DOCUMENT RELIED UPON MAY NOT HAVE BEEN INCLUDED IN THE RULEMAKING RECORD AND DOCUMENTS INCLUDED IN THE RULEMAKING RECORD MAY NOT HAVE BEEN MADE AVAILABLE TO THE PUBLIC.

Government Code section 11346.2 requires in subdivision (b)(2) that the initial statement of reasons include:

> "An identification of each technical, theoretical, and empirical study, report, or similar document, if any, upon which the agency relies in proposing the adoption, amendment, or repeal of a regulation."

Government Code section 11347.3 requires in subdivision (b)(7) that the rulemaking file include:

> "All data and other factual information, technical, theoretical, and empirical studies or reports, if any, on which the agency is relying in the adoption, amendment, or repeal of a regulation, including any cost impact estimates as required by Section 11346.3."

The initial statement of reasons prepared for this rulemaking action identifies on page 3 as "Underlying Data" an "American Heart Association, report of 2000." The file submitted to OAL for this rulemaking contains under Tab III, "Material Relied Upon," an AHA publication entitled "Emergency Cardiovascular Care Program, Program Administration Manual, Guidelines for Program Administration and Training 3rd Edition-Effective July 1, 2004". Not under Tab III but clipped to the back cover of the binder containing the file is a bound AHA publication entitled "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care". Neither of these documents appear to be the report identified or relied upon in the initial statement of reasons.

In addition, since these two documents were not identified in the initial statement of reasons, it is not clear whether their presence is in violation of Government Code sections 11346.8(d) and 11347.1.

Subdivision (d) of Government Code section 11346.8 provides:

> "No state agency shall add any material to the record of the rulemaking proceeding after the close of the public hearing or comment period, unless the agency complies

with Section 11347.1. This subdivision does not apply to material prepared pursuant to Section 11346.9."

Government Code section 11347.1 provides in pertinent part:

"(a) An agency that adds any technical, theoretical, or empirical study, report, or similar document to the rulemaking file after publication of the notice of proposed action and relies on the document in proposing the action shall make the document available as required by this section.

(b) At least 15 calendar days before the proposed action is adopted by the agency, the agency shall mail to all of the following persons a notice identifying the added document and stating the place and business hours that the document is available for public inspection:

(1) Persons who testified at the public hearing.

(2) Persons who submitted written comments at the public hearing.

(3) Persons whose comments were received by the agency during the public comment period.

(4) Persons who requested notification from the agency of the availability of changes to the text of the proposed regulation.

(c) The document shall be available for public inspection at the location described in the notice for at least 15 calendar days before the proposed action is adopted by the agency. . . ."

2. THE REVISION TO SUBSECTION (b) OF SECTION 1017 DOES NOT COMPLY WITH THE REQUIREMENTS FOR INCORPORATION BY REFERENCE.

OAL has adopted section 20 of Title 1 of the California Code of Regulations to assure that material incorporated by reference in regulations conforms to the requirements of the APA. Subsection (c) of this section provides the requirements for a state agency that wishes to incorporate another document as part of a regulation by reference to that document. Subsection (c) of section 20 provides:

"An agency may 'incorporate by reference' only if the following conditions are met:

. . .

(4) The regulation text states that the document is incorporated by reference and identifies the document by title and *date of publication or issuance*. Where an authorizing California statute or other applicable law requires the adoption or enforcement of the incorporated provisions of the document as well as any subsequent amendments thereto, no specific date is required. . ." (Emphasis added.)

Existing section 1017 of title 16 of the California Code of Regulations provides in subsection (b):

". . . Each licentiate who holds a general anesthesia permit shall take and complete, at least once every two years, either (1) and advanced cardiac life support course which is approved by the American Heart Association and which includes an

> examination on the materials presented in the course or (2) any other advanced cardiac life support course which is identical in all respects, except for the omission of materials that relate solely to hospital emergencies or neonatology, to the course published by the American Heart Association *in April 1983*, which is incorporated by reference. . .." (Emphasis added.)

This rulemaking action would amend subsection (b) to delete "in April 1983."

In addition to violating subsection (c)(4) of section 20 of title 1 of the California Code of Regulations, failure to specify the date of publication or issuance of the particular version incorporated by reference makes the provision difficult to understand. One cannot understand from the text of the regulatory provision which particular text has been incorporated by reference. Consequently this provision fails to satisfy the clarity standard of Government Code section 11349.1 as well.

Further, a prospective incorporation by reference (one that automatically incorporates future changes to an incorporated document) is of questionable validity. While prospective incorporation by reference could cut down on periodic rulemaking to incorporate future changes made by the body that originally issued the incorporated document, it also eliminates the opportunity for public participation in the decision to give regulatory effect to those changes. This problem has been described as follows:

> ". . . . Prospective incorporation entirely removes from the usual rule-making process individual consideration, by the public and the agency, of each future change to the matter incorporated by reference, thereby effectively denying the many benefits of that process to those who may object to the legality or merits of the new amendments or editions. This is not an inconsiderable loss. It is equivalent to a declaration by the agency that it will not hold rule-making proceedings of any kind on the specific contents of each of those future amendments to or editions of that matter incorporated by reference, even though such changes will become effective law of the agency, and even if many of them turn out to be very controversial and of doubtful legality. Furthermore, it should be obvious that no one could effectively object to such later changes at the time of the original rule-making proceeding in which the wholesale incorporation by reference of future changes was adopted, the specific content of those future changes would be unknown and unknowable."
>
> "In addition, allowing agencies to incorporate by reference, as rules, future amendments to or editions of the matter already incorporated in their rules involves an inappropriate delegation of power by the state legislature and the agencies involved to the body subsequently altering the incorporated matter. That is, in addition to being deprived of the benefits of the rule-making process for such future amendments or editions, the state legislature and the agencies issuing the rules containing the incorporated matter lose control over the content of the law involved. It is true, of course, that they can disapprove after the fact any specific amendment to or edition of the matter prospectively incorporated by reference. But it should be stressed that such action may be taken only after that new matter has become law. This is also why, in many states, prospective adoption of future amendments to or

> editions of the materials incorporated in rules by reference would be an unconstitutional delegation of authority to the body initially making those new amendments or editions, or would at least present serious questions of that nature." [Footnote omitted. Bonfield, State Administrative Rule-Making (1986) p. 325-326.]

The validity of prospective incorporation by reference has been questioned by the California Court of Appeal in a case involving a Department of Health Services regulation incorporating by reference standards issued by the Department of Finance:

> "There is no procedural barrier prohibiting the enacting agency from adopting by reference a set of standards issued by another agency if supporting evidence is made available at a public hearing, opportunity for refutation is given, the pro and con evidence considered and the evidentiary material assembled in an identifiable record. On the other hand, an attempt to embody by reference future modifications of the incorporated material without additional hearings would have dubious validity. (See Olive Proration etc. Com. V. Agric. Etc. Com., Supra, 17 Cal.2d at p. 209, 109 p.2d 918.)" [California Ass'n of Nursing Homes, Etc. v. Williams (1970) 4 Cal.App.3d 800, 814, 84 Cal.Rptr. 590.]

3. CHANGES MADE TO SECTION 1017 WOULD APPEAR TO APPLY RETROACTIVELY WITHOUT AUTHORITY TO DO SO.

Government Code section 11349.1(a)(2) requires that OAL review all regulations for compliance with the "authority" standard. Government Code section 11349(b) defines "authority" to mean ". . . the provision of law which permits or obligates the agency to adopt, amend, or repeal a regulation."

Section 1017 of title 16 of the California Code of Regulations specifies the units of continuing education required for renewal of a license. This regulatory action revises the required subjects and breaks them down into two categories which have an 80/20 split as to the number of units in two categories without modifying the introductory language in subsection (a) which provides that these requirements are "Effective with the 2004-2005 renewal cycle…" No statutory citation is provided that would allow the retroactive application of these requirements to those who may have already renewed their license.

4. SOME PROVISIONS ARE UNCLEAR.

The Legislature in establishing OAL, found that regulations, once adopted, were frequently unclear and confusing to the persons who must comply with them. (Gov. Code sec. 11340(b).) For this reason, OAL is mandated to review each regulation adopted pursuant to the APA to determine whether the regulation complies with the "clarity" standard. (Gov. Code, sec. 11349.1(a)(3).) "Clarity" as defined by Government Code section 11349 (c) means "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."

a. Existing section 1017 (c) of title 16 of the California Code of Regulations provides in part:

> ". . . Interactive instruction courses via computers …or other electronic mediums *approved by the Board shall be accepted for full credit.*" (Emphasis added.)

As revised in this rulemaking, this provision in section 1017(c) provides:

> ". . . Interactive instruction courses such as live lecture . . . or live classroom study *shall be approved by the Board and will be accepted for full credit.*" (Emphasis added.)

A person directly affected by this regulation might understand this provision as revised to mean that the Board is required to approve and provide full credit for any live lecture or live classroom study. This is probably not the Board's intent.

b. Existing section 1016 (a) specifies the subject area of acceptable continuing education courses. This rulemaking would add a new subsection 1016(a)(2)(G) which includes "courses in other subjects of direct concern to dentistry such as d*entolegal* matters, including but not limited to risk management, liability, and malpractice, employment law and employment practices." (Emphasis added.)

OAL has been unable to verify that "dentolegal" is even a word, let alone its meaning, nor is there any evidence in the rulemaking record that "dentolegal" is a term of art generally understood within the regulated community.

5. THE FINAL STATEMENT OF REASONS DOES NOT CONTAIN A SUMMARY AND RESPONSE TO ALL COMMENTS SUBMITTED DURING THE PUBLIC COMMENT PERIOD.

Since its inception in 1947, the APA has afforded interested persons the opportunity to participate in quasi-legislative proceedings conducted by state agencies. The APA currently requires that rulemaking agencies provide notice and at least a 45-day comment period prior to adoption of a proposed regulatory action. (Gov. Code, secs. 11346.4 and 11346.5). By requiring the state agency to summarize and respond in the record to comments received during the comment period, the Legislature has clearly indicated its intent that an agency account for all relevant comments received, and provide written evidence of its meaningful consideration of all timely, relevant input. Section 11346.9(a)(3) of the Government Code requires that the adopting agency prepare and submit to OAL a final statement of reasons which shall 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 reason for making no change."

The final statement of reasons for this regulatory action does not contain an adequate summary and response to the following concerns on subsections 1016(a) and (d), respectively, raised by Robert Stine on page 2 of a comment included in Tab VIII of the rulemaking file.

> "Sterilization of instruments is one of the more important parts of an office infection control program. Therefore, we do not believe that this course content should be

classified as category II. Infection control course are classified as Category I yet the most critical procedure for infection control, sterilization, appears to be placed in the Category II classification. Category I courses will always be preferred by most licensees since 80% or more of their credits must be from that category. Category II classes will be seen as less important and less valuable to most licensees if only because the term Category II implies that the course is subordinate to Category I."

"This amendment ensures that providers of mandatory courses adhere to the course content requirements specified in Proposed Section 1016 (a)(1)(A). The following question arises with this amendment. How often must approved providers resubmit the course outlines? Any time the content is changed or added to? Must approved providers resubmit the outlines with each license renewal? What is the estimated time for approval of the mandatory course outlines?"

Because of the nature of the questions raise in the second paragraph, OAL must reserve its review of section 1016(d) for compliance with the "clarity" standard until it has an opportunity to review the Board's response upon resubmission.

6. THE INITIAL STATEMENT OF REASONS DOES NOT CONTAIN INFORMATION EXPLAINING THE NEED FOR ALL OF THE REGULATORY PROVISIONS.

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

To further explain the meaning of substantial evidence in the context of the "necessity" standard, subdivision (b) of section 10 of the Title 1 of the California Code of Regulations (CCR) provides:

"In order to meet the 'necessity' standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:

"(1) a statement of the specific propose of each adoption, amendment, or repeal; and

"(2) information explaining why each provision of the adopted regulations 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 order to provide the public with an opportunity to review and comment upon an agency's perceived need for a regulation, the APA requires that the agency describe the need for the regulation in the initial statement of reasons. (Gov. Code, sec. 11346.2(b).) The initial statement of reasons must include a statement of the specific purpose for each adoption, amendment, or repeal, and the rationale for the determination by the agency that each regulation is reasonably necessary to carry out the purpose for which it is proposed. (Gov. Code, sec. 11346.2(b)(1)) or, simply restated, "why" a regulation is needed and "how" this regulation fills that need. The initial statement of reasons must be submitted to OAL with the initial notice of the proposed action and made available to the public during the public comment period, along with all the information upon which the proposal is based. (Gov. Code, secs. 11346.2(b) and 11346.5(a)(16) and (b).) In this way the public is informed of the basis of the regulatory action and may comment knowledgeably. The initial statement of reasons and all data and other factual information, studies or reports upon which the agency is relying in the regulatory action must also be included in the rulemaking file. (Gov. Code, secs. 11347.3(b)(2) and (7).)

The initial statement of reasons provided with this regulatory action failed to include an explanation of the reasons for the new mandatory class requirements in section 1016(d) nor the reasons for the 80/20 split specified in section 1017(a) for Category I and Category II courses. This information needs to be added to your final statement of reasons upon resubmission.

We further note that the text of section 1017 submitted to OAL for filing with the Secretary of State deletes a few words without showing them in strikeout. Also, the STD 399 form included in this rulemaking file has an agency signature date that is later than the date of closure and execution given in the Board's certification following the table of contents.

CONCLUSION

For the reasons set forth above, OAL has disapproved this regulatory action. If you have any questions, please contact me at (916) 323-6808.

Date: June 2, 2005

CRAIG S. TARPENNING
Senior Staff Counsel

WILLIAM GAUSEWITZ
Director

Original: Cynthia Gatlin, Executive Officer
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