

**State of California
Office of Administrative Law**

In re:
Medical Board of California

**DECISION OF DISAPPROVAL OF
REGULATORY ACTION**

**Regulatory Action: Title 16
California Code of Regulations**

Government Code Section 11349.3

**Adopt sections: 1361.5, 1361.51,
1361.52, 1361.53,
1361.54, 1361.55**

OAL File No. 2014-0827-02 S

Amend sections: 1361

Repeal sections:

SUMMARY OF REGULATORY ACTION

This rulemaking action by the Medical Board of California (Board) proposes to amend section 1361 and adopt six new sections in title 16 of the California Code of Regulations (CCR) to implement the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees, April 2011 (Uniform Standards) in accordance with Business and Professions Code section 315. The Uniform Standards were developed by the Substance Abuse Coordination Committee (Committee) that was established by the Department of Consumer Affairs pursuant to Senate Bill 1441 (Stats. 2008, ch. 548).

On August 27, 2014, the Board submitted the above-referenced regulatory action to the Office of Administrative Law (OAL) for review. On October 9, 2014, OAL notified the Board that OAL disapproved the proposed regulations because the regulations failed to comply with the consistency standard of Government Code section 11349.1, subdivision (a)(4). The Board also failed to follow procedures required by the California Administrative Procedure Act (APA). This Decision of Disapproval of Regulatory Action explains the reasons for OAL's action.

DECISION

OAL disapproved the above-referenced regulatory action for the following reasons:

1. The proposed regulations failed to comply with the consistency standard of Government Code section 11349.1, subdivision (a)(4); and
2. The Board failed to follow the required APA procedures by omitting to:
 - a. provide a sufficient Economic Impact Assessment pursuant to Government Code section 11346.3, subdivision (b)(1); and

- b. summarize and respond to all of the public comments submitted regarding the proposed action pursuant to Government Code section 11346.9, subdivision (a)(3).

All APA issues must be resolved prior to OAL's approval of any resubmission.

DISCUSSION

The Board's regulatory action must satisfy requirements established by the part of the APA that governs rulemaking by a state agency. Any regulation adopted, amended, or repealed by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a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. (Gov. Code, sec. 11346.)

Before any regulation subject to the APA may become effective, the regulation is reviewed by 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 APA standards, a 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 check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on regulations before they become effective.

1. Consistency Standard

OAL is mandated to review each regulation adopted pursuant to the APA to determine whether the regulation complies with the "consistency" standard. (Gov. Code, sec. 11349.1, subd. (a)(4).) Government Code section 11349, subdivision (d), defines "consistency" to mean "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 fail to comply with the consistency standard of the APA.

Senate Bill 1441 (Stats. 2008, ch. 548) established the Substance Abuse Coordination Committee (Committee) within the Department of Consumer Affairs. Business and Professions Code section 315 required the Committee to "formulate uniform and specific standards ... that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program...." (Emphasis added.) The Committee completed this task in April of 2011. This rulemaking action proposes to implement the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees, April 2011 (Uniform Standards) prepared by the Committee, in accordance with Business and Professions Code section 315.

In its notice of proposed action, the Board describes the broad objective of this rulemaking action as follows:

This regulation will incorporate the Uniform Standards for Substance Abusing Healing Arts Licensees, as required by SB 1441 by proposing to add the standards, which shall be adhered to in all cases in which a licensee is placed on probation due, in part, to a substance abuse problem. These standards shall be followed in all instances, but will also allow the Board to impose more restrictive conditions, if necessary, to protect the public.

As explained above, Section 315 of the Business and Professions Code requires the Board to adhere to the Uniform Standards developed by the Committee when dealing with substance-abusing licensees. The Board is free to impose other conditions or requirements upon substance-abusing licensees in addition to the Uniform Standards, but the Board has no discretion to modify the content of the specific terms or conditions of the Uniform Standards. Thus, failure to implement all of the applicable provisions of the Uniform Standards in the proposed regulations violates the consistency standard of the APA.

The following provisions shown in underline of the Uniform Standards are missing from the Board's proposed regulatory language:

- A. "Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program ... Number of licensees who successfully returned to practice...." (Emphasis added.) (Uniform Standard #16.)
- B. "Tolling ... If the licensee returns to employment in a health care field, and has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect." (Emphasis added.) (Uniform Standard #4.)
- C. "Testing Frequency Schedule ... Any board who finds or has suspicion that a licensee has committed a violation of a board's testing program ... may reestablish the testing cycle by placing that licensee at the beginning of level I, in addition to any other disciplinary action that may be pursued." (Emphasis added.) (Uniform Standard #4.)
- D. "Violation(s) Outside Employment. An individual whose license is placed on probation for a single conviction or incident or two convictions or incidents, spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass level I and participate in level II of the testing frequency schedule." (Emphasis added.) (Uniform Standard #4.)

The aforementioned provisions of the Uniform Standards apply to the Board's practices and thus, shall be used by the Board in dealing with substance-abusing licensees. Pursuant to Business and Professions Code section 315, the Board does not have discretion to modify the content of the specific terms or conditions of the Uniform Standards. Failure to include the aforementioned

language, or equivalent language, in the proposed regulations violates the consistency standard in Government Code section 11349.1, subdivision (a)(4). The Board must revise the regulation text to be consistent with the aforementioned provisions of the Uniform Standards.

2. Failure to Follow Required APA Procedures

The APA requires agencies to follow specific procedures. In this rulemaking action, the Board failed to follow the required procedures by neglecting to include in the rulemaking file a sufficient Economic Impact Assessment and by omitting to summarize and respond to all of the public comments.

2.1 Insufficient Economic Impact Assessment

On September 6, 2013, the Board published a public notice of proposed action, which commenced this regulatory action. At that time, Government Code section 11346.3, subdivision (b)(1), provided the following:

(b)(1) All state agencies proposing to adopt, amend, or repeal a regulation ... shall prepare an economic impact assessment that assesses whether and to what extent it will affect the following:

- (A) The creation or elimination of jobs within the state.
- (B) The creation of new businesses or the elimination of existing businesses within the state.
- (C) The expansion of businesses currently doing business within the state.
- (D) The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment

The Economic Impact Assessment (EIA) required by Government Code section 11346.3, subdivision (b)(1), mandates an assessment of the economic impacts described in subdivisions (b)(1)(A) through (C), and the benefits of the regulation described in subdivision (b)(1)(D). The EIA that the Board provided to OAL in the rulemaking record is not sufficient because it fails to comply with all of the elements required by subdivisions (b)(1)(A) through (D) of Government Code section 11346.3. The EIA provided includes an assessment of the benefits of the regulations to the health and welfare of California residents that is required in subdivision (b)(1)(D) of Government Code section 11346.3. However, the EIA does not contain the economic impact assessments that are required in subdivisions (b)(1)(A) through (C) of Government Code section 11346.3, or an assessment of the benefits of the regulations to worker safety and the state's environment that is required in subdivision (b)(1)(D) of Government Code section 11346.3.

To address the missing elements of its EIA, the Board must perform an analysis explaining why and how it made the initial determinations stated in its 45-day notice that the proposed regulatory action would not have an impact on the creation or elimination of jobs (subdivision (b)(1)(A)), creation of new businesses or the elimination of existing businesses (subdivision (b)(1)(B)), or the expansion of businesses currently doing business within the state (subdivision (b)(1)(C)).

The Board must also assess the benefits of the regulations to worker safety and the state's environment (subdivision (b)(1)(D)).

The Board will need to prepare an addendum to its EIA that assesses all of the required elements addressed in Government Code section 11346.3, subdivision (b)(1). The Board must then make this document available to the public for at least 15 days and add it to the rulemaking record before adopting the regulations and resubmitting these regulations to OAL. (Gov. Code, sec. 11347.1.) Additionally, any comments made in relation to this addendum to the Board's EIA must be considered by the Board and summarized and responded to in the final statement of reasons. (Gov. Code, sec. 11347.1, subd. (d).)

2.2 Missing Summary and Response to Public Comments

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

(a)(3) 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 this rulemaking action, the Board provided a 45-day public comment period for its originally proposed text, conducted one public hearing, and issued two notices to the public providing two additional 15-day public comment periods for substantive changes to the text of the regulations. Numerous comments were received during these comment periods, but the Board did not summarize and respond to the following comment:

A. Ron Thurston, M.D., President, on behalf of the California Psychiatric Association (CPA), written comment dated October 22, 2013. The commenter submitted the following regarding proposed section 1361.5, subdivision (c)(8)(A):

The proposed text in paragraph (A) refers to return to practice after issuance of a cease practice order or imposition of practice restrictions. Subparagraph (A)(iii) sets out criteria for return to practice. In the instance that a cease practice order IS in place for significant period of time it will not be possible to have the referenced positive worksite monitor reports if the individual is not at work. The language should clearly indicate that such reports and compliance requirements commence with return to the workplace if that is the intent. [*Sic.*] [Original capitalization.]

The Board is required to summarize and respond to all comments made during the 45-day and 15-day comment periods and at the public hearing before resubmitting the rulemaking action to OAL for review.

OAL also notes that the Board's responses to the public comments contain a number of inaccurate statements and incorrect citations to the regulation text.

3. Miscellaneous

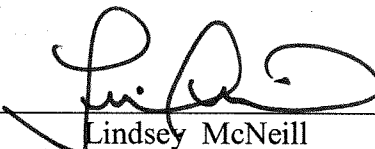
OAL also notes the following issues that must be addressed prior to any resubmission of this rulemaking action:

- 3.1 **Regulation Text.** The proposed regulations contain a number of punctuation and underline and strikeout illustration errors.
- 3.2 **Internal Inconsistency.** Proposed section 1361.5, subdivision (c)(3)(G), contains a cross-reference error.
- 3.3 **Reference Citations.** The Board must consider the addition of Business and Professions Code sections 315, 315.2, and 315.4 to its listing of Reference citations after sections 1361 through 1361.54.
- 3.4 **File Certification.** The closure date on the rulemaking file Certification is earlier than the signature date on the rulemaking file Certification.

CONCLUSION

For the foregoing reasons, OAL disapproved the above-referenced rulemaking action. Pursuant to Government Code section 11349.4, subdivision (a), the Board may resubmit revised regulations within 120 days of its receipt of this Decision of Disapproval. The Board shall make all substantial regulatory text changes, which are sufficiently related to the original text, and any documents to be added to the record, available for at least 15 days for public comment pursuant to Government Code sections 11346.8 and 11347.1. If you have any questions, please contact me at (916) 323-6820.

Date: October 15, 2014



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