

State of California
Business, Consumer Services and Housing Agency

MEDICAL BOARD OF CALIFORNIA

Board Meeting
December 1, 2014





MEDICAL BOARD OF CALIFORNIA



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Barbara Yaroslavsky

Felix Yip, M.D.

BOARD MEETING AGENDA

Monday, December 1, 2014

4:00 p.m. – 5:00 p.m.

Teleconference – See Attached
Meeting Information

Medical Board of California
Hearing Room

2005 Evergreen Street

Sacramento, CA 95815

Kaiser Permanente

1950 Franklin Street

2nd Floor Conference Room 2-C

Oakland, CA. 94612

Note: Guests will have to check in with Lobby Security
before entering the conference room floor.

Jones Day

555 South Flower Street, 50th Floor

Los Angeles, CA 90071

Note: Guests will have to check in with Lobby Security
before entering the conference room floor.

*Action may be taken
on any item listed
on the agenda.*

*While the Board intends to
webcast this meeting, it may
not be possible to webcast the
entire open meeting due to
limitations on resources.*

Arrowhead Regional

Medical Center

400 North Pepper Avenue

Room #3M308-5

Colton, CA 92324

Hospital Council of

Northern CA

235 Montgomery Street,

Suite 1158

San Francisco, CA 94104

Grounds Bakery & Café

Conference Room

6277 E. Spring St.

Long Beach, CA 90808

11645 Wilshire Blvd.

First Floor Lobby

Los Angeles, CA. 90025

Cedars Sinai Lab Services

8711 West Third Street

Los Angeles, California

90048

600 N Garfield Ave. # 308

Monterey Park, CA. 91754

Monday December 1, 2014

1. 4:00 p.m. Call to Order/Roll Call
2. Public Comments on Items not on the Agenda
Note: The Board may not discuss or take action on any matter raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7 (a)]
3. Review and Consideration of Revised Regulatory Language Amending Section 1361 and Adding Sections 1361.5, 1361.51, 1361.52, 1361.53, 1361.54, and 1361.55 to Title 16, California Code of Regulations - Uniform Standards for Substance-Abusing Licensees – Ms. Webb
4. Adjournment

Meeting Information

This meeting will be available via teleconference. Individuals listening to the meeting will have an opportunity to provide public comment as outlined below.

The call-in number for teleconference comments is: (800) 230-1092.

Please wait until the operator has introduced you before you make your comments.

To request to make a comment during the public comment period, press *1; you will hear a tone indicating you are in the queue for comment. If you change your mind and do not want to make a comment, press #. Assistance is available throughout the teleconference meeting. To request a specialist, press *0.

Each person will be limited to two minutes per agenda item. However, during Agenda Item 2, Public Comments on Items Not on the Agenda, the Board has limited the public comment period for individuals on the teleconference to 20 minutes. Therefore, after 20 minutes no further comments will be accepted. During public comment on any other agenda item 10 minutes will be allowed for comments from individuals on the teleconference line. After 10 minutes, no further comments will be accepted.

Comments for those in attendance at the meeting locations will have the same time limitations as those identified above for individuals on the teleconference line.

The mission of the Medical Board of California is to protect health care consumers through the proper licensing and regulation of physicians and surgeons and certain allied health care professions and through the vigorous, objective enforcement of the Medical Practice Act, and to promote access to quality medical care through the Board's licensing and regulatory functions.

Meetings of the Medical Board of California are open to the public except when specifically noticed otherwise in accordance with the Open Meeting Act. The audience will be given appropriate opportunities to comment on any issue presented in open session before the Board, but the President may apportion available time among those who wish to speak.

For additional information, call (916) 263-2389.

NOTICE: *The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Lisa Toof at (916) 263-2389 or lisa.toof@mbc.ca.gov or send a written request to Lisa Toof. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.*

MEDICAL BOARD STAFF REPORT

DATE REPORT ISSUED: November 24, 2014
ATTENTION: Board Members
SUBJECT: SB 1441 – Proposed Regulations to Implement the Uniform Standards for Substance-Abusing Licensees
FROM: Kerrie Webb, Senior Staff Counsel

REQUESTED ACTION:

After review and consideration, make a motion to approve the recommended changes to the attached proposed language to implement the Uniform Standards for Substance-Abusing Licensees (**Attachment A**). Further direct staff to notice the modified language for a third 15-day comment period. If no negative comments are received during the 15-day comment period, authorize the Executive Director to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopting Title 16 California Code of Regulations (CCR) section 1361, and adding sections 1361.5, 1361.51, 1631.52, 1361.53, 1361.54, and 1361.55 with the modified text.

BACKGROUND:

On October 15, 2014, the Board received a Decision of Disapproval of Regulatory Action from the Office of Administrative Law (**Attachment B**). This Decision pertained to the regulations the Medical Board of California (Board) submitted to implement the Uniform Standards for Substance-Abusing Licensees. Based upon this notice, Board staff met with staff from the Office of Administrative Law to discuss the decision and to identify changes needed in order to have the regulations approved. It was determined that amendments were needed to the language, as well as changes to the documents submitted in the regulatory package. Any changes to the language must be approved by the Board.

The proposed changes (third modified) have been identified by ~~double-strikethrough-italicized text in red~~ for the deleted text and **bold double-underlined italicized text in blue** for new modified language.

**TITLE 16. MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS**

Third Modified Text

Proposed amendments are shown by ~~striketrough~~ for deleted text and underline for new text.

Changes to the originally proposed language are shown by ~~double-strikethrough~~ for deleted text and by double underline for new text.

Second modified text is shown by ~~double-strikethrough with highlight~~ for deleted text and **bold double underline with highlight** for new modified language.

Third modified text is shown by ~~double-strikethrough italicized text in red~~ for deleted text and *bold double-underlined italicized text in blue* for new modified language.

(1) Amend title of Article 4, Chapter 2, Division 13 of Title 16 of the California Code of Regulations to read as follows:

Article 4. Disciplinary Guidelines and Uniform Standards for Substance-Abusing Licensees

(2) Section 1361 of Article 4, Chapter 2, Division 13 of Title 16 of the California Code of Regulations is amended to read:

§ 1361. Disciplinary Guidelines and Exceptions for Uniform Standards Related to Substance-Abusing Licensees.

(a) In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code ~~§~~section 11400 et seq.), the Medical Board of California shall consider the disciplinary guidelines entitled "Manual of Model Disciplinary Orders and Disciplinary Guidelines" (11^{~~th~~}th Edition/2011) which are hereby incorporated by reference. Deviation from these orders and guidelines, including the standard terms of probation, is appropriate where the ~~Medical Board of California~~ in its sole discretion determines by adoption of a proposed decision or stipulation that the facts of the particular case warrant such a deviation – for example: the presence of mitigating factors; the age of the case; evidentiary problems.

(b) Notwithstanding subsection (a), the Board shall use the ~~Uniform~~sStandards for ~~Substance-Abusing~~sLicensees as provided in ~~§~~section 1361.5, without deviation, for each individual determined to be a substance-abusing licensee.

(c) Nothing in this section or section 1361.5 shall be construed as a limitation on the Board's authority to seek an interim suspension order against a licensee pursuant to ~~§~~Section 11529 of the Government Code.

NOTE: Authority cited: Sections s 315, 315.2, 315.4, and 2018, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 2227, 2228, 2229, and 2234, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

(3) Section 1361.5 is added to Article 4, Chapter 2, Division 13 of Title 16 of the California Code of Regulations to read:

§ 1361.5. Uniform Standards for Substance-Abusing Licensees.

(a) If the licensee is to be disciplined, for unprofessional conduct involving the use of illegal drugs, the abuse of drugs and/or alcohol or ~~both~~, the use of another prohibited substance as defined herein, the licensee shall be presumed to be a substance-abusing licensee for purposes of sSection 315 of the Code. ~~The terms and conditions specified in subsection (c) shall be used in any probationary order of the Board affecting that licensee.~~

(b) Nothing in this section shall prohibit the Board from imposing additional terms or conditions of probation that are specific to a particular case or that are derived from the Board's disciplinary guidelines referenced in ~~S~~ection 1361 ~~in any order~~ that the Board determines ~~would provide greater~~ is necessary for public protection or to enhance the rehabilitation of the licensee.

(c) The following probationary terms and conditions shall be used without deviation in the case of a substance-abusing licensee:

~~(1) Notice of Employment Information. If a licensee whose license is on probation has an employer, the licensee shall provide to the Board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent for the Board and his or her employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.~~

(1) Clinical Diagnostic Evaluations and Reports; Temporary Removal From Practice.

(A) If the Board orders a licensee who is on probation due to a substance abuse problem to undergo a clinical diagnostic evaluation, the following applies:

1. The clinical diagnostic evaluation shall be conducted by a licensed physician and surgeon who holds a valid, unrestricted license, ~~§~~ has three (3) years' experience in providing evaluations of physicians and surgeons with substance abuse disorders, ~~§~~ and is approved by the Board.

2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.

3. The evaluator shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. The evaluator shall provide an objective, unbiased, and independent evaluation.

4. The clinical diagnostic evaluation report shall set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem; whether the licensee is a threat to himself or herself or others; and recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and ability to practice safely. If the evaluator determines during the evaluation process that a licensee is a threat to himself or herself or others, the evaluator shall notify the Board within 24 hours of such a determination.

5. In formulating his or her opinion as to whether the licensee is safe to return to either part-time or full-time practice, and what restrictions or recommendations should be imposed, including participation in an inpatient or outpatient treatment program, the evaluator shall consider the following factors:

- a. License type;
- b. Licensee's history;
- c. Documented length of sobriety/time that has elapsed since substance use;
- d. Scope and pattern of substance abuse;
- e. Treatment history;
- f. Medical history;
- g. Current medical condition;
- h. Nature, duration, and severity of substance abuse problem; and
- i. Whether the licensee is a threat to himself or herself or the public.

6. The cost of an evaluation shall be borne by the licensee.

7. For all evaluations, a final written report shall be provided to the Board no later than ten (10) days from the date the evaluator is assigned the matter. If the evaluator requests additional information or time to complete the evaluation and report, an extension may be granted, but shall not exceed 30 days from the date the evaluator was originally assigned the matter.

(B) Whenever the Board orders a licensee to undergo a clinical diagnostic evaluation, the Board shall order the licensee to cease practice pending the results of the clinical diagnostic evaluation and review by the Board.

(C) While awaiting the results of the clinical diagnostic evaluation, the licensee shall undergo random biological fluid testing at least two (2) times per week.

(D) The Board shall review the clinical diagnostic evaluation report within five (5) business days of receipt to determine whether the licensee is safe to return to either part-time or full-time practice and what restrictions or recommendations shall be imposed on the licensee based on the recommendations made by the evaluator. No licensee shall be returned to practice until he or she has at least 30 days of negative biological fluid tests **or biological fluid tests indicating that a**

licensee has not used, consumed, ingested or administered to himself or herself a prohibited substance, as defined in section 1361.51(e).

(2) Clinical Diagnostic Evaluations and Reports:

(A) Whenever a licensee on probation due to a substance abuse problem is ordered to undergo a clinical diagnostic evaluation, the evaluator shall be a licensed physician and surgeon who holds a valid, unrestricted license to conduct clinical diagnostic evaluations, has three (3) years' experience in providing evaluations of physicians and surgeons with substance abuse disorders, and is approved by the Board. The evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations. The evaluator shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. The evaluator shall provide an objective, unbiased, and independent evaluation. The cost of an evaluation shall be borne by the licensee.

(B) For a licensee who undergoes a clinical diagnostic evaluation, the Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the Board.

(C) While awaiting the results of the clinical diagnostic evaluation, the licensee shall be randomly drug tested at least two (2) times per week.

(D) The clinical diagnostic evaluation report shall set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem, whether the licensee is a threat to himself or herself or others, and recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice. If the evaluator determines during the evaluation process that a licensee is a threat to himself or herself or others, the evaluator shall notify the Board within 24 hours of such a determination. In determining whether the licensee is safe to return to either part time or full time practice and what restrictions or recommendations should be imposed, including participation in an inpatient or outpatient treatment program, the evaluator shall consider the following factors:

(i) License type, licensee's history, documented length of sobriety, scope and pattern of substance abuse, treatment history, medical history, current medical condition, nature, duration and severity of substance abuse problem, and whether the licensee is a threat to himself or herself or others.

(E) For all evaluations, a final written report shall be provided to the Board no later than ten (10) days from the date the evaluator is assigned the matter, unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.

(F) The Board shall review the clinical diagnostic evaluation report to determine whether the licensee is safe to return to either part time or full time practice and what restrictions or recommendations shall be imposed on the licensee based on the recommendations made by the evaluator.

(2) Notice of Employer or Supervisor Information. If a licensee whose license is on probation has an employer or supervisor, the licensee shall provide to the Board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent for the Board, the worksite monitor, and his or her employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring. For purposes of this section, "supervisors" shall include the Chief of Staff and the Health or Well Being Committee Chair, or equivalent, if applicable, when the licensee has medical staff privileges.

~~(3) Worksite Monitor Requirements and Responsibilities:~~

~~(A) If the Board determines that a worksite monitor is necessary for a particular licensee, the licensee shall, within 30 calendar days of the effective date of that determination, submit to the Board or its designee for prior approval the names of a worksite monitor(s). The worksite monitor shall meet the following criteria to be approved by the Board:~~

~~(i) The worksite monitor shall not have a current or former financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the Board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the Board; however, under no circumstances shall a licensee's worksite monitor be an employee or supervisee of the licensee.~~

~~(ii) The worksite monitor's license scope of practice shall include the scope of practice of the licensee who is being monitored or be another physician and surgeon if no monitor with like scope of practice is available.~~

~~(iii) The worksite monitor shall have an active unrestricted license with no disciplinary action within the last five (5) years.~~

~~(B) The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and agrees to monitor the licensee as set forth by the Board.~~

~~(C) The worksite monitor shall adhere to the following required methods of monitoring the licensee:~~

~~(i) Have face-to-face contact with the licensee in the work environment on as frequent a basis as determined by the Board but not less than once per week.~~

~~(ii) Interview other staff in the office regarding the licensee's behavior, if requested by the Board.~~

~~(iii) Review the licensee's work attendance.~~

~~(D) The worksite monitor shall verbally report any suspected substance abuse to the Board and the licensee's employer within one (1) business day of occurrence. If the suspected substance~~

~~abuse does not occur during the Board's normal business hours, the verbal report shall be made to the Board within one (1) hour of the next business day. A written report that includes the date, time, and location of the suspected abuse, the licensee's actions and any other information deemed important by the worksite monitor shall be submitted to the Board within 48 hours of the verbal report.~~

~~(E) The worksite monitor shall complete and submit a written report monthly or as directed by the Board. The report shall include: the licensee's name; license number; the worksite monitor's name and signature; worksite monitor's license number; worksite location(s); the dates licensee had face-to-face contact with monitor; worksite staff interviewed, if applicable; attendance report; any change in behavior and/or personal habits; any indicators that can lead to suspected substance abuse.~~

~~(F) The licensee shall execute agreements with the approved worksite monitor(s) and the Board authorizing the Board and worksite monitor to exchange information.~~

~~(G) If the monitor resigns or is no longer available, licensee shall, within 5 calendar days of such resignation or unavailability, submit to the Board the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If licensee fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, licensee shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. Licensee shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.~~

(3) Biological Fluid Testing.

(A) The Board shall require biological fluid testing of substance-abusing licensees.

(B) For the purposes of this section, the terms "biological fluid testing" and "testing" mean the acquisition and chemical analysis of a licensee's urine, blood, breath, or hair.

(C) The Board may order a licensee to undergo a biological fluid test on any day, at any time, including weekends and holidays. Additionally, the licensee shall be subject to 52 - 104 random tests per year within the first year of probation, and 36 - 104 random tests per year *during the second year of probation and* for the duration of the probationary term, up to five (5) years. If there has been no positive biological fluid tests in the previous five (5) consecutive years of probation, testing may be reduced to one (1) time per month.

(D) Nothing precludes the Board from increasing the number of random tests *to the first-year level of frequency* for any reason, *including, but not limited to, if the Board finds or has suspicion that a licensee has committed a violation of the Board's testing program or has committed a violation as identified in section 1361.52(a).* in addition to ordering any other disciplinary action that may be warranted.

(E) The scheduling of biological fluid testing shall be done on a random basis, preferably by a computer program, except when testing on a specific date is ordered by the Board or its designee.

(F) The licensee shall be required to make daily contact with the Board or its designee to determine if biological fluid testing is required. The licensee shall be tested on the date of the notification as directed by the Board or its designee.

(G) Prior to changing testing locations for any reason, including during vacation or other travel, alternative testing locations must be approved by the Board, and meet the requirements set forth in section 1361.542.

(H) The cost of biological fluid testing shall be borne by the licensee.

(I) Exceptions to Testing Frequency Schedule.

1. Previous Testing Orders/Sobriety. In cases where the Board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing prior to being subject to testing by the Board, the Board may give consideration to that testing in altering the Board's own testing schedule so that the combined testing is equivalent to the requirements of this section.

2. Violation(s) Outside of Employment. A licensee 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 the first-year testing frequency requirements, and participate in the second-year testing frequency requirements.

3. Not Employed in Health Care Field. The Board may reduce the testing frequency to a minimum of 12 times per year for any licensee who is not practicing or working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the Board. Prior to returning to any health care employment, the licensee shall be required to test at the first-year testing frequency requirement for a period of at least 60 days. At such time the person returns to employment in a health care field, if the licensee has not previously met the first-year testing frequency requirement, the licensee shall be required to test at the first-year testing frequency requirement for a full year before he or she may be reduced to testing frequency of at least 36 tests per year.

4. Tolling. A Board may postpone all testing for any licensee whose probation is placed in a tolling status while the licensee is not residing in California, provided the overall length of the probationary period is also tolled. A licensee shall notify the Board upon the licensee's return to California and shall be subject to biological fluid testing as provided in this section. *If the licensee returns to employment in a health care field, and has not previously met the first-year testing frequency requirements, the licensee shall be subject to completing a full year at the first-year testing frequency requirements, otherwise the second-year testing frequency requirements shall be in effect.*

5. Substance Abuse Disorder Not Diagnosed. In cases where no current substance abuse disorder diagnosis is made, a lesser period of monitoring and biological fluid testing may be adopted by the Board, but ~~not~~ shall not be less than 24 times per year.

(J) Reinstatement of License or Reduction of Penalty. Nothing herein shall limit the Board's authority to reduce or eliminate the penalties herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code ~~S~~section 11522.

(4) Group Support Meetings.

~~(A) The Board may require a licensee to participate in group support meetings. The Board may impose participation in group support meetings following such recommendation by the evaluator or in a clinical diagnosis report. If the Board requires a licensee to participate in group support meetings, the following shall apply:~~

~~(B)~~ ~~(A)~~ When determining the frequency of group support meetings to be attended, the Board or the evaluator shall give consideration to the following:

1. ~~The~~ licensee's history;
2. The documented length of sobriety-/time that has elapsed since substance use;
3. The recommendation of the clinical evaluator;
4. The scope and pattern of use;
5. The licensee's treatment history; and
6. The nature, duration, and severity of substance abuse.

~~(C)~~ ~~(B)~~ The facilitator of a group support meeting shall conform to the following requirements:

~~(i)~~ 1. He or she shall have a minimum of three (3) years' experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or nationally certified organizations.

~~(ii)~~ 2. He or she shall not have a current or former financial, personal, or business relationship with the licensee within the last five (5) years. A licensee's previous participation in a group support meeting led by the same facilitator does not constitute a current or former financial, personal, or business relationship.

~~(iii)~~ 3. He or she shall provide to the Board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

~~(iv)~~ 4. He or she shall report a licensee's unexcused absence to the Board within 24 hours.

~~(C)~~ Any costs associated with attending and reporting on group support meetings shall be borne by the licensee.

~~(5) Biological Fluid Testing. The Board shall require biological fluid testing of substance-abusing licensees.~~

~~(A) For the purposes of this subsection, biological fluid testing means the acquisition and chemical analysis of a licensee's urine, blood, breath, or hair.~~

~~(B) The following standards shall apply to a licensee ordered to undergo biological fluid testing:~~

~~(i) The licensee shall be tested a minimum of 52-104 times per year for the first year of probation and at any time ordered by the Board. After the first year of probation, licensees who are practicing shall be randomly drug tested at least 36-104 times per year, and at any time as directed by the Board.~~

~~(1) The Board may revise the frequency specified in section (i) upon a determination that the licensee is not currently employed in a health care field, the licensee suffers from a substance use or abuse disorder, or other circumstances in which a revision of the testing frequency would not impair public protection. In no case may the testing frequency be reduced below twenty-four (24) times per calendar year.~~

~~(ii) Drug testing may be required on any day, including weekends and holidays.~~

~~(iii) The scheduling of testing shall be done on a random basis, preferably by a computer program, except when testing on a specific date is ordered by the Board.~~

~~(iv) Licensees shall be required to make daily contact with the Board to ascertain if testing is required.~~

~~(v) Licensees shall submit to all random and specifically ordered biological fluid tests.~~

~~(vi) The cost of biological fluid testing shall be borne by the licensee.~~

~~(vii) Licensees may elect to have the tests performed by an entity under contract with the Board or by another entity, provided that the entity meets all the following standards:~~

~~(1) Its specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the United States Department of Transportation.~~

~~(2) It conforms to the current United States Department of Transportation Guidelines for Specimen Collection.~~

~~(3) Its testing locations comply with the Urine Specimen Collection Guidelines published by the United States Department of Transportation without regard to the type of test administered.~~

~~(4) The collection of testing specimens shall be observed.~~

~~(5) Its laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.~~

~~(6) Its collection sites submit a specimen to a laboratory within one (1) business day of receipt and all specimens collected shall be subjected to chain of custody procedures. The entity shall process and analyze the specimen and provide legally defensible test results to the Board within seven (7) days of receipt of the specimen.~~

(5) Worksite Monitor Requirements and Responsibilities.

(A) The Board may require the use of worksite monitors. If the Board determines that a worksite monitor is necessary for a particular licensee, the licensee shall, within 30 calendar days of the effective date of that determination, submit to the Board or its designee for prior approval the name of a worksite monitor. The worksite monitor shall meet the following criteria to be approved by the Board:

1. The worksite monitor shall not have a current or former financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the Board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the Board; however, under no circumstances shall a licensee's worksite monitor be an employee or supervisee of the licensee.

2. The worksite monitor's scope of practice shall include the scope of practice of the licensee being monitored, be another licensed health care professional if no monitor with like scope of practice is available, or, as approved by the Board, be a person in a position of authority who is capable of monitoring the licensee at work.

3. If a licensed professional, the worksite monitor shall have an active unrestricted license with no disciplinary action within the last five (5) years.

4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and agrees to monitor the licensee as set forth by the Board.

(B) The worksite monitor shall adhere to the following required methods of monitoring the licensee:

1. Have face-to-face contact with the licensee in the work environment on as frequent a basis as determined by the Board, but not less than once per week.

2. Interview other staff in the office regarding the licensee's behavior, if requested by the Board.

3. Review the licensee's work attendance.

(C) Reporting by the worksite monitor to the Board shall comply with the following:

1. The worksite monitor shall verbally report any suspected substance abuse to the Board and the licensee's employer or supervisor as defined in subsection (c)(2) within one (1) business day of occurrence. If the suspected substance abuse does not occur during the Board's normal business hours, the verbal report shall be made to the Board within one (1) hour of the next business day. A written report that includes the date, time, and location of the suspected abuse, the licensee's actions and any other information deemed important by the worksite monitor shall be submitted to the Board within 48 hours of the occurrence, ~~or the next business day.~~

2. The worksite monitor shall complete and submit a written report monthly or as directed by the Board. The report shall include the following:

- a. The licensee's name and license number;
- b. The worksite monitor's name and signature;
- c. The worksite monitor's license number, if applicable;
- d. The worksite location(s);
- e. The dates the licensee had face-to-face contact with the monitor;
- f. The names of worksite staff interviewed, if applicable;
- g. An attendance report;
- h. Any change in behavior and/or personal habits; and
- i. Any indicators that can lead to suspected substance abuse.

(D) The licensee shall complete any required consent forms and execute agreements with the approved worksite monitor(s) and the Board authorizing the Board and worksite monitor to exchange information.

(E) If the monitor resigns or is no longer available, the licensee shall, within five (5) calendar days of such resignation or unavailability, submit to the Board the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If the licensee fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, the licensee shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. The licensee shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.

(F) Worksite monitoring costs shall be borne by the licensee.

(6) The licensee must remain in compliance with all terms and conditions of probation. If the licensee commits a major or minor violation, as defined in section 1361.52, the Board will execute the disciplinary actions required by that section, and impose any additional terms or conditions necessary for public protection or to enhance the rehabilitation of the licensee.

NOTE: Authority cited: Sections 315, 315.2, 315.4, and 2018, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections [315](#), [315.2](#), [315.4](#), [2227](#), [2228](#),

2229, and 2234, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

~~(6) Results of Biological Fluid Tests.~~

~~(A) If the results of a biological fluid test indicates that a licensee has used, consumed, ingested or administered to himself or herself a prohibited substance, the Board shall order the licensee to cease practice and instruct the licensee to leave any place of employment where he or she is practicing medicine or providing medical services. The Board shall also immediately notify all the licensee's employers that the licensee may not provide medical services or practice medicine while the cease practice order is in effect.~~

~~(B) After the issuance of a cease practice order, the Board shall determine whether the test is in fact evidence of prohibited substance use by consulting with the specimen collector and the laboratory, communicating with the licensee, his or her treating physician(s), other health care provider, or group facilitator, as applicable.~~

~~(C) If no prohibited substance use exists, the Board shall immediately lift the cease practice order.~~

~~(D) For the purposes of this section, "prohibited substance" means an illegal or unlawful drug, a lawful drug not prescribed or ordered by an appropriately licensed health care provider for use by the licensee and approved by the Board, alcohol, or other substance.~~

~~(7) Actions by Licensees and Consequences Thereof.~~

~~(A) A licensee who does any of the following shall be deemed to have committed a major violation of his or her probation:~~

~~(i) Fails to undergo a required clinical diagnostic evaluation;~~

~~(ii) Commits multiple minor violations of probation conditions and terms;~~

~~(iii) Treats a patient or patients while under the influence of drugs or alcohol;~~

~~(iv) Commits any drug or alcohol offense that is a violation of state or federal law or any regulation adopted thereto;~~

~~(v) Fails to undergo biological testing when ordered;~~

~~(vi) Uses, consumes, ingests, or administers to himself or herself a prohibited substance;~~

~~(vii) Knowingly uses, makes, alters or possesses any object or product in such a way as to defraud a biological fluid test designed to detect the presence of a prohibited substance.~~

~~(B) If a licensee commits one or more major violation, the Board may take the following actions:~~

~~(i) Issue an immediate cease practice order.~~

~~(ii) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee. Any order issued by the Board pursuant to this subsection may state that the licensee must test negative for at least a month of continuous drug testing before being allowed to resume practice.~~

~~(iii) Increase the frequency of biological fluid testing.~~

~~(C) A licensee who does any of the following shall be deemed to have committed a minor violation of his or her probation:~~

~~(i) Failure to submit required documentation to the Board in a timely manner;~~

~~(ii) Unexcused absence at required meetings;~~

~~(iii) Failure to contact a worksite monitor as required;~~

~~(iv) Failure to comply with another term or condition of his or her probation that does not impair public safety.~~

~~(D) If a licensee commits one or more minor violations, the Board may take the following actions:~~

~~(i) Issue a cease practice order;~~

~~(ii) Issue a citation and fine;~~

~~(iii) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee.~~

~~(E) Nothing in this section shall be considered a limitation on the Board's authority to revoke the probation of a licensee who has violated a term or condition of that probation.~~

~~(8) Request to Return to Full or Partial Practice.~~

~~(A) Before determining whether to authorize the return to practice after the issuance of a cease practice order or after the imposition of practice restrictions following a clinical diagnostic evaluation, the Board in conjunction with the evaluator shall ensure that the licensee meets the following criteria:~~

~~(i) A demonstration of sustained compliance with his or her current treatment or recovery program, as applicable;~~

~~(ii) A demonstration of the capability to practice medicine safely as evidenced by current worksite monitor reports, evaluations conducted by licensed health care practitioners, and any other information relating to the licensee's substance abuse and recovery therefrom.~~

~~(iii) Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of probation.~~

(4) Section 1361.51 is added to Article 4, Chapter 2, Division 13 of Title 16 of the California Code of Regulations to read:

§ 1361.51. Results of Biological Fluid Tests of Substance-Abusing Licensees.

(a) If the results of a biological fluid test indicate that a licensee has used, consumed, ingested, or administered to himself or herself a prohibited substance, the Board shall order the licensee to cease practice and instruct the licensee to leave any place of work where he or she is practicing medicine or providing medical services. The Board shall also immediately notify all of the licensee's employers, and supervisors as defined under section 1361.5(c)(2), if any, and work site monitor, if any, that the licensee may not provide medical services or practice medicine while the cease-practice order is in effect.

(b) A biological fluid test will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

(c) After the issuance of a cease-practice order, the Board shall determine whether the positive biological fluid test is in fact evidence of prohibited substance use by consulting with the specimen collector and the laboratory, communicating with the licensee, his or her treating physician(s), other health care provider, or group facilitator, as applicable.

(d) If no prohibited substance use exists, the Board shall lift the cease-practice order within one (1) business day.

(e) For the purposes of this Article, "prohibited substance" means an illegal drug, a lawful drug not prescribed or ordered by an appropriately licensed health care provider for use by the licensee and approved by the Board, alcohol, or other substance the licensee has been instructed by the Board not to use, consume, ingest, or administer to himself or herself.

(f) If the Board confirms that a positive biological fluid test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in section 1361.52, and the Board shall impose any or all of the consequences set forth in section 1361.52, in addition to any other terms or conditions the Board determines are necessary for public protection or to enhance the rehabilitation of the licensee.

NOTE: Authority cited: Sections 315, 315.2, 315.4, and 2018, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 2227, 2228, 2229, and 2234, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

(5) Section 1361.52 is added to Article 4, Chapter 2, Division 13 of Title 16 of the California Code of Regulations to read:

§ 1361.52. Actions by Substance-Abusing Licensees and Consequences Thereof.

(a) A licensee who does any of the following shall be deemed to have committed a major violation of his or her probation:

- (1) Fails to undergo a required clinical diagnostic evaluation;
- (2) Commits multiple minor violations of probation conditions and terms;
- (3) Treats a patient or patients while under the influence of a prohibited substance;
- (4) Engage in any drug or alcohol related act that is a violation of state or federal law or regulation;
- (5) Fails to undergo biological fluid testing when ordered;
- (6) Uses, consumes, ingests, or administers to himself or herself a prohibited substance;
- (7) Knowingly uses, makes, alters or possesses any object or product in such a way as to defraud, or attempt to defraud, a biological fluid test designed to detect the presence of a prohibited substance; or
- (8) Fails to comply with any term or condition of his or her probation that impairs public safety.

(b) If a licensee commits a major violation, the Board will take one or more of the following actions:

- (1) Issue an immediate cease-practice order, and order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee. Any order issued by the Board pursuant to this subsection shall state that the licensee must test negative for at least a month of continuous biological fluid testing before being allowed to resume practice.
- (2) Increase the frequency of biological fluid testing.
- (3) Refer the licensee for further disciplinary action, such as suspension, revocation, or other action as determined by the Board.

(c) A licensee who does any of the following shall be deemed to have committed a minor violation of his or her probation:

- (1) Fails to submit required documentation to the Board in a timely manner;
- (2) Has an unexcused absence at a required meeting;
- (3) Fails to contact a worksite monitor as required; or

(4) Fails to comply with any term or condition of his or her probation that does not impair public safety.

(d) If a licensee commits a minor violation, the Board will take one or more of the following actions:

(1) Issue a cease-practice order;

(2) Order practice limitations;

(3) Order or increase supervision of licensee;

(4) Order increased documentation;

(5) Issue a citation and fine, or a warning letter;

(6) Order the licensee to undergo a clinical diagnostic evaluation at the expense of the licensee;

(7) Take any other action as determined by the Board.

(E) Nothing in this section shall be considered a limitation on the Board's authority to revoke the probation of a licensee who has violated a term or condition of that probation.

NOTE: Authority cited: Sections 315, 315.2, 315.4, and 2018, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 2227, 2228, 2229, and 2234, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

(6) Section 1361.53 is added to Article 4, Chapter 2, Division 13 of Title 16 of the California Code of Regulations to read:

§ 1361.53. Request by a Substance-Abusing Licensee to Return to Practice.

Before determining whether to authorize the return to practice after the issuance of a cease-practice order or after the imposition of practice restrictions following a clinical diagnostic evaluation, the Board in conjunction with the evaluator shall ensure that the licensee meets the following criteria:

(a) A demonstration of sustained compliance with his or her current treatment or recovery program, as applicable;

(b) A demonstration of the capability to practice medicine safely as evidenced by current worksite monitor reports (if currently being monitored), evaluations conducted by licensed health care practitioners, and any other information relating to the licensee's substance abuse and recovery therefrom; and

(c) Negative biological fluid testing reports or biological fluid tests indicating that a licensee has not used, consumed, ingested or administered to himself or herself a prohibited substance, as defined in section 1361.51(e), for at least six (6) months, two (2) positive worksite monitor reports (if currently being monitored), and complete compliance with other terms and conditions of probation.

NOTE: Authority cited: Sections 315, 315.2, 315.4, and 2018, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 2227, 2228, 2229, and 2234, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

(7) Section 1361.54 is added to Article 4, Chapter 2, Division 13 of Title 16 of the California Code of Regulations to read:

§ 1361.54. Requirements for Laboratories/Testing Locations and Specimen Collectors for Testing Substance-Abusing Licensees.

Licensees shall contract with a laboratory or service approved in advance by the Board, provided that the laboratory or service meets all the following standards:

(a) Its specimen collectors shall either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the United States Department of Transportation.

(b) Its specimen collectors shall conform to the current United States Department of Transportation Specimen Collection Guidelines.

(c) Its testing locations shall comply with the Urine Specimen Collection Guidelines published by the United States Department of Transportation without regard to the type of test administered.

(d) Its specimen collectors shall observe the collection of testing specimens.

(e) Its laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

(f) Its testing locations shall submit a specimen to a laboratory within one (1) business day of receipt and all specimens collected shall be handled pursuant to chain of custody procedures. The laboratory shall process and analyze the specimen and provide legally defensible test results to the Board within seven (7) business days of receipt of the specimen. The Board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

(g) Its testing locations shall possess all the materials, equipment and technical expertise necessary in order to test every licensee for which it is responsible on any day of the week.

(h) Its testing locations shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.

(i) It must have testing sites that are located throughout California.

(j) It must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the licensee to check in daily for testing.

(k) It must have a secure, HIPAA-compliant website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

(l) It shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory biological fluid test results, medical histories, and any other information relevant to biomedical information.

(m) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

NOTE: Authority cited: Sections 315, 315.2, 315.4, and 2018, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 315, 315.2, 315.4, 2227, 2228, 2229, and 2234, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

(8) Section 1361.55 is added to Article 4, Chapter 2, Division 13 of Title 16 of the California Code of Regulations to read:

§ 1361.55. Reporting Requirements Relating to Substance-Abusing Licensees.

(a) The 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 on probation:

(1) Number of probationers whose conduct was related to a substance abuse problem;

(2) Number of relapses (break in sobriety);

(3) Number of cease-practice orders;

(4) Number of suspensions;

(5) Number of major violations; nature of violation and action taken;

(6) Number of petitions to revoke probation filed; and

(7) Number of licensees who successfully completed probation.

(b) For each reporting category described in subsection (a), the Board shall identify the licensing category, and the specific substance abuse problem (i.e., cocaine, alcohol, Demerol, etc.).

(c) If the reporting data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information

shall be taken into account when determining the success of terms and conditions of probation. The information may also be used to determine the risk factor when the Board is determining whether a license should be revoked or placed on probation.

(d) The Board shall use the following criteria to determine if its terms and conditions of probation protects patients from harm and is effective in assisting its licensees in recovering from substance abuse problems in the long term:

(1) One hundred percent of licensees whose licenses were placed on probation as a result of a substance abuse problem successfully completed probation, or had their licenses to practice revoked or surrendered on a timely basis based on noncompliance with terms and conditions of probation.

(2) At least 75 percent of licensees who successfully completed probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

(e) For purposes of measuring outcomes and effectiveness relating to biological fluid testing as described in section 1361.5(c)(3), the Board shall collect and report historical data (as available) and post-implementation data as follows:

(1) Historical Data. The Board should collect the following historical data (as available) for a period of two years prior to implementation of the Uniform Standards for Substance-Abusing Licensees, for each person subject to testing for banned substances, who has done any of the following:

(A) Tested positive for a banned substance;

(B) Failed to appear or call in for testing on more than three occasions;

(C) Failed to pay testing costs; or

(D) Given a diluted or invalid specimen.

(2) Post-Implementation Data – Three Years

The Board shall collect data annually for a period of three years following implementation of the Uniform Standards for Substance-Abusing Licensees for every licensee subject to testing for banned substances pursuant to section 1361.5(c)(3). The data collected shall be reported to the Department of Consumer Affairs and the Legislature, upon request, and shall include, but may not be limited to:

(A) Licensee identification;

(B) License type;

(C) Probation effective date;

(D) General range of testing frequency for each licensee;

(E) Dates testing requested;

(F) Dates tested;

(G) Identity of the entity that performed each test;

(H) Date(s) licensee tested positive;

- (I) Date(s) Board was informed of positive test(s);
- (J) Date(s) of questionable tests (e.g. dilute, high levels);
- (K) Date(s) Board was notified of questionable test(s);
- (L) Identification of substances detected or questionably detected;
- (M) Date(s) licensee failed to appear for testing;
- (N) Date(s) Board notified of licensee's failure to appear;
- (O) Date(s) licensee failed to call in for testing;
- (P) Date(s) Board was notified that licensee failed to call in for testing;
- (Q) Date(s) licensee failed to pay for testing;
- (R) Date(s) licensee was removed/suspended from practice (identify which); and
- (S) Final outcome and effective date (if applicable).

Note: Authority cited: Sections 315, 315.2, 315.4, and 2018, ~~of the~~ Business and Professions Code. Reference: Sections 315, 315.2, and 315.4, ~~of the~~ Business and Professions Code.

**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.

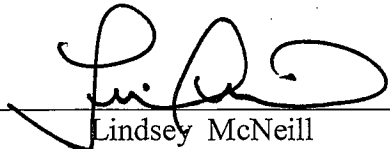
3.3 Reference Citations. The Board must consider the addition of Business and Professions Code sections 315, 315.2, and 315.4 to its listing of Reference citations after sections 1361 through 1361.54.

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



Lindsey McNeill
Attorney

FOR: DEBRA M. CORNEZ
Director

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