

**AVAILABILITY OF MODIFIED TEXT AND
DOCUMENTS ADDED TO THE RULEMAKING FILE**

NOTICE IS HEREBY GIVEN that the Osteopathic Medical Board of California has proposed modifications to the text of section 1663 in Title 16 of the California Code of Regulations which were the subject of a regulatory hearing on September 17, 2015. A copy of the modified text, including any document incorporated by reference, is enclosed.

NOTICE IS ALSO GIVEN that the following document is being added to the rulemaking record for the regulatory proceeding concerning sections 1661.2 and 1663 of Title 16 of the California Code of Regulations:

- *Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (04/2011)*

The above documents are now available for public inspection and/or comment until April 14, 2016 at the location referenced below.

Any person who wishes to comment on the proposed modifications may do so by submitting written comments on or before April 14, 2016 to the following:

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Materials regarding this proposal can be found at www.ombc.ca.gov.

DATED: March 31, 2016



Angelina Burton
Executive Officer
Osteopathic Medical Board of California

OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
ADDENDUM TO THE INITIAL STATEMENT OF REASONS

Hearing Date: September 17, 2015

Subject Matter of Proposed Regulations: Uniform Standards for Substance Abusing Licensees and Disciplinary Guidelines as required by SB 1441

Sections Affected: California Code of Regulations, title 16, sections 1661.2 and 1663

Updated Underlying Data:

Technical, theoretical or empirical studies or reports relied upon (if any): *Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (04/2011)*

OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

INITIAL STATEMENT OF REASONS

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Sections affected: Division 16 of Title 16 of California Code of Regulations Sections 1661.2 and 1663

Introduction

Senate Bill 1441: On June 30, 2008, the Medical Board of California was scheduled to sunset its Diversion Program and reverted to disciplinary action as the only means of addressing physicians with substance abuse problems. The sunset was primarily due to the program's failure of its fifth audit, conducted by the Center for Public Interest Law (the Medical Board's Enforcement Monitor), for overall ineffectiveness, lack of standards and failure to protect the public from harm. At the same time, there was extensive media coverage citing deficiencies in the Medical Board's Diversion Program, including patients harmed by physicians who continued to practice even after testing positive for drugs. On January 24, 2008, with the sunset of its Diversion Program imminent, the Medical Board held a Diversion Summit to discuss other options for physicians with substance abuse problems.

On March 10, 2008, the Senate Business, Professions and Economic Development Committee (Senate Committee) held a hearing to review physician's and health practitioner's substance abuse programs. The resulting legislation, authored by the Senate Committee Chair, Senator Ridley-Thomas, was Senate Bill (SB) 1441: Healing arts practitioners: substance abuse (Chapter 548, Statutes of 2008).

In September 2008, SB 1441 was signed into law. The Legislature declared that substance abuse monitoring programs, particularly for health care professionals, must operate with the highest level of integrity and consistency. Patient protection is paramount. The legislation, in part, mandated that the Department of Consumer Affairs (Department) establish a Substance Abuse Coordination Committee (Committee) subject to the Bagley-Keene Open Meeting Act comprised of the Executive Officers of the Department's healing arts boards, a representative of the California Department of Alcohol and Drug Programs, and chaired by the Director of the Department. The Committee was charged with developing consistent and uniform standards and best practices in sixteen specific areas for use in dealing with substance abusing licensees, whether or not a Board chooses to have a formal diversion program. The Department is committed to ensuring that licensees who are confirmed to be abusing drugs and/or alcohol, and who pose a risk to the public, are not diverted from an enforcement action or public

disclosure of that action. The Department is also committed to ensuring that licensees who have undergone treatment and have made steps towards recovery can safely return to practice. The Committee has developed sixteen uniform standards as required by SB 1441. The Board is proposing to implement Uniform Standards 1-12 in its Disciplinary Guidelines through the regulatory process.

Other Amendments/Deletions: The disciplinary and probationary environments have changed significantly since 1996 and the Board's proposed changes are meant to address this. Many of the changes are based on best practices exemplified by the Department of Consumer Affairs' various Boards and Bureaus that have proven to be effective and in the best interest for consumers and the licensees receiving discipline.

Specific Purpose of each adoption, amendment, or repeal:

The Board proposes to add specified uniform standards related to substance abuse by incorporating them by reference into CCR section 1661.2. This proposal also updates the Board's existing standards and optional terms of probation. The following describes those uniform standards being added by the Board, including the updates of its Disciplinary Guidelines and other clarifying and minor changes.

CCR section 1661.2

Section 1661.2 is amended as follows:

- Incorporates by reference the new guidelines, including the "Uniform Standards Regarding Substance-Abusing and Healing Arts Licensees" (04/2011).

CCR section 1663

Section 1663 is amended as follows:

- Incorporates by reference the Board's Disciplinary Guidelines entitled "Osteopathic Medical Board of California Disciplinary Guidelines of 2014" (Rev 08/14).
- Adds clarifying language indicating when it is appropriate to use the Disciplinary Guidelines and Uniform Standards.

Factual Basis/Rationale:

In order to comply with SB 1441, the Board proposes to add the following standards, which shall be adhered to in every case where a licensee is placed on probation due, in part, to a substance abuse problem. These standards are not guidelines and shall be followed in all instances, except that the Board may impose more restrictive conditions, if necessary, to protect the public.

Standard 1. Clinical Diagnostic Evaluation and Reports

Requires that if a licensee is ordered to undergo a clinical diagnostic evaluation, the evaluation must be conducted by a licensed practitioner who holds a valid, unrestricted license to conduct clinical diagnostic evaluations, has three (3) years of experience in providing evaluations of

health care professionals with substance abuse disorders and is approved by the Board. This standard also identifies the information that must be addressed or contained in the evaluation report and timeframes for submitting the report to the Board.

The purpose of this standard is to increase consumer protection by: 1) specifying requirements for a clinical diagnostic evaluation of the licensee and the required qualifications for the providers charged with evaluating the licensee along with timeframes for completing the clinical diagnostic evaluation; 2) ensuring that the Board is notified quickly if the licensee is a threat to himself or herself or the public; 3) ensuring the Board is provided with a professional opinion as to whether the licensee has a substance abuse problem, and whether the licensee is a threat to himself or herself or others; and 4) prohibiting personal, financial and business relationships between the evaluator and licensee, thereby ensuring objectivity in assessments.

Because of the complexity of an addictive disease, professional substance abuse evaluations are needed to assist the Board in making informed decisions regarding a licensee's ability to practice safely. The evaluator can present recommendations for a therapeutic treatment plan.

The treatment recommendations may be incorporated into a Board order as elements for monitoring. By specifying that the Board be provided with expert recommendations for treatment and practice restrictions, the standard also ensures that licensees who have undergone treatment and have made steps towards recovery can safely return to practice.

Standard 2. Diversion Program – Alcohol and Drugs

Requires that the licensee shall enroll and participate in the Board's Diversion Program within thirty (30) days of the effective date of decision, and remain in the program until the Board determines that further treatment and rehabilitation is no longer necessary. The standard makes note that quitting the Diversion Program without permission or being expelled for cause shall constitute a violation of probation by the licensee.

This standard also requires that the vendor providing diversion services report any major violations committed by the licensee to the board within one (1) business day and any minor violations within five (5) business days. It also outlines standards for testing, specimen collection and handling and requirements for the laboratories who perform the handling and processing of test results.

This standard would increase consumer protection because it requires that the licensee enroll in a program where he or she is regularly monitored by an alternate party, and ensures that they remain in compliance during the term of their probationary period through randomly regulated specimen collections.

Standard 3. Drugs – Abstain from Use

This standard requires that the licensee shall abstain completely from the personal use or possession of controlled substances as defined in the California Uniform Controlled Substances Act, and dangerous drugs as defined in the California Business and Professions Code, or any

drugs requiring a prescription except for ordering or possessing medications lawfully prescribed to the licensee by another practitioner, for a bona fide illness or condition.

As controlled substances impair a licensee's ability to practice safely the board requires all licensee to comply with the Uniform Standards developed by the Substance Abuse Coordination Committee. The boards highest priority is maintaining the protection of consumers and this standard would ensure consumer safety by prohibiting probationers use of controlled substances as a condition of their probation.

Standard 4. Alcohol – Abstain from Use

Requires that the licensee shall abstain completely from the use of alcoholic beverages.

As alcohol impairs a licensee's ability to practice safely the board requires all licensee to comply with the Uniform Standards developed by the Substance Abuse Coordination Committee. The boards highest priority is maintaining the protection of consumers and this standard would ensure consumer safety by prohibiting probationers use of alcohol as a condition of their probation.

Standard 5. Notification to Employer

Requires a licensee who has an employer to provide the Board with the names, physical addresses, mailing addresses and phone numbers of all employers and supervisors. This standard also requires that the licensee provide written consent to allow Board staff to communicate with the work site monitor and employer about the licensee's work status, performance and monitoring.

Standard 6. Biological Fluid Testing

Requires the Board to randomly test a licensee whose license is placed on probation due to substance abuse and establishes guidelines for the testing frequency.

Randomness is a very important component in drug testing. The testing frequency schedule being proposed by the Board allows for appropriate randomness in testing (without regular interval or pattern), preventing licensees from gauging when they will be tested. By establishing minimum testing frequency "ranges" and employing randomness in testing, licensees will not be able to consider one or more days as a "safety period" following the submission of a biological sample for testing. Requiring a licensee to submit a specimen on the same day as directed will eliminate the ability of a licensee to "flush" their system overnight. The standard is broad enough to allow the Board to evaluate each licensee's situation on a case-by-case basis, if appropriate. For example, one of the exemptions allows the Board to adjust the testing frequency schedule in cases where a licensee who is an admitted recovered substance abuser or addict, has already participated in a rehabilitation program before being placed on probation. In cases where there is evidence that the person has randomly tested and has maintained sobriety, some flexibility should be granted to the Board in determining the duration of high frequency testing, that is equivalent to the proposed testing schedule. Allowing exceptions will not only

protect the public and fit each licensee's needs, but it will ensure successful rehabilitation of the licensee by providing a plan that is manageable and realistic.

Standard 7. Group Support Meetings

Requires that if the Board orders a licensee to participate in group support meeting, the criteria established in the uniform standards must be used to determine the frequency of group meeting attendance and to verify that the meeting facilitator are experienced, mental health professionals.

The purpose of this standard is to increase consumer protection by:

- Holding licensees placed on probation due to substance abuse accountable for attending meetings and being active in their own recovery;
- Allowing the group meeting facilitator and the Board to work together to assist in the licensee's recovery and quickly prevent relapse with open channels of communication; and
- Ensuring that licensees are receiving professional help from a person not related to them in any way that will allow for objectivity and balance during their recovery.

Standard 8. Worksite Monitor

Requires the Board to determine if a worksite monitor is necessary for a particular licensee and outlines the requirements the proposed monitor must meet in order to be approved by the Board to serve as a monitor. In addition, this standard outlines the duties and responsibilities a worksite monitor must perform.

SB 1441 required the Department to establish monitor requirements and standards, including, but not limited to: (1) required qualification of monitors; (2) required methods of monitoring by monitors; and (3) required reporting by monitors. The worksite monitor's role is to have face-to-face contact with a licensee who has a substance abuse history to ensure that the licensee is not abusing drugs and/or alcohol. The monitor is also responsible for reporting to the Board whether patient safety may be at risk and any change in the licensee's behavior that may be cause for suspected substance abuse.

The licensee and the worksite monitor must sign and submit consent forms in order for the Board to communicate with the monitor regarding the licensee's performance while at work. Implementing this standard provides (1) ongoing documentation of the licensee's behavior and would ensure the public's safety; and (2) immediate notification to the Board if a licensee is suspected of working under the influence of drugs and/or alcohol.

Standard 9. Results of Biological Fluid Tests

Requires the Board to suspend the licensee if he or she tests positive for a prohibited substance and notify the licensee's employers that he or she cannot provide medical services while the suspension or cease practice order is in place.

Protection of the public is the highest priority of the Board in exercising its licensing, regulatory and disciplinary functions. In order to carry out this mandate, it is appropriate for the Board to immediately suspend a licensee's license if he or she tests positive for a prohibited substance until he or she has been assessed and the results interpreted. It is also appropriate for the Board to notify the licensee's employer that the licensee may not practice until the suspension is lifted. Testing positive for a prohibited substance is a violation of their probation and the Board shall pursue disciplinary action based on the probation violation.

Standard 10. Major and Minor Violations

In compliance with SB 1441, major and minor violations and consequences are being defined. If a licensee commits a major violation, the Board could issue an immediate cease practice order and refer the matter for disciplinary action or other action as determined by the Board. If a licensee commits a minor violation, the Board would be required to determine what action is appropriate based on the violation.

Protection of the public is the highest priority of the Board in exercising its licensing regulatory and disciplinary functions. The Board protects the public through its Practice Act, regulations and related statutes. Major violations would result in consequences that would be the maximum allowed by law under the Board's Practice Act and regulations.

Minor violations would result in consequences determined appropriate by the Board, e.g., issuing a cease practice order or issuing a citation, which is not considered discipline.

Standard 11. Request by a Substance-Abusing Licensee to Return to Practice

In compliance with SB 1441, this standard defines the criteria that a licensee must meet in order to return to practice after practice restrictions were deemed appropriate by the evaluator performing a clinical diagnostic evaluation or following the issuance of a cease practice order.

This standard would increase consumer protection because it requires the licensee to be completely compliant with the conditions in their recovery program and/or probation before the Board will even consider this type of request. All licensees will be held to the same standard.

Standard 12. Request by a Substance-Abusing Licensee for Reinstatement of a full and unrestricted license – Petition for Reinstatement

This standard defines the criteria that licensee must meet in order to request reinstatement of a full and unrestricted license and clarifies the meaning of "Petition for Reinstatement."

This standard would ensure consumer protection as it requires the licensee to meet certain criteria and maintain a level of compliance with terms of their disciplinary order prior to submitting a request for "Petition for Reinstatement" of licensure.

Underlying Data:

Technical, theoretical or empirical studies or reports relied upon (if any): [Uniform Standards Regarding Substance-Abusing Healing Arts Licensees \(04/2011\)](#)None

Business Impact/Specific Technologies or Equipment:

This regulation will not have a significant adverse economic impact on businesses, specific technologies, or equipment. This regulation only impacts licensees disciplined by the Osteopathic Medical Board of California. This regulation does not mandate the use of specific technologies or equipment.

Economic Impact Assessment:

This regulation will not have a significant adverse economic impact on the creation or elimination of jobs or businesses in the State of California. This initial determination is based on the fact that the regulation will only impact physicians who have been placed on probation who are ordered to cease practice for testing positive for drugs and/or alcohol use. The number of physicians impacted would be less than a half of one percent of the licensee population.

The regulation will not affect the expansion of businesses currently doing business within the State of California because the regulations will only affect licensed individuals and not businesses already operating in the State.

Benefits of the Proposed Action: This regulatory proposal benefits the health and welfare of California residents by providing protection from substance-abusing osteopathic physicians, requiring the osteopathic physicians to be completely compliant with the conditions in their recovery program and/or probation, or the Board can issue a cease practice order.

The regulatory proposal does not affect worker safety nor will it affect the state's environment because it does not affect those areas of law.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

Proposed Language

Changes to the originally proposed language are shown by underlining for new text and strikethrough for deleted text.

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

1. Amend Section 1661.2 of Division 16 of Title 16 of the California Code of Regulations to read as follows:

§ 1661.2 Diversion Evaluation Committee Duties and Responsibilities.

A diversion evaluation committee shall have the following duties and responsibilities in addition to those set forth in Section 2366 of the Code:

- (a) To consider recommendations of the program manager and any consultants to the committee;
- (b) To set forth in writing for each physician in a program a treatment and rehabilitation plan established for that physician with the requirement for supervision and surveillance.
- (c) To use the uniform standards for substance-abusing licensees contained in "Uniform Standards Regarding Substance-Abusing Healing Arts Licensees" (04/2011), which is hereby incorporated by reference.

NOTE: Authority cited: Osteopathic Act (Initiative Measure, Stats. 1923, p.xciii), Section 1; and Section 3600-1, Business and Professions Code. Reference: Section 2366, Business and Professions Code.

2. Amend Section 1663 of Division 16 of Title 16 of the California Code of Regulations to read as follows:

§ 1663. Disciplinary Guidelines.

(a) In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code Section 11400 et seq.), the Osteopathic Medical Board of California shall consider the disciplinary guidelines entitled "Osteopathic Medical Board of California Disciplinary Guidelines of 1996 ~~2014~~"(Rev 08/14) ("Guidelines"), which are hereby incorporated by reference. Deviation from ~~these~~ gGuidelines and orders, including the standard terms of probation, is appropriate where the Osteopathic Medical Board of California in its sole discretion determines 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) (1) Notwithstanding the Guidelines, any proposed decision issued in accordance with the procedures set forth in Chapter 5 (commencing with Section 11500) of Part 1 of

Division 3 of Title 2 of the Government Code that contains any finding of fact that the licensee engaged in any act of sexual contact, as defined in subdivision (c) of Section 729 of the Code, with a patient, or any finding that the licensee has committed a sex offense or been convicted of a sex offense, shall contain an order revoking the license. The proposed decision shall not contain an order staying the revocation of the license.

- (2) As used in this section, the term "sex offense" shall mean any of the following:
- (a) Any offense for which registration is required by Section 290 of the Penal Code or a finding that a person committed such an offense.
 - (b) Any offense defined in Section 261.5, 313.1, 647b, or 647 subdivision (a) or (d) of the Penal Code or a finding that a person committed such an offense.
 - (c) Any attempt to commit any of the offenses specified in this section.
 - (d) Any offense committed or attempted in any other state or against the laws of the United State which, if committed or attempted in this state, would be punishable as one or more of the offenses specified in this section.

(c) If the conduct found to be a violation involves drugs, alcohol, or both, and the individual is permitted to practice under conditions of probation, a clinical diagnostic evaluation shall be ordered as a condition of probation in every case, without deviation. The clinical diagnostic evaluator's report shall be submitted in its entirety to the board.

- (1) Each of the "Terms and Conditions of the Uniform Standards for Substance-Abusing Licensees," as set forth in the Guidelines, shall be included in any order subject to this subsection, but may be imposed contingent upon the outcome of the clinical diagnostic evaluation.
- (2) The Substance Abuse Coordination Committee's *Uniform Standards Regarding Substance Abusing Healing Arts Licensees (04/2011)*, which are hereby incorporated by reference, shall be used in applying the probationary conditions imposed pursuant to this subsection.

(d) Nothing in this section shall prohibit the Board from imposing additional terms or conditions of prohibition in any order that the Board determines would provide greater public protection.

NOTE: Authority cited: Osteopathic Act (Initiative Measure, Stats. 1923, p.xciii), Sections 1, 2018, 2451, and 3600-1, Business and Professions Code; and Section 11400.21, Government Code. Reference: Sections 315, 726 and 729, 2246, 2452, 3600-1, and 3600-2 Business and Professions Code; Sections 11400.21 and 11425.50(e), Government Code; Sections 261.5, 290, 313.1, 647b, and 647 subdivision (a) or (d), Penal Code.