

TITLE 16 OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA

(Notice published September 27, 2017)

NOTICE OF PROPOSED RULEMAKING

The Osteopathic Medical Board of California (Board) proposes to adopt the proposed regulation described below after considering all comments, objections, and recommendations regarding the proposed action.

PUBLIC HEARING

The Board will hold a public hearing starting at 10:00 a.m. on October 13, 2017, located at the Osteopathic Medical Board of California Conference Room, 1300 National Drive, Suite 150, Sacramento, CA 95834. The conference room is wheelchair accessible. At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed action described in the informative Digest. The Board requests but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Board. Comments may also be submitted by facsimile (FAX) at (916)928-8392 or by email to Terri.Thorfinnson@dca.ca.gov. The written comment period closed at 5:00 p.m. on October 13, 2017. The Board will consider only comments received at the Board offices by that time. Submit comments to:

Terri Thorfinnson, Assistant Executive Director
Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento, CA 95834

AUTHORITY AND REFERENCE

Osteopathic Act (Initiative Measure, Stats. 1923, p.xciii), Business and Professions Code Sections 1, 2018, 2451 and 3600-1 authorizes the Board to adopt this proposed regulation. The proposed regulation implements, interprets, and makes specific Sections 315, 2366, 726, 729, 2246 of the Business and Professions Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

This rule making action revises and corrects the proposed regulatory language and the Initial Statement of Reasons that were disapproved by the Office of Administrative Law December 9, 2016. The Board approved the proposed language at their June 28, 2017 Board meeting.

Goals and Objectives of Proposed Regulations

The goal and objectives of this proposed regulation is to increase consumer protection through compliance with laws that relate to the Board's enforcement, and improvement of the Board's enforcement oversight of the osteopathic profession. The Board proposes to implement Senate Bill (SB) 1441, Business and Professions Code Section 315 et seq.; update the Disciplinary Guidelines of 1996 to reflect subsequent statutory changes including adding conforming language related to sexual contact and sexual exploitation; and to improve the overall Disciplinary Guidelines with more detail, model language and disciplinary recommendations.

Summary of Existing Law and Proposed Changes

Existing law, SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) was signed into law and enacted Business and Profession Code Section (BPC) 315). Existing law requires healing arts Boards to adopt Uniform Standards regarding substance abusing licensees. The Department of Consumer Affairs formed a workgroup to create uniform standards regarding substance abusing licensees which was completed in 2011. Existing law, pursuant to BPC Section 315, the Board is required to adopt these standards as part of their disciplinary guidelines and adhere to them in cases involving self-use of substance abuse or alcohol.

Existing law, BPC Section 315.2 specifies that a healing arts board within DCA is required to order a licensee to cease practice if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program. The cease practice order pursuant to this section does not constitute disciplinary action and is not subject to adjudicative hearings.

Existing law, BPC 315.4 authorizes healing arts boards within DCA to order a licensee on probation or in a diversion program to cease practice for major violations and when the Board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the Uniform Standards and specific standards adopted and authorized under Section 315. The cease practice order pursuant to this Section does not constitute disciplinary action and is not subject to adjudicative hearings.

Existing law, BPC Section 2246, added Statutes of 2002, Ch. 1085, Sec. 22, effective January 1, 2003, requires revocation without stay for any case involving a licensee, in which there was a finding of any act of sexual exploitation as defined in BPC Section 729. In 2011, the legislature further amended BPC Section 729 to define specific violations by licensees involving sexual contact with and sexual exploitation of their patients and criminal penalties.

Existing law, BPC Section 2018 authorizes the Board to adopt, amend, or repeal such rules and regulations as may be reasonably necessary to enable the Board to carry into effect the provisions of the Osteopathic Act and Medical Practice Act.

This rulemaking action clarifies and makes specific changes to the Board's Disciplinary Guidelines of 1996 CCR Section 1663. The amendments include adding the Uniform Standards for Substance Abusing Licensees to the Disciplinary Guidelines pursuant to BPC Sections 315 and 2366; and amending CCR Section 1661.2 to require the Board's Diversion Program to comply with the Uniform Standards. The Board amends the Disciplinary Guidelines (Guidelines) pursuant to BPC Sections 726, 729, 2246 related to sexual contact discipline.

Other Amendments/Deletions: This rulemaking action clarifies and makes changes to the Board's Guidelines revising and updating the existing 1996 standards to comply with statutory changes since 1996: repealed statutory provisions have been deleted and new statutory provisions added along with new model disciplinary language and proposed discipline. The Board proposes to update its Quarterly Declaration Form OMBC 10 (1/18) that is being incorporated by reference within the Guidelines.

Summary of Updated Changes

The proposed language and initial statement of reasons have been revised as follows:

- Update and incorporate by reference the "Board's Disciplinary Guidelines and Uniform Standards for Substance Abusing Licensees of 2018" (1/18).
- Incorporate and integrate the "Uniform Standards for Substance Abusing Licensees" (April 2011) into the Guidelines.
- Amend CCR 1661.2 to require the Diversion Program to use the adopted Uniform Standards.
- Amend the Guidelines to add new model language and a violation to Guidelines related to sexual contact and sexual exploitation.
- Update and incorporate by reference the "Quarterly Declaration" Form OMBC 10 (1/18).

In this proposed regulatory action, the Board adds the entire Uniform Standards into the Guidelines and then integrated them into the model language and penalties sections of the Guidelines. The Board removed prior references to incorporating the Uniform Standards separate from the Guidelines that were included in the prior Initial Statement of Reasons. The revised Guidelines now include the Uniform Standards; and, the Guidelines are incorporated

by reference.

To improve clarity as to when the Uniform Standards applied, the relevant Uniform Standards language was integrated into each violation that involves substance abusing licensees. A note was added to the sections, in which the Uniform Standards were mandated. Finally, the Board also added the definition of what a substance abusing licensee is and how that status is determined.

The Board revised the Guidelines so they are divided into four parts to improve the usability as follows:

- Part I: Overview-- adding clarifying language
- Part II: Uniform Standards for Substance Abusing Licensees—all 16 standards.
- Part III: Model Language for Probationary Orders—terms and conditions including the Uniform Standards for Substance Abusing Licensees.
- Part IV: Recommended Discipline By Violation—modified existing discipline and added new discipline for existing terms and added new violations and discipline.

In Part II, the Board added the Uniform Standards for Substance Abusing Licensees in its entirety.

In Part III, the Board added the following new Standards Terms and Conditions:

- Notification to Board of Employers; Notification to Employers of Discipline
- Supervision of Physician Assistants and Advanced Practice Nurses

In Part III, the Board added the following new Optional Terms and Conditions:

- Record Keeping Course
- Professional Boundaries Course
- Clinical Assessment and Training Program
- Physical Health Evaluation
- Monitoring: Billing/Practice

In Part III, the Board modified the following Optional Terms and Conditions:

- Controlled Drugs: Total Restriction of DEA Permit
- Controlled Drugs: Surrender of DEA Permit
- Controlled Drugs: Partial Restriction of DEA Permit
- Controlled Drugs: Maintain Record
- Pharmacology/ Prescribing Course
- Written Examination

In Part III, the Board added the following Uniform Standards terms and conditions, which embody all 16 Uniform Standards:

- Clinical Diagnostic Evaluation: this condition of probation requires probationer to undergo a clinical diagnostic evaluation.
- Diversion Program—Alcohol and Drugs: all substance abusers on probation are required to enroll in and complete the Board’s Diversion Program that utilizes Uniform Standards.
- Drugs—Abstain from Use: This is an existing term that has been expanded within the Uniform Standards and thus modified.
- Alcohol—Abstain from Use: This is an existing term that has been expanded within the Uniform Standards and thus modified.
- Notification to Employer: The Board has adopted the Uniform Standards requirements with respect to notification of employer, what notice requirements must be met by licensee.
- Biological Fluid Testing: The Board has adopted the Uniform Standards testing frequency, protocols and requirements.
- Group Support Meetings: The Board has adopted the Uniform Standards requirement and protocols with respect to group support meetings.
- Worksite Monitor: The Board has adopted the Uniform Standards requirement and protocols with respect to requiring a worksite monitor.
- Results of Biological Fluid Tests: The Board has adopted the Uniform Standards requirement and protocols with respect to the process for positive test results and requiring immediate cease practice order.
- Major and Minor Violations: The Board has adopted the Uniform Standards requirement and protocols with respect to the criteria and discipline for major and minor violations of Diversion Program treatment and overall probation.
- Request by a Substance Abusing Licensee to Return to Practice: The Board has adopted the Uniform Standards process with respect to how a licensee can return to practice.
- Request by a Substance Abusing Licensee for Reinstatement of a Full and Unrestricted License—Petition for Reinstatement: The Board has adopted the Uniform Standards criteria for determine whether a licensee is safe to return to practice.

In Part IV, the Board updated the following existing violations to add new recommended discipline:

- BPC 810 Insurance Fraud
- BPC 2234 (b) Gross Negligence
- BPC 2234 (c) Repeated Negligence Acts
- BPC 2234 (e) Dishonesty
- BPC 2237 Drug Related Conviction
- BPC 2238 Violation of Drug Statute
- BPC 2239 Self Abuse of Drugs or Alcohol
- BPC 2241 Furnishing Drugs to and Addict
- BPC 2250 Failure to Comply with Sterilization Consent Provisions
- BPC 2251 Use of Silicone
- BPC 2261 Making or Signing False Document
- BPC 2262 Alteration of Medical Records/ False Medical Records

- BPC 2271,651 Deceptive Advertising
- BPC 2272 Anonymous Advertising
- BPC 2273 Employment of Runners, Cappers and Steerers
- BPC 2274 Misuse of Title
- BPC 2275 Use of “M.D.”
- BPC 2276 Use of “D.O.”

In Part IV, the Board modified the following violations and recommended discipline:

- BPC 725 Excessive Prescribing or Treatments
- BPC 729 Sexual Misconduct
- BPC 2236 Criminal Conviction: Felonies/Multiple Misdemeanors
- BPC 2236 Criminal Conviction: Single Misdemeanor

In Part IV, the Board added the following new violations and recommended discipline:

- BPC 729 Sexual Exploitation
- BPC 2235 Obtaining License by Fraud
- BPC 2288 Impersonation of Applicant in Exam
- BPC Practice During Suspension
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In Part IV, The Board deleted the following violation due to its repeal:

- BPC 2265 Use of Qualified Physician Assistant Without Approval

Anticipated Benefits of the Proposed Regulation:

The Board’s primary mission is to protect public safety. The Board has determined that this proposed regulatory change updating the Board’s Guidelines will result in increased protection of the public as a result of improved oversight and higher standards for treatment of substance abusing licensees. These regulatory changes will benefit California consumers by enhancing the Board’s ability to discipline osteopathic physicians and surgeons who violate the Osteopathic Act or Medical Practice Act or other laws and regulations regarding the practice of medicine by an osteopathic physician and surgeon.

There is a specific anticipated benefit from amending the regulation to require revocation for licensees that sexually exploit their patients. This amendment related to sexual exploitation is protecting patients from being sexually exploited and further harmed by predatory licensees.

It is anticipated that Administrative Law Judges and Deputy Attorney Generals will also benefit from the updated Guidelines when drafting decisions, which will have ensured consistency in interpretation and application of discipline in disciplinary matters.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations:

The Board has determined that this proposed regulation is not inconsistent or incompatible with existing regulations. After conducting a review for any regulations that would relate to or affect this area, the Board has concluded that these are the only regulations that concern the discipline of osteopathic physicians and surgeons in California.

INCORPORATION BY REFERENCE

1. "Osteopathic Medical Board of California Disciplinary Guidelines and Uniform Standards for Substance Abusing Licensees of 2018," (1/ 2018); and
2. Quarterly Declaration form OMBC 10 (1/18).

DISCLOSURES REGARDING THE PROPOSED ACTION

FISCAL IMPACT ESTIMATES

The Board has made the following determinations:

Fiscal Impact on Public Agencies including Costs or Savings to State Agencies or Cost/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Mandate on local agencies and school districts: None.

Cost or savings to any state agency: None.

Cost to any local agency or school district which must be reimbursed in accordance with Government Code Sections 17500 through 17630: None.

Other nondiscretionary cost or savings imposed on local agencies: None.

Business Impact

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states because it will only impact osteopathic physicians and surgeons' licensees subject to disciplinary action. The Board only has authority to take administrative action against a licensee and not a business. Accordingly, the initial or ongoing impact to a business at which a licensee works who is the subject of disciplinary action cannot be projected. Businesses employing licensees who are in compliance with the law will not incur any fiscal impact.

The following studies/ relevant data were relied upon in making the above determination:

The Board currently regulates approximately 9,848 osteopathic physicians and surgeons. Any “adverse economic impact” would only occur as the result of a disciplinary order following a formal administrative proceeding and a finding of fact affirming a violation of the Board’s laws or regulations and would only affect individuals who are disciplined by the Board. Any potential “adverse economic impact” may be avoided simply by complying with the law. Licensees who are placed on probation as a result of a violation involving drugs or alcohol and are deemed to be substance abusing licensees may incur additional costs as set forth in the “Cost Impact or Representative Private Person or Business” section below.

Cost Impacts on a Representative Private Person or Business:

The Board identified potentially significant costs which only impact those licensees who have been deemed substance abusing licensees and are subject to the Uniform Standards. The Uniform Standards are part of the Board’s Diversion Program in which substance abusing licensees are required to enroll and complete the program, pursuant to their terms of their probation. The Diversion Program has already implemented the Uniform Standards.

The following costs may be incurred by the licensees enrolled in the Board’s Diversion Program:

1. Diversion Program fee (includes clinical assessment evaluation):
 - \$338.00 Monthly Cost
 - \$4,056 Annual Cost
 - \$12,168 3 Year Term Cost
 - \$ 20,280 5 Year Term Cost
2. Diversion Drug Testing Costs (\$62.50 per test X 52 minimum tests per year):
 - \$250 Monthly Cost Estimate
 - \$3,250 Annual Cost Estimate
 - \$9,750 3 Year Term Estimate
 - \$16,250 5 Year Term Estimate
3. Support Groups Meeting Treatment
 - \$200-\$400 Monthly Cost
 - \$2,400-\$4,800 Annual Cost
 - Varies for 3 Year Term
 - Varies for 5 Year Term

The following are costs that licensees may incur as a requirement of probation:

1. Mental or Physically Impaired Evaluation: \$300-\$3,000 one-time cost
2. Cost Recovery Term of Probation (investigation, AGO, OAH, evidence costs) \$3,500-\$60,000.
3. Education and Training Course work: \$800- \$18,000
4. Additional Continuing Medical Education: \$50-\$2,000

EFFECT ON HOUSING COSTS: None.

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations would not affect small businesses. The proposed regulation will only affect individual licensees. The Board only has authority to take administrative action against a licensee and not a business. Accordingly, the initial or ongoing costs for a small business at which a licensee works who is the subject of disciplinary action cannot be projected. Businesses employing licensees who are in compliance with the law will not incur any fiscal impact.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/Businesses:

The Osteopathic Medical Board has determined that this regulatory proposal will not have any significant impact on the creation of jobs or new businesses or the expansion of businesses in the State of California because it will only impact licensees subject to disciplinary action. The Board only has authority to take administrative action against a licensee and not a business. Businesses employing licensees who are in compliance with the law will not incur any fiscal impact.

This proposed regulation will not eliminate jobs within the State of California because the proposal imposes specific requirements on a specific set of licensees who are subject to disciplinary action due to violations of the law and may be subject to more rigorous Uniform Standards due to the violations of law involving drugs or alcohol. A business owned by a licensee who faces disciplinary action may incur a significant fiscal impact depending on the nature and severity of the violation. The Board does not maintain data relating to the number or percentage of licensees who own a business; therefore, the number or percentage of businesses that may be impacted cannot be predicted. Similarly, the initial or ongoing costs for a small business at which the licensee works who is the subject of disciplinary action cannot be projected.

Benefits of Regulation:

There is no specific benefit to businesses, since the benefits more broadly apply to consumers and public safety. The regulations do not add any requirements for businesses. The regulations impact licensees only, not businesses.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5, subdivision (a) (13), the Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention of the Board would be 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 implementing the statutory policy or other provisions of law.

The Board invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Inquiries concerning the proposed administrative action may be directed to:

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