

TITLE 16. MEDICAL BOARD OF CALIFORNIA

NOTICE IS HEREBY GIVEN that the Medical Board of California (Board) is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at The Westin San Diego, 400 West Broadway, San Diego, CA 92101, 619-239-4500, at 9:00 a.m., on October 30, 2015.

Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board at its office not later than 5:00 p.m. on October 19, 2015, or must be received at the hearing. The Board, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Section 2018 of the Business and Professions Code (BPC) and Section 11400.20 of the Government Code (GC), and to implement, interpret or make specific Sections 2227, 2228, and 2229 of the BPC, as well as Sections 11400.20, 11425.50(e), and 11529 of the GC, the Board is considering changes to Section 1361 of Division 13 of Title 16 of the California Code of Regulations (CCR) as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

A. Informative Digest

In reaching its disciplinary decisions, the Board uses the Manual of Model Disciplinary Orders and Disciplinary Guidelines (Disciplinary Guidelines) incorporated by reference into 16 CCR section 1361. Currently, the Board uses the 11th Edition of the Disciplinary Guidelines, which were adopted by regulation in 2011.

Proposed Amendment to 16 CCR section 1361:

This rulemaking proposes to amend 16 CCR section 1361 to incorporate by reference the 12th Edition/2015 of the Disciplinary Guidelines, instead of the 11th Edition/2011. It is necessary to incorporate the Disciplinary Guidelines by reference due to the size of the document.

Proposed Amendments to the Disciplinary Guidelines

The Disciplinary Guidelines will be amended to identify it as the 12th Edition, amended in 2015, instead of the 11th Edition, amended in 2011. Further, the Disciplinary Guidelines will be updated to reflect the new agency name of "Business, Consumer Services, and Housing Agency," from the prior name of "State and Consumer Services Agency."

The instructions for writing or calling the Board for additional copies of the Disciplinary Guidelines will be deleted, and interested parties will be advised that the document is accessible on the Board's website.

In the past, the Board has provided a summary of changes for each new addition at the beginning of the document. This summary will be deleted as it is unnecessary, since the rulemaking file is the official record for the justification and summary of all changes.

The Table of Contents will be changed to reflect the title changes to conditions 18, 19, and 28. Page number changes will be made, if necessary.

Conditions 9 (Controlled Substances – Abstain from Use), 10 (Alcohol – Abstain from Use), and 11 (Biological Fluid Testing) of the Disciplinary Guidelines currently authorize the issuance of a cease practice order for non-compliance, but require that an accusation be filed within 15 days, or the cease practice order will be dissolved. They also provide that a decision shall be received from the Administrative Law Judge (ALJ) or the Board within 15 days unless good cause can be shown for the delay.

The proposed amendments to **Conditions 9, 10, and 11** will reflect a change in GC 11529, effective January 1, 2014, which extended the timeframe for filing an accusation following the issuance of a suspension order from 15 days to 30 days. The proposed amendments to these conditions will also clarify that the ALJ and the Board would each have 15 days to issue a decision, and will define good cause for a delay in issuing such decision. Additionally, under **Condition 11**, the option to use a breathalyzer will be specifically included in the definition of "biological fluid testing."

Conditions 14 (Prescribing Practices Course), 15 (Medical Records Keeping Course), 17 (Professional Boundaries Program), 18 (Clinical Training Program), and 23 (Monitoring – Practice/Billing) currently specify that the courses are to be equivalent to the courses at the Physician Assessment and Clinical Education Program (PACE) at the University of California, San Diego School of Medicine.

The proposed amendments to these conditions will remove reference to PACE to eliminate the appearance of endorsing one program's courses over others.

Condition 18 (Clinical Training Program) describes the Board's requirements for a clinical training program. Current law requires a two-day comprehensive assessment of respondent's physical and mental health; basic clinical and communication skills common to all clinicians; and medical knowledge, skill and judgment related to the respondent's area of practice in which he or she was alleged to be deficient, and required a minimum 40-hour program of clinical education in that area.

Current law further provides that the program will advise the Board of its recommendations for any additional education, training, or treatment for any medical or psychological condition, or anything else affecting respondent's practice of medicine.

Current law also requires respondent to pass an examination at the end of any additional education or clinical training.

Under Option #1: Condition Precedent of Condition 18, current law allows a respondent to practice medicine in a clinical training program approved by the Board, and indicates that respondent's practice shall be restricted to that which is required by the approved training program.

Under the proposed amendments, Condition 18 will be renamed "Clinical Competence Assessment Program." Moreover, the specific time-frame requirements of a two-day assessment and a 40-hour program will be deleted to permit the program to design an assessment and program particular to each respondent's circumstance. The proposed amendments will require a comprehensive assessment of respondent's physical and mental health; and the six general domains of clinical competence as defined by the Accreditation Council on Graduate Medical Education and the American Board of Medical Specialties pertaining to respondent's current or intended area of practice. The proposed amendments identify what the program shall consider during its assessment of the respondent, and specifies that the program shall require the respondent's on-site participation for a minimum of three to five days as determined by the program.

The proposed amendments require the program to submit a comprehensive assessment to the Board that unequivocally states whether the respondent has demonstrated the ability to practice safely and independently, and provide its recommendations for any further education, clinical training, or evaluation or treatment for any medical or psychological condition, or anything else affecting respondent's practice of medicine.

The proposed amendments will eliminate the requirement that the respondent pass an examination at the completion of additional education or clinical training.

Under Option #1: Condition Precedent of Condition 18, the proposed amendment eliminates the exception allowing respondent to practice medicine in a clinical training program.

Condition 19 (Oral and/or Written Examination) currently provides for the option of requiring the respondent to submit to an oral or written examination when appropriate.

The proposed amendments will strike the option of an oral examination as a condition that could be ordered.

It also strikes the language indicating that the respondent shall be allowed to take a second exam if he or she fails the first one.

Condition 25 (Third Party Chaperone) currently allows a respondent to nominate a replacement chaperone within 60 days after a chaperone leaves the respondent's employ.

The proposed amendment will reduce the time allowed to replace a chaperone from 60 days to 30 days.

Condition 28 (Supervision of Physician Assistants) currently prohibits a respondent from supervising physician assistants while on probation.

The proposed amendment will prohibit a respondent from supervising physician assistants and advanced practice nurses, and will change the title of the condition from “Supervision of Physician Assistants” to “Supervision of Physician Assistants and Advanced Practice Nurses.”

Condition 31 (General Probation Requirements) currently provides that the respondent shall comply with the Board’s probation unit and all terms and conditions of the Decision.

The proposed amendment will eliminate the phrase “and all terms and conditions of this Decision,” to reflect different requirements for respondents residing within California, and those residing in other states, during periods of non-practice, as further described under Condition 33, below.

Condition 33 (Non-practice While on Probation) currently does not well-differentiate what is expected from a respondent who is not practicing medicine during probation while residing in California versus while residing in another state. Additionally, current law requires the completion of a clinical training program following a period of non-practice exceeding 18 months.

The proposed amendments clarify that a respondent residing in California during periods of non-practice shall comply with all terms and conditions of probation. A respondent residing outside of California will be relieved of the responsibility to comply with the probationary terms and conditions with the exception of this condition (Condition 33), and the following terms and conditions of probation: Obey All Laws; General Probation Requirements; Quarterly Declarations; Abstain from the Use of Alcohol and/or Controlled Substances; and Biological Fluid Testing.

Additionally, the proposed amendments allow the respondent to complete the Special Purpose Examination (SPEX) before returning to practice in lieu of requiring a comprehensive assessment program after 18 months of non-practice.

The Titles of Probation Conditions in the Section on Recommended Range of Penalties for Violations currently references “Clinical Training Program” for Condition 18, and “Oral or Written Examination” for Condition 19. The proposed amendments will change the titles of these conditions to “Clinical Competence Assessment Program,” for each reference to Condition 18, and to “Written Examination” for the reference to Condition 19 to reflect the proposed changes to the titles of these conditions.

B. Anticipated Benefits of Proposal

This regulatory action will update the Board’s Disciplinary Guidelines used in its enforcement decisions, and will amend 16 CCR section 1361 to incorporate

these updated Disciplinary Guidelines by reference as the 12th Edition/2015. The proposed amendments make the Disciplinary Guidelines consistent with current law and the current educational and probationary environment, clarify the terms and conditions of probation to reduce the likelihood of misinterpretation, and strengthen consumer protection.

C. Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

D. Incorporated by Reference Document

Manual of Model Disciplinary Orders and Disciplinary Guidelines, 12th Edition, 2015.

FISCAL IMPACT ESTIMATES

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

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Sections 17500 - 17630 Require Reimbursement: 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. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. The representative private persons or directly affected businesses are physicians and surgeons, advanced practice nurses, and clinical competence assessment programs.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board has made an initial determination that the proposed regulatory action will have no effect on small businesses. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

The Board has made the initial determination that this regulatory proposal will have the following impact:

- It is not likely to create or eliminate jobs within the State of California. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.
- It is not likely to create new businesses or eliminate existing businesses within the State of California. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.
- It will not likely affect the expansion of businesses currently doing business within the State of California. This initial determination is based on the fact that these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.
- It will benefit the health and welfare of California residents because it updates and clarifies the terms and conditions of probation for physicians and surgeons subject to discipline, makes the Disciplinary Guidelines consistent with current law, and strengthens consumer protection.
- It will not have a significant impact on worker safety because these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

- It will not have an impact on the state's environment because these proposed amendments to the Disciplinary Guidelines will simply make this document consistent with current law, amend the document to reflect the changes that have occurred in the educational and probationary environment since the last update, clarify terms and conditions of probation, and improve consumer protection.

CONSIDERATION OF ALTERNATIVES

In accordance with GC section 11346.5(a)(13), the Board must determine that no reasonable alternative considered or brought to the attention of the Board would be more effective in carrying out the purpose for which this regulatory action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision 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.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the person designated in the Notice under Contact Person, below, or by accessing the Board's website at http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Paulette Romero, Enforcement Program Manager
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The backup contact person is:

Name: Kevin A Schunke, Regulations Manager
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Website Access Materials regarding this proposal can be found at [http://www.mbc.ca.gov/About Us/Laws/Proposed Regulations](http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations).