

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 on October 28, 2016, at 9:05 a.m., at the Sheraton Mission Valley San Diego located at 1433 Camino Del Rio South, San Diego, California.

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 no later than 5:00 p.m. on October 25, 2016, 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 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, and to implement, interpret or make specific section(s) 2227, 2228, and 2229 of said Code, the Board is considering changes to Division 13 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST**A. Informative Digest**

This rulemaking action seeks to amend Division 13 of Title 16 of the California Code of Regulations (CCR) section 1358.

Existing law under CCR section 1358 provides the following:

Each physician and surgeon who has been placed on probation by the division shall be subject to the division's Probation Surveillance Compliance Program and shall be required to fully cooperate with representatives of the division and its investigative personnel. Such cooperation shall include, but is not necessarily limited to, submission to laboratory testing for the purpose of determining the existence of alcohol, narcotics, other controlled substances and/or dangerous drugs in his or her system. Such tests shall be made at the times and places required by the division or its duly authorized representative. Any monetary fees incurred as a result of such laboratory tests shall be borne by the physician-probationer.

Reference to the terms "division," "Probation Surveillance Compliance Program," and "laboratory testing" are obsolete, and are no longer used by the Board. Moreover, this section indicates that physicians on probation are required to fully cooperate with the "division" and personnel, and indicates that cooperation shall

include submission to “laboratory testing” for the purpose of determining the existence of alcohol or drugs in the physician’s system. The requirement for cooperation is more expansive, and extends to all terms and conditions in the order placing the physician on probation.

Accordingly, this proposed rulemaking seeks to remove obsolete language referencing the “division” and the “Probation Surveillance Compliance Program” and replace it with current references to the “Board” and “Probation Program.” It also replaces “laboratory” with “biological fluid” testing, which is the term currently used by the Board. The proposed amendments further specify that probationers are required to bear the costs and be in compliance with all of the terms and conditions of the Order placing them on probation, in addition to referrals for biological fluid testing. These are existing requirements for probationers pursuant to the Board’s Manual of Model Disciplinary Orders and Disciplinary Guidelines incorporated by reference into 16 CCR section 1361.

The proposed changes are necessary to eliminate obsolete language and to clarify the Board’s requirements for probationers.

At the Board’s quarterly meeting held on May 6, 2016, Board staff requested the Board to authorize staff to prepare the necessary regulatory documents to formally notice the proposed regulatory amendment, to submit the documents to the Office of Administrative Law (OAL) for approval, and to schedule a hearing on the rulemaking. The Board granted the request to initiate the rulemaking process and authorized a hearing to be held after the 45-day comment period.

B. Policy Statement Overview/Anticipated Benefits of Proposal

The proposed amendments will eliminate obsolete language within CCR section 1358 and prevent confusion to the reader of the regulation, as the existing language in this section referencing the “division” and the “Probation Surveillance Compliance Program” is not currently used by staff, stakeholders, or the public in written or verbal communications. It further updates the term “laboratory” with “biological fluid” testing.

Moreover, the proposed amendments specify that probationers are required to bear the costs and be in compliance with all of the terms and conditions of the order placing them on probation, in addition to referrals for biological fluid testing. These are existing requirements for probationers pursuant to the Board’s Manual of Model Disciplinary Orders and Disciplinary Guidelines incorporated by reference into 16 CCR section 1361. This provides clarity to the Board’s requirements for probationers.

C. Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board has 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.

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 no additional requirements are being created by the proposed amendments, as they are simply clarifying changes.

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, since no additional requirements are being created by the proposed amendments, as they are simply clarifying changes.

Effect on Housing Costs: None

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

The Board has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts:

- Analysis of creation/elimination of jobs: The Board has made an initial determination that this regulatory proposal will not likely have any impact on the creation of jobs or the elimination of jobs in the State of California. This initial determination is based on the fact that the proposed changes simply eliminate obsolete language from CCR section 1358, and clarify the Board's requirements for physicians on probation. They do not add any new requirements not already in existence.
- Analysis of creation/elimination of businesses: The Board has made an initial determination that this regulatory proposal will not likely have any impact on the creation of new businesses or the elimination existing businesses or the expansion of businesses in the State of California. This initial determination is based on the fact that the proposed changes simply

eliminate obsolete language from CCR section 1358, and clarify the Board's requirements for physicians on probation. They do not add any new requirements not already in existence.

- Analysis of expansion of business: This proposal is not expected to lead to the expansion of new businesses within California. This initial determination is based on the fact that the proposed changes simply eliminate obsolete language from CCR section 1358, and clarify the Board's requirements for physicians on probation. They do not add any new requirements not already in existence.
- Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: The Board has determined that this regulatory proposal will benefit the health and welfare of California residents because the proposed amendments eliminate obsolete language from CCR section 1358, and clarify the Board's requirements for physicians on probation. Improved clarity in the Board's regulations furthers consumer protection.

This proposed rulemaking is not anticipated to have an impact on worker safety or the state's environment.

EFFECT ON SMALL BUSINESS

The Board has determined that the proposed regulations would not affect small businesses, since no additional requirements are being created by the proposed amendments, as they are simply clarifying changes.

CONSIDERATION OF ALTERNATIVES

The Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board has prepared an initial statement of the reasons for the proposed action and has made 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, 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 this Notice under Contact Person, or by accessing the Board's website at [http://www.mbc.ca.gov/About Us/Laws/Proposed Regulations](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 in this Notice.

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 or by accessing the website listed below.

CONTACT PERSON

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

Name: Christina Delp, Chief of Enforcement
Address: 2005 Evergreen Street, Ste. 1200
Sacramento, CA 95815
Telephone No.: 916-263-2389
Fax No.: 916-263-2387
E-Mail Address: Christina.delp@mbc.ca.gov

The backup contact person is:

Name: Kevin A Schunke, Regulations Manager
Address: Medical Board of California
2005 Evergreen St, Ste. 1200
Sacramento, CA 95815
Telephone No.: (916) 263-2368
Fax No.: (916) 263-8936
E-Mail Address: regulations@mbc.ca.gov

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).

**MEDICAL BOARD OF CALIFORNIA
REQUIREMENTS FOR PHYSICIANS ON PROBATION
Specific Language of Proposed Changes**

Underlined Indicates proposed additions to the existing regulation.

~~Strikeout~~ Indicates proposed deletions to the existing regulation

Amend Section 1358 in Article 3, of Chapter 2, Division 13, of Title 16 of the California Code of Regulations to read as follows:

§1358. Requirements for Physicians on Probation

Each physician and surgeon who has been placed on probation by the ~~division~~ Board shall be subject to the ~~division's~~ Board's Probation ~~Surveillance Compliance~~ Program and shall be required to fully cooperate with representatives of the ~~division~~ Board and its ~~investigative~~ personnel. Such cooperation shall include, but is not necessarily limited to, compliance with each term and condition in the order placing the physician and surgeon on probation, and submission to laboratory biological fluid testing for the purpose of determining the existence of alcohol, narcotics, other controlled substances and/or dangerous drugs in his or her system. Such biological fluid tests shall be made at the times and places required by the ~~division~~ Board or its duly authorized representative. Any monetary fees incurred as a result of ~~such laboratory tests a term or condition of probation, or biological fluid testing,~~ shall be borne by the physician-probationer.

NOTE: Authority cited: Section 2018, Business and Professions Code. Reference: Section(s) 2227, 2228, and 2229, Business and Professions Code.

MEDICAL BOARD OF BOARD

INITIAL STATEMENT OF REASONS

Hearing Date: October 28, 2016

Subject Matter of Proposed Regulations: Requirements for Physicians on Probation

Section(s) Affected: Title 16, Division 13, Chapter 2, Article 3, California Code of Regulations (CCR), Section 1358

Introduction:

The Medical Board of California (Board) licenses and regulates physicians and surgeons. Through this proposed rulemaking, the Board seeks to amend CCR section 1358 to improve the clarity of the regulation, as described below. These changes support the Board's mission of consumer protection.

Specific Purpose of Each Amendment and Factual Basis/Rationale:

Existing law under CCR section 1358 provides the following:

Each physician and surgeon who has been placed on probation by the division shall be subject to the division's Probation Surveillance Compliance Program and shall be required to fully cooperate with representatives of the division and its investigative personnel. Such cooperation shall include, but is not necessarily limited to, submission to laboratory testing for the purpose of determining the existence of alcohol, narcotics, other controlled substances and/or dangerous drugs in his or her system. Such tests shall be made at the times and places required by the division or its duly authorized representative. Any monetary fees incurred as a result of such laboratory tests shall be borne by the physician-probationer.

Reference to the terms "division," "Probation Surveillance Compliance Program," and "laboratory testing" are obsolete, and are no longer used by the Board. Moreover, this section indicates that physicians on probation are required to fully cooperate with the "division" and personnel, and indicates that cooperation shall include submission to "laboratory testing" for the purpose of determining the existence of alcohol or drugs in the physician's system. The requirement for cooperation is more expansive, and extends to all terms and conditions in the order placing the physician on probation.

Accordingly, this proposed rulemaking seeks to remove obsolete language referencing the "division" and the "Probation Surveillance Compliance Program" and replace it with current references to the "Board" and "Probation Program." It also replaces "laboratory" with "biological fluid" testing, which is the term currently used by the Board. The proposed amendments further specify that probationers are required to bear the costs

and be in compliance with all of the terms and conditions of the order placing them on probation, in addition to referrals for biological fluid testing. These are existing requirements for probationers pursuant to the Board's Manual of Model Disciplinary Orders and Disciplinary Guidelines incorporated by reference into 16 CCR section 1361.

The proposed changes are necessary to eliminate obsolete language and to clarify the Board's requirements for probationers.

Anticipated benefits from this regulatory action:

The proposed language will eliminate confusion to the reader of the regulation, as the current language referencing the "division" and the "Probation Surveillance Compliance Program" is not used by staff or stakeholders in written or verbal communication. It further updates the term "laboratory" with "biological fluid" testing. Moreover, the proposed amendments specify that probationers are required to bear the costs and be in compliance with all of the terms and conditions of the order placing them on probation, in addition to referrals for biological fluid testing. These are existing requirements for probationers pursuant to the Board's Manual of Model Disciplinary Orders and Disciplinary Guidelines incorporated by reference into 16 CCR section 1361. This provides clarity and consistency to the Board's requirements for probationers.

Underlying Data

At the May 6, 2016 quarterly Board meeting, Board staff requested the Board to authorize staff to prepare the necessary regulatory documents to formally notice the proposed regulatory amendment to submit the documents to the Office of Administrative Law (OAL) for approval, and to schedule a hearing on the rulemaking. The Board adopted a motion to approve staff to begin the regulatory process to formally notice the proposed regulatory amendments and schedule a hearing on the rulemaking to amend Title 16, Division 13, Chapter 2, Article 3, California Code of Regulations, section 1358.

Business Impact

This regulation will not have any adverse economic impact on businesses. This initial determination is based on the following facts: The proposed changes do not affect businesses within the State of California, as the proposed amendments merely change obsolete language and create consistency with the requirements for physicians on probation. No additional requirements are being created by the proposed amendments.

Economic Impact Assessment

This regulatory proposal will have the following effects:

- Analysis of creation/elimination of jobs: The Board has made an initial determination that this regulatory proposal will not likely have any impact on the creation of jobs or the elimination of jobs in the State of California. This initial determination is based on the fact that the proposed changes simply eliminate obsolete language from CCR section 1358, and clarify the Board’s requirements for physicians on probation. They do not add any new requirements not already in existence.
- Analysis of creation/elimination of businesses: The Board has made an initial determination that this regulatory proposal will not likely have any impact on the creation of new businesses or the elimination existing businesses or the expansion of businesses in the State of California. This initial determination is based on the fact that the proposed changes simply eliminate obsolete language from CCR section 1358, and clarify the Board’s requirements for physicians on probation. They do not add any new requirements not already in existence.
- Analysis of expansion of business: This proposal is not expected to lead to the expansion of new businesses within California. This initial determination is based on the fact that the proposed changes simply eliminate obsolete language from CCR section 1358, and clarify the Board’s requirements for physicians on probation. They do not add any new requirements not already in existence.
- Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State’s Environment: The Board has determined that this regulatory proposal will benefit the health and welfare of California residents because the proposed amendments eliminate obsolete language from CCR section 1358, and clarify the Board’s requirements for physicians on probation. Improved clarity in the Board’s regulations furthers consumer protection.

This proposed rulemaking is not anticipated to have an impact on worker safety or the state’s environment.

Economic Impact for “Major Regulations” (If applicable)

Non-Applicable.

Specific Technologies or Equipment

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

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed, or would be as effective or 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 current law.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

1. Do not seek a change. This alternative was rejected because the language in the regulation is outdated and not consistent with the terminology used by the Board, stakeholders, and the public. Further, the requirements for physicians on probation needed to be clarified to specify they are required to be in compliance with all of the terms and conditions of the order placing them on probation, in addition to referrals for biological fluid testing.
2. Adopt the proposed regulatory amendments. This alternative was determined to be the most appropriate, because the proposed language will eliminate confusion to the reader of the regulation, as the language in the regulation referencing the “division,” “Probation Surveillance Compliance Program,” and “laboratory testing” is not currently used by the Board, stakeholders, or the public in written or verbal communications. It will also clarify requirements for physicians on probation.