

**DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 13.**

MEDICAL BOARD OF CALIFORNIA

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
Physician and Surgeon Health and Wellness Program**

Section(s) Affected: Title 16, Division 13, Chapter 2, California Code of Regulations (CCR) amend Article 2, sections 1357, 1357.1, 1357.9, and Article 4, section 1361.5(c)(3); repeal Article 2, sections 1357.2, 1357.3, 1357.4, 1357.5, 1357.6, and 1357.8; and adopt Article 2, sections 1357.10, 1357.11, 1357.12, 1357.13, and 1357.14.

NOTICE IS HEREBY GIVEN that the Medical Board of California (Board) proposes to take the action described in the Informative Digest below, after considering all comments, objections, and recommendations regarding the proposed action.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing upon a written request for a public hearing from any interested person, or their authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under Contact Person in this notice.

COMMENT PERIOD

Any person interested may present statements or arguments relevant to the action proposed in writing. 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 by 5:00 p.m., Tuesday, November 14, 2023**, or at the hearing, if applicable.

AVAILABILITY OF MODIFICATIONS

The Board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations 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, with the modifications clearly indicated, will be available for review and written comment 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 and 2340 of the Business and Professions Code (BPC), and to implement, interpret or make specific section 2340, 2340.2, 2340.4, and 2340.6 of said Code, the Board proposes to amend sections 1357, 1357.1, 1357.9, and 1361.5(c)(3); repeal sections 1357.2, 1357.3, 1357.4, 1357.5, 1357.6, and 1357.8; and adopt sections 1357.10, 1357.11, 1357.12, 1357.13, and 1357.14 of Articles 2 and 4 of Chapter 2 of Division 13 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST / POLICY STATEMENT OVERVIEW

Senate Bill (SB) 1177 (Galgiani, Chapter 591, Statutes of 2016), under BPC section 2340, authorized the Board to establish a Physician and Surgeon Health and Wellness Program (PHWP) with the goal of providing early identification of, and appropriate interventions to support rehabilitation from, substance abuse to ensure physicians remain able to practice medicine in a manner that will not endanger the public and that will maintain the integrity of the medical profession.

BPC section 2340.2 generally sets forth the PHWP program requirements and specifies that the PHWP shall comply with the Uniform Standards Regarding Substance-Abusing Healing Arts Licensees (Uniform Standards) adopted by the Substance Abuse Coordination Committee (SACC) of the Department of Consumer Affairs (DCA) pursuant to BPC section 315.

BPC section 2340.4 generally sets forth the requirements for the entity (vendor) that contracts with the Board to administer the PHWP, including requirements for reporting information to the Board about participants, communicating data and program statistics to the Board, and submitting to periodic mandatory audits.

BPC section 2340.6 generally sets forth provisions for participants to enter into an individual agreement with the PHWP that contains certain requirements and disclosures. Additionally, this section sets forth when confidentiality applies to a licensee's participation in the PHWP.

BPC section 2340.8 provides that the PHWP Account is established within the Contingent Fund of the Board, and that the Board shall adopt regulations to determine the appropriate fee that a participant in the PHWP shall pay to the Board. Additionally, this section provides that the Board may use money from its Contingent Fund to support

the initial costs for establishing the PHWP, but these moneys shall not be used to cover any costs for individual licensees participating in the program.

(Note: This current proposed rulemaking does not address the issue of fees for participants in the PHWP. The Board will move forward with proposed regulations to set fees only once the proposed regulations in this current rulemaking are adopted, and the vendor for the PHWP is selected.)

On October 28, 2016, the Board voted to move forward with establishing a PHWP. Board staff held interested parties meetings on January 11, 2017, and October 4, 2017, to review the applicable statutes, the Uniform Standards, and to obtain input on draft regulatory language. On October 27, 2017, the Board authorized staff to move forward with noticing proposed regulations for a 45-day comment period and hearing. While the draft regulations were under review, the SACC of DCA met and approved changes to the Uniform Standards. This development caused Board staff to reconsider the format of the PHWP regulations. On November 8, 2019, staff presented modified language to the Board, and the Board authorized staff to move forward with submitting that language to DCA for review. After additional review and modifications to the proposed text, the Board authorized staff to move forward with this proposed rulemaking on August 25, 2022.

Specifically, this proposed rulemaking will do the following:

Amend the Title of Article 2 of Chapter 2 of Division 13 of Title 16 of the CCR

Under existing law, Article 2 of Chapter 2 of Division 13 of Title 16 of the CCR is titled, “Impaired Physician Program.”

This rulemaking proposes to change the title from “Impaired Physician Program” to “Physician and Surgeon Health and Wellness Program.” The “Impaired Physician Program” refers to the Board’s old diversion program, which was discontinued as of July 1, 2008. Consequently, this rulemaking would change the title consistent with the establishment of the PHWP.

Amend 16 CCR section 1357

Existing law sets forth definitions relating to the Board’s defunct diversion program. This rulemaking proposes to delete definitions relating to the Board’s defunct diversion program and add definitions applicable to the PHWP.

Amend 16 CCR section 1357.1

Existing law sets forth the criteria for admission relating to the Board’s defunct diversion program. This rulemaking proposes to amend this section to make it applicable to the

PHWP. The amendments set forth the criteria for admission to the PHWP and specify contractual requirements the licensee must agree to in order to participate in the PHWP.

Repeal 16 CCR sections 1357.2, 1357.3, 1357.4, 1357.5, 1357.6, and 1357.8

Existing law under these sections relate to the Board's defunct diversion program that was discontinued as of July 1, 2008. This rulemaking proposes to repeal these sections in their entirety.

Amend 16 CCR section 1357.9

Existing law sets forth record retention requirements relating to the Board's defunct diversion program. This rulemaking proposes to amend this section to make it applicable to the PHWP and to specify retention of program and participant records.

Adopt 16 CCR section 1357.10

This new section specifies certain requirements for the PHWP vendor and participants, including compliance with statutes and regulations applicable to the PHWP; clinical diagnostic evaluations; notification of employer or supervisor information; biological fluid testing; notification of positive biological fluid tests; testing locations, laboratories and specimen collectors; types of treatment; treatment providers; group support meetings; worksite monitors; and return to practice.

Adopt 16 CCR section 1357.11

This new section sets forth the vendor's reporting requirements when it imposes a practice restriction on a participant and establishes public disclosure requirements regarding practice restrictions on the participant's profile on the Board's website.

Adopt 16 CCR section 1357.12

This new section sets forth the vendor's reporting requirements if a participant withdraws from the program, is terminated, or commits any major or minor violation(s), and requires the vendor to provide specific information about a licensee's participation upon inquiry by the Board.

Adopt 16 CCR section 1357.13

This new section sets forth the requirements for the vendor to communicate certain information and data to the Board for inclusion in the Board's annual reports and within 30 days of the Board's written request.

Adopt 16 CCR section 1357.14

This new section sets forth the requirements for an external independent audit of the vendor at least once every three years to ensure compliance; establishes timelines to respond and cure deficiencies; establishes grounds for the Board to terminate the

contract with the vendor for non-compliance; and requires the vendor to have a written plan to transfer the care and monitoring of participants if the vendor's contract is terminated.

Amend 16 CCR section 1361.5(c)(3)

Existing law sets forth the requirements for biological fluid testing for substance abusing licensees. This rulemaking proposes to amend this section to make it consistent with changes the SACC made to the Uniform Standards effective March 2019 to clarify biological fluid testing requirements and testing frequency.

ANTICIPATED BENEFITS OF PROPOSAL

This proposed rulemaking will repeal old regulations relating to the Impaired Physician Program, which implemented the Board's diversion program and which was terminated as of July 2008. Repealing obsolete sections will improve the clarity of the Board's regulations.

Further, this proposed rulemaking amends existing regulations and adds new regulatory sections necessary to implement the PHWP, as authorized by BPC section 2340, and to further define BPC sections 2340.2, 2340.4, and 2340.6 to make specific the requirements for the PHWP.

The Board anticipates that the PHWP will provide for the early identification of licensees with substance abuse issues, and appropriate intervention and monitoring, consistent with the Uniform Standards, to support licensees in their rehabilitation from substance abuse to ensure they remain able to practice medicine safely. The Board anticipates that this program will provide a framework to assist licensees in overcoming substance abuse issues while rigorously protecting the public from licensees who are not safe to practice, thereby furthering the Board's mission of consumer protection.

This regulatory proposal intends to improve the health and welfare of California residents and worker safety by identifying, assisting, and monitoring physicians with substance abuse issues. This regulatory proposal will not have an impact on the state's environment.

CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS

The Board conducted a search for any similar regulations on these topics and has concluded that these regulations are neither duplicative, inconsistent, nor incompatible with existing state regulations.

DISCLOSURES REGARDING THIS PROPOSED ACTION

The Board has made the following initial determinations:

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: The regulations are necessary to implement SB 1177 and to establish and maintain the PHWP. The total fiscal impact from this proposal is unknown at this time.

The Board received resources in a 2017-18 Budget Change Proposal to fund one Associate Governmental Program Analyst (AGPA) and to contract with a third-party auditor to implement the provisions of SB 1177. The Board estimates current AGPA costs of \$166,000 per year and notes any future auditing costs will be paid by the vendor.

The Board notes participants will be charged a fee for the PHWP, but the fee level amount and revenues are unknown at this time. The fee will be set through regulations once a vendor is selected.

The regulations do not result in costs or savings in federal funding to the state.

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

RESULTS OF ECONOMIC IMPACT ASSESSMENT / ANALYSIS:

BUSINESS IMPACT ESTIMATES

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 there are vendors within the State of California with employees and contractors that already provide these services, and it is likely that one of them will contract with the Board to administer the PHWP. Further, this rulemaking will not increase or decrease the number of individuals

identified as substance abusing licensees in need of monitoring and rehabilitation. Accordingly, it is not likely that this rulemaking will create or eliminate jobs in California.

- **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 there are vendors within the State of California that already provide these services, and it is likely that one of them will contract with the Board to administer the PHWP. Further, this rulemaking will not increase or decrease the number of individuals identified as substance abusing licensees in need of monitoring and rehabilitation. Accordingly, it is not likely that this rulemaking will create or eliminate businesses in California.
- **It is not likely to impact expansion of businesses currently doing business within the State of California.** This initial determination is based on the fact that this rulemaking will not increase or decrease the number of individuals identified as substance abusing licensees in need of monitoring and rehabilitation. Accordingly, it is not likely that this rulemaking will impact expansion of businesses currently doing business in California.
- **It is likely to benefit the health and welfare of California residents.** This initial determination is based on the fact that the regulations establish the PHWP to support the early detection, treatment, and monitoring of physicians dealing with substance abuse issues, while rigorously protecting consumers from licensees who, due to substance abuse issues, are unsafe to practice.
- **It is likely to have a positive impact on worker safety.** This initial determination is based on the fact that the regulations establish the PHWP to support the early detection, treatment, and monitoring of licensees dealing with substance abuse issues, while rigorously protecting consumers from licensees who are unsafe to practice.
- **It is not likely to have an impact on the state's environment.** This initial determination is based on the fact that the regulations are designed to establish the PHWP to detect, assist, and monitor licensees dealing with substance abuse issues, and do not address environmental issues.

IMPACT ON JOBS / BUSINESSES

The Board has made an initial determination that this proposed regulatory action would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Further, the Board has determined that this regulatory proposal will not have any significant impact on the creation of jobs or new businesses, or the elimination of jobs or existing businesses, or the expansion of businesses in the State of California.

These initial determinations are based on the fact that the Board currently disciplines and monitors licensees who have been found in violation of the Medical Practice Act due to substance abuse issues. The Board does not anticipate that the number of licensees treated and monitored for substance abuse issues will increase or decrease following implementation of the PHWP.

Business Reporting Requirements

The regulatory action does not require businesses to file a report with the Board.

Effect on Small Business

The Board has determined that the proposed regulations would not affect small businesses. This initial determination is based on the fact that the Board currently disciplines and monitors licensees who have been found in violation of the Medical Practice Act due to substance abuse issues. The Board does not anticipate that the number of licensees treated and monitored for substance abuse issues will increase or decrease following implementation of the PHWP.

Cost Impact on Representative Private Person or Business

The Board has made the initial determination that there will be cost impacts that a representative private person would necessarily incur in reasonable compliance with the proposed action. These costs will apply to licensees subject to discipline by the Board as a substance abusing licensee, or who self-refer into the PHWP.

Based on 2020-2021 and 2021-2022 licensee probation data, the Board estimates 40 licensees will be placed in the PHWP per year for the duration of their five-year probation period. As a result, PHWP participation is anticipated to increase in the first five years before leveling off as probation periods expire.

Of these 40 probationers each year, the Board estimates eight participants will be required to undergo a 30-day in-patient treatment program and may be subject to lost wages during that time.

The Board has identified PHWP activities and costs as follows:

- **Clinical Diagnosis:** Licensees participating in the PHWP will likely have to undergo an initial clinical diagnostic evaluation and pay approximately \$3,100 in a one-time payment to the evaluation program, which results total costs of \$124,000 per year and up to \$1.24 million over a ten-year period.
- **Biological Fluid Testing:** Participants will be required to be tested between 52 to 104 times and pay \$6,948 (flat-fee) during the first year and be tested between 36 to 104 times per year thereafter and pay \$5,439 (flat-fee) per year in years two through five, which results in costs ranging from \$277,920 to \$1.15 million per year and up to \$9.3 million over a ten-year period.
- **Group Support Meetings:** Participants may be required to attend monthly support group meetings and pay estimated fees of \$5,460 per year, which results in estimated annual costs ranging from \$218,400 to 1.5 million per year and up to \$9.5 million over a ten-year period.
- **Worksite Monitoring:** Licensees may be required to have a worksite monitor and pay estimated costs of \$15,600 per year, which results in estimated annual costs ranging from \$624,000 to \$3.1 million and up to \$24.96 million over a ten-year period.
- **In-Patient Treatment:** Licenses may be subject to a 30-day in-patient treatment program with estimated one-time costs of \$40,000, plus lost wages of \$35,583.
- **Other Future Costs:** Participants will have to pay a fee to participate in the PHWP in the future, but the Board does not have an estimate for the fee at this time. The fee will be set through the rulemaking process once the vendor is selected.

PHWP Costs per Licensee: An individual licensee participating in the PHWP for the duration of their five-year probation period will incur costs of approximately \$31,108 in year one and \$26,499 in years two through five and up to \$137,104 over a five-year period. Those individuals requiring in-patient treatment will incur an additional \$40,000 in costs in year one.

Income Loss: Licensees referred to in-patient treatment will be required to cease practicing medicine for a 30-day period. Each licensee is estimated to lose \$35,583 of income during this time, which results in total income losses (8 licensees) of approximately \$284,664 per year and up to \$2.8 million over a ten-year period.

Effect on Housing Costs: None

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5, subdivision (a)(13), the Board must determine that no reasonable alternative it considered to the regulation 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; 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 submit comments to the Board in writing relevant to the above determinations at the address listed for the Contact Person during the written comment period.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information on which this proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

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 upon request from the Board by contacting the person named 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 PERSONS

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

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The backup contact person is:

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AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Actions, the Initial Statement of Reasons, and the text of the regulations can be accessed through the Board's website at http://www.mbc.ca.gov/About_Us/Laws/Proposed_Regulations.